CONSENSUS STATEMENT

Treatment of Scalp Psoriasis: Review of the Evidence and Delphi Consensus of the Psoriasis Group of the Spanish Academy of Dermatology and Venereology

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KEYWORDS
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Scalp;
Treatment;
Process;
Delphi;
Topical corticosteroids;
Calcipotriol

Abstract
Scalp lesions are common in psoriasis and difficult to treat. Scientific evidence on the topic is scant and fragmentary, especially with respect to long-term treatment. This consensus statement is based on a critical assessment of the results of a MEDLINE search for clinical trials of the efficacy and safety of therapies used to treat scalp psoriasis. The recommendations were developed by an expert panel using the Delphi process to reach a consensus and then ratified by the members of the Psoriasis Group of the Spanish Academy of Dermatology and Venereology. The recommended induction therapy for scalp psoriasis is either a topical corticosteroid or a topical treatment combining calcipotriol and betamethasone. The choice of an appropriate vehicle is crucial in improving effectiveness and patient adherence to treatment. The only formulations that have been studied in the long-term treatment of scalp psoriasis are a combination of calcipotriol and betamethasone in gel and calcipotriol alone in solution.

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Introduction

The scalp is affected in 70% to 80% of patients with psoriasis.\(^1\) Scalp lesions have specific characteristics that distinguish them from lesions on other parts of the body and make treatment more challenging. Hair makes topical treatments difficult to apply, and the proximity of the face limits the use of certain preparations because facial skin is more susceptible to adverse effects, such as iatrogenic rosacea, glaucoma, iatrogenic acne, and irritation.\(^3\)

Moreover, many of the available topical therapies are rejected by patients because of their cosmetically unattractive effects. Almost half of patients with itchy and scaly psoriatic lesions on the scalp report having problems with social relationships as a result of their disease,\(^4\) an indication that scalp involvement has a negative impact on the patients’ health and quality of life because of the persistence and visibility of the lesions.\(^5\)

The literature offers little evidence on the treatment of psoriasis of the scalp, and the treatment of scalp lesions is often based on studies of the response to the treatment of psoriasis on other areas of the body. Only very few controlled studies offering a high level of evidence (randomized double blind vehicle-controlled trials) have assessed pharmacologic treatments for psoriatic scalp lesions. This consensus statement reviews studies dealing specifically with the efficacy and safety of therapies used to treat psoriasis of the scalp and proposes recommendations drawn up by an expert panel using the Delphi process to reach a consensus, which was then ratified by the members of the Psoriasis Group of the Spanish Academy of Dermatology and Venereology.

Methods

Controlled trials and some observational studies dealing specifically with psoriasis affecting the scalp were selected for review. All were identified by a MEDLINE search (cut-off date, January 12, 2010) using the term “scalp psoriasis” followed by the different treatments and drugs used. The clinical trials were then evaluated according to the scale of the Scottish Intercollegiate Guidelines Network (SIGN).\(^6\) Also reviewed were recently published guidelines\(^7\) and review articles on the topical treatment of psoriasis of the scalp\(^8\) as well as the Cochrane Collaboration review on the topical treatment of plaque psoriasis, which also deals with scalp involvement.\(^9\)

The recent European consensus on the treatment of psoriatic scalp lesions—also considered in the present review—presents a treatment algorithm that includes recommendations for patients with mild, moderate, or severe scalp lesions.\(^10\)

This Spanish consensus statement was developed using the Delphi process.\(^11\) The trials selected were appraised by a panel of 7 experts (the first 7 authors of this article), who indicated their degree of agreement with 57 statements on a Likert scale from 1 to 7. These questionnaire items were subsequently reassessed and redefined in a teleconference. Positive consensus was defined as assignment of a score of 6 or 7 by at least 70% of the expert appraisers. Negative consensus was defined as assignment of a score of 1 or 2 by at least 70% of the appraisers. The definitive list of items in the questionnaire the expert panel responded to was then submitted to 77 dermatologists throughout Spain, all members of the Psoriasis Group of the Spanish Academy of Dermatology and Venereology. This larger group also responded using the same Likert scale and the percentages were recorded.

Based on the available evidence, the expert panel then made a series of recommendations, which were rated according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria.\(^12,13\) These recommendations are described below and summarized in tables.
Severity, Quality of Life, and General Treatment Considerations

How the baseline severity of psoriasis is defined and how the effect of treatment is measured are crucial factors in assessing the response to treatment of psoriatic scalp lesions in clinical trials. The instruments used include the percentage of body surface area affected and the Psoriasis Area and Severity Index (PASI). The PASI has become the standard among the instruments used to measure the intensity of psoriasis.\textsuperscript{14} It is used particularly in clinical trials, and a 75\% reduction in PASI compared to baseline (PASI 75) is considered to be a standard measure of efficacy.\textsuperscript{15} Validated and used as a measure of severity of psoriasis, PASI assessment separately considers the intensity of erythema, induration, and desquamation on 4 areas of the body, one of which is the head, an area that includes the face, neck, and scalp and accounts for 10\% of the total body surface area. Another instrument used is the Psoriasis Scalp Severity Index (PSSI). This is also based on the degree of erythema, induration, and desquamation and the extent of the affected surface area, but only takes into account the scalp.\textsuperscript{16}

A recent European consensus statement used a simple classification to define the severity of scalp lesions in its treatment algorithm\textsuperscript{10} using the following categories: mild (involvement of <50\% of the scalp and mild or minimal erythema, infiltration, and pruritus); moderate (involvement of >50\% of the surface with moderate erythema, infiltration, and pruritus); and severe (involvement of >50\% of the surface with moderate to severe erythema, infiltration, and pruritus and/or cicatricial alopecia or lesions on visible areas of the face). These categories are illustrated with photographs. In short, scaling, pruritus, and infiltration are minimal in cases of mild disease, moderate in moderate disease, and severe in severe cases, when they may be accompanied by evidence of hair loss.\textsuperscript{10}

Scalp psoriasis, and especially moderate to severe disease, is associated with emotional and social consequences that affect the patient’s overall health and wellbeing.\textsuperscript{17} While psoriatic scalp lesions may last for many years—over 2 decades in 50\% of patients\textsuperscript{18}—and this highlights the importance of the psychological consequences, very few studies have evaluated the specific emotional repercussions of scalp involvement in this setting.

Health-related quality of life is usually measured with general questionnaires, such as the 36-Item Short Form Health Survey (SF-36)\textsuperscript{18} or specific dermatology questionnaires, such as Skindex-29 and the Dermatology Life Quality Index, instruments that have been validated in Spain.\textsuperscript{19} Scalpdex is a new 23-item tool that was recently developed to measure the quality of life of patients with psoriasis of the scalp.\textsuperscript{20}

Topical treatment is the main therapeutic approach to scalp psoriasis, but the patients’ attitude to such treatment, and in particular to the vehicle used, is different when the lesions are located on the scalp rather than on other parts of the body. The pharmaceutical formulation should be designed to prevent the easy spread of the preparation from the scalp to the face, and the patient must understand that the product should only be applied to the affected zone. Patients will not accept treatments that are unpleasant, difficult, or time consuming to apply; they demand easy-to-apply, fast-acting, and effective therapies. On the scalp, patients are reluctant to use creams and ointments, preferring lotions, gels, foams, and shampoos.

The many different types of treatment that have been used to treat scalp lesions include the classic tars and more refined coal tar derivatives, anthralin, keratolytic agents, vitamin A derivatives, phototherapy, corticosteroids, vitamin D analogs, and different combinations of topical products. Classic systemic treatments, such as methotrexate, ciclosporin, and the more recent biologic agents, can be prescribed for the more severe forms of the disease. This variety, particularly in the range of topical treatments available, reflects the generally poor patient adherence to treatment, which is probably due to patient dissatisfaction with many of the formulations either because of their low efficacy or the inconvenience and unpleasantness of their application.\textsuperscript{21} The clinician must therefore focus not only on the efficacy of the treatment but also on finding a therapy with minimal local adverse effects that is cosmetically acceptable.

Table 1 shows the responses of the expert panel and the members of the Psoriasis Group of the Spanish Academy of Dermatology and Venereology on items for this section of the questionnaire.

Treatments for Psoriasis of the Scalp: Review of the Literature

Topical Corticosteroids

Corticosteroid creams have been the mainstay of treatment for psoriasis of the scalp for over 30 years, as the efficacy and rapid action of this family of topical treatments has made them one of the most frequently prescribed. Corticosteroids can be added to a number of different vehicles, for application as ointments, creams, emulsions, foams, gels, lotions, and shampoos. They can also be used in combination with other substances, such as salicylic acid, urea, coal tars, and vitamin D derivatives. Most randomized trials in the literature have studied formulations in shampoo or solution. No trials have been published on the foam products intended exclusively for scalp lesions, although novel alcohol-free foam products have been shown to be safe and effective in the treatment of psoriasis on other areas of the body.\textsuperscript{22}

Efficacy

Betamethasone dipropionate or valerate, fluocinolone acetonide, mometasone furoate, and clobetasol propionate are some of the topical corticosteroids that have been most frequently studied in controlled clinical trials. Sixteen controlled trials of topical corticosteroids in the treatment of psoriasis of the scalp have been published (Table 2). In 5 trials studying a total of 807 patients these products were compared with a variety of vehicles and placebo.\textsuperscript{23-27} The authors of a further 6 trials, including 1204 patients, compared 2 corticosteroids.\textsuperscript{28-33} Finally, topical
Corticosteroids were compared with a vitamin D analog, coal tar or a combination of betamethasone plus salicylic acid in 5 trials enrolling 936 patients. Treatment efficacy was expressed as clearance or an excellent response reflected in the physician’s global assessment or as a reduction in the total symptom score or global severity score.

In total, 807 patients with moderate to severe scalp psoriasis participated in 5 double blind placebo-controlled clinical trials of 2 to 4 weeks duration testing agents in a variety of vehicles (Table 2).

Six trials compared different corticosteroids applied for 2 to 4 weeks in 1204 patients with moderate to severe
### Table 2  Clinical Trials Evaluating the Efficacy of Topical Corticosteroids Compared to Other Treatments or Placebo

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Design</th>
<th>Severity</th>
<th>Dose Regimens</th>
<th>Pharmaceutical Preparation</th>
<th>No. of Study Patients</th>
<th>Study Duration</th>
<th>% Response Overall</th>
<th>Overall Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comparison with vehicle</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lepaw(^{23})</td>
<td>db, r, cr</td>
<td>ND</td>
<td>Halcinonide 0.1 bid/plac</td>
<td>Solution</td>
<td>27</td>
<td>2 wks</td>
<td>59 vs 4(^a)</td>
<td>plac 1(−)</td>
</tr>
<tr>
<td>Olsen et al(^{24})</td>
<td>db, r</td>
<td>M/S</td>
<td>Clob 0.05 bid/plac</td>
<td>Solution</td>
<td>188/189</td>
<td>2 wks</td>
<td>69 vs 8.5(^a)</td>
<td>plac 1(+)</td>
</tr>
<tr>
<td>Pauporte et al(^{25})</td>
<td>db, r</td>
<td>M/S</td>
<td>Fluo 0.01% od vs plac</td>
<td>Oil</td>
<td>43/46</td>
<td>3 wks</td>
<td>83 vs 36(^a)</td>
<td>plac 1(+)</td>
</tr>
<tr>
<td>Jarrat et al(^{26})</td>
<td>db, r 2:1</td>
<td>M/S</td>
<td>Clob (0.05%)/plac</td>
<td>Shampoo</td>
<td>95/47</td>
<td>4 wks</td>
<td>42 vs 2(^b)</td>
<td>plac 1(+)</td>
</tr>
<tr>
<td>Franz et al(^{27})</td>
<td>db, r 2:1</td>
<td>M/S</td>
<td>Bet Val bid (0.1%)/plac</td>
<td>Foam</td>
<td>57/28</td>
<td>4 wks</td>
<td>74 vs 10(^a)</td>
<td>plac 1(+)</td>
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<tr>
<td><strong>Comparison between corticosteroids</strong></td>
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<tr>
<td>Andreassi et al(^{28})</td>
<td>ib, r, cr</td>
<td>M/S</td>
<td>Bet Dip 0.05 bid</td>
<td>Shampoo</td>
<td>232</td>
<td>4 wks</td>
<td>88 vs 66(^a)</td>
<td>Bet &gt; standard 1(−)</td>
</tr>
<tr>
<td>Katz et al(^{29})</td>
<td>ib, r</td>
<td>M/S</td>
<td>Bet Dip 0.05 bid</td>
<td>Solution</td>
<td>128</td>
<td>2 wks</td>
<td></td>
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</tr>
<tr>
<td>Brenemann et al(^{30})</td>
<td>op, r</td>
<td>M/S</td>
<td>Bet Dip 0.05 bid</td>
<td>Solution</td>
<td>96</td>
<td>3 wks</td>
<td>83 vs 75(^c)</td>
<td>Bet &gt; clob 1(+)</td>
</tr>
<tr>
<td>Feldman et al(^{31})</td>
<td>ib, r</td>
<td>M/S</td>
<td>Fluo (0.05%) bid Bet val bid</td>
<td>Solution</td>
<td>84</td>
<td>3 wks</td>
<td>61 vs 52(^c)</td>
<td>bid=od 1(−)</td>
</tr>
<tr>
<td>Vanderploeg et al(^{32})</td>
<td>ib, r</td>
<td>M/S</td>
<td>Bet Val od Mom 0.1% od</td>
<td>Foam</td>
<td>46</td>
<td></td>
<td>85 vs 70(^c)</td>
<td>Mom &gt; bet val 1(+)</td>
</tr>
<tr>
<td>Swinehart et al(^{33})</td>
<td>ib, r</td>
<td>M/S</td>
<td>Bet val 0.1% bid Mom 0.1% od</td>
<td>Solution</td>
<td>102</td>
<td></td>
<td>78 vs 73(^c)</td>
<td>Mom &gt; bet val 1(+)</td>
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<tr>
<td><strong>Tripolar corticosteroids</strong></td>
<td></td>
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<tr>
<td>Triam 0.1% bid</td>
<td>Solution</td>
<td>99</td>
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<th>Dose Regimens</th>
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<th>No. of Study Patients</th>
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<tbody>
<tr>
<td><strong>Comparison with other drugs</strong></td>
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<tr>
<td>Reygagne et al(^{34})</td>
<td>ib, r</td>
<td>M/S</td>
<td>Clob 0.05% od</td>
<td>Shampoo</td>
<td>76</td>
<td>4 wks</td>
<td>50 vs 28(^a)</td>
<td>Clob &gt; vitD 1(++)</td>
</tr>
<tr>
<td>Klaber et al(^{35})</td>
<td>db, r</td>
<td>M/M</td>
<td>Cal bid Bet val 0.1 bid</td>
<td>Solution</td>
<td>75</td>
<td>4 wks</td>
<td>75 vs 59(^a)</td>
<td>Bet &gt; vitD 1(++)</td>
</tr>
<tr>
<td>Andreassi et al(^{36})</td>
<td>ib, r, cr</td>
<td>M/S</td>
<td>Cal bid Bet dip 0.05 od</td>
<td>Solution</td>
<td>232</td>
<td>4 wks</td>
<td>73 vs 46(^c)</td>
<td>Bet &gt; vitD 1(−)</td>
</tr>
<tr>
<td>Griffiths et al(^{37})</td>
<td>ib, r (3:1)</td>
<td>M/S</td>
<td>Cal Clob 0.05% od</td>
<td>Solution</td>
<td>104</td>
<td>4 wks</td>
<td>50 vs 15(^c)</td>
<td>Clob &gt; tar 1(++)</td>
</tr>
<tr>
<td>Hillström et al(^{38})</td>
<td>db, r</td>
<td>M/S</td>
<td>Tar 0.05 2/wk Bet dip 0.05 + salicylic acid 2% bid Clob 0.05 bid</td>
<td>Shampoo</td>
<td>41</td>
<td>3 wks</td>
<td>84 vs 60(^a)</td>
<td>Bet sal &gt; clob 1(−)</td>
</tr>
</tbody>
</table>

Abbreviations: bid, twice daily; bet dip, betamethasone dipropionate; bet sal, betamethasone combined with salicylic acid; bet val, betamethasone valerate; cal, calcipotriol; clob, clobetasol; cr, crossover; db, double blind; fluo, fluocinolone; ib, investigator blinded; M/M, mild to moderate; M/S, moderate to severe; mom, mometasone; op, open; plac, placebo; r, randomized; triam, triamcinolone; vitD, vitamin D.

\(^{a}\)Physician’s global assessment: excellent response or cleared.

\(^{b}\)Global severity score: clear or minimal disease.

\(^{c}\)Reduction in total symptom score.

\(^{d}\)Complete remission of signs and symptoms (pruritus).
psoriatic scalp lesions (Table 2).38-32 Three of these trials evaluated the effect on the global severity score of the administration once or twice daily of betamethasone valerate in foam31 or mometasone furoate in solution32,33 compared to other corticosteroids. While in the first of those trials a reduction in symptoms was observed with twice daily administration of the drug, the study lacked the necessary statistical power to demonstrate differences between the 2 groups.31 By contrast, once daily application of mometasone produced better results than twice daily applications of the comparison corticosteroid.32,33

In 5 randomized trials, a corticosteroid in shampoo or lotion was compared to a lotion combining a corticosteroid with salicylic acid, calcipotriol, or tar blend shampoo.24,34-37 The corticosteroids produced better results than the comparators after 3 to 4 weeks of treatment. In a double blind trial in which 51 patients were assigned randomly to 0.05% clobetasol lotion or 2% betamethasone dipropionate with salicylic acid, the efficacy after 3 weeks was similar in both groups, although the combination yielded better results than clobetasol alone with respect to antipruritic effect.37

Safety
The safety of topical corticosteroid therapy depends both on the type of corticosteroid and the formulation used. The short contact time involved in the use of corticosteroid shampoos may minimize both local and systemic adverse effects. In a 4-week double blind trial enrolling 142 patients, 0.05% clobetasol propionate shampoo had the same safety profile as its vehicle, with the most frequently reported side effect being skin discomfort,26 and patients do express preference for a corticosteroid over a tar-based product. Clobetasol shampoo (0.05%) has been shown to be better tolerated than calcipotriol solution.34 Clobetasol has no systemic effects on either the hypothalamic-pituitary-adrenal axis or the eyes.38 The effects on adrenal function have been assessed for up to 79 days. In a study that compared betamethasone dipropionate with a clobetasol propionate lotion (0.05%), no differences were found with respect to tolerability.37 In another similar comparison, however, betamethasone was associated with a higher rate of folliculitis.39

Summary of the Review
Topical corticosteroids are a first-line option in the short term treatment of psoriasis of the scalp. Although high-potency corticosteroids are effective and reasonably safe, in general the recommended option is to use the lowest strength that will effectively clear the lesions since drug absorption is higher on the scalp. Compared to other topical treatments, corticosteroids are more effective than calcipotriol and coal tar, although there are very few comparative studies in the literature. Regarding long-term treatment (more than 4 weeks), there is insufficient evidence to support any conclusions concerning the efficacy and safety of corticosteroids in general or the advantages of one formulation over another. Most studies with corticosteroids have been carried out using twice daily applications. Regimens requiring only one application daily using vehicles such as shampoo or lotion tend to favor adherence to treatment, in particular when the more potent preparations are being used. The application of a topical corticosteroid in the form of shampoo improves the quality of life and satisfaction of patients with psoriasis of the scalp.40,41

Topical corticosteroids should be applied with special care on the scalp because this highly vascularized area allows more of the active substance to enter into circulation. Moreover, when the lesions are located on the more sensitive facial skin adjacent to the scalp, there is a greater risk of skin atrophy and telangiectasia, especially in the case of long-term treatment. For all these reasons, corticosteroids work well in combination with vitamin D derivatives.

Table 3 summarizes the responses of the expert panel and the members of the Spanish Psoriasis Group (medians and percentages) for items related to this topic.

Recommendation of the Expert Panel
Based on published experience and the responses recorded, the use of topical corticosteroids in lotion or shampoo form is a first-line treatment for psoriasis of the scalp.

Grade of recommendation: A

Vitamin D and Its Analogs
The vitamin D products and vitamin D analogs used in the treatment of scalp psoriasis are calcitriol, the dihydroxylated active form of vitamin D (1,25-dihydroxycholecalciferol), falecalcitriol, and the vitamin D analogs calcipotriol and tacalcitol. Vitamin D and its derivatives act by inhibiting the proliferation of keratinocytes, stimulating their differentiation, and inhibiting inflammation.42

Efficacy
The use of topical vitamin D analogs in the treatment of psoriatic scalp lesions has been studied in a number of controlled trials. There have also been several uncontrolled studies of large case series, which are not discussed in this article. A total of 1833 patients with mild to moderate psoriasis of the scalp have been included in clinical trials (322 in placebo-controlled trials). All of these trials used calcipotriol except for one in which the drug studied was tacalcitol. Most compared calcipotriol with a topical corticosteroid in monotherapy or in combination with salicylic acid, although it was also compared with coal tar products (Table 4). In a 4-week double blind randomized clinical trial, calcipotriol solution was more effective than a placebo solution.43 In the other randomized clinical trials, calcipotriol solution was compared to corticosteroids, coal tar shampoo, and a combination of betamethasone and salicylic acid.34,35,44-48 Treatment efficacy was defined as clearance or an excellent response as per the physician’s global assessment or as a reduction in the total symptom score or the global severity score after 4 to 12 weeks of treatment. When calcipotriol was compared to corticosteroids, the
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### Table 3  Positive or Negative Consensus on Treatment With Topical Corticosteroids

<table>
<thead>
<tr>
<th>General considerations</th>
<th>Consensus of the Expert Panel</th>
<th>Consensus of the Psoriasis Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical corticosteroids are the first-line therapy for short-term use.</td>
<td>6 71.4 7 83.1</td>
<td>X</td>
</tr>
<tr>
<td>Topical corticosteroids are the treatment for use when others have failed.</td>
<td>2 X 5</td>
<td>X</td>
</tr>
<tr>
<td>Topical corticosteroids are the treatment best accepted by patients.</td>
<td>6 85.7 5 X</td>
<td>X</td>
</tr>
<tr>
<td>Topical corticosteroids are the most effective treatment for psoriasis of the scalp.</td>
<td>6 71.4 5 X</td>
<td>X</td>
</tr>
</tbody>
</table>

Which topical corticosteroid is the first-line treatment?

- Betamethasone dipropionate: 6 85.7 5 X
- Betamethasone valerate: 5 X 5 X
- Clobetasol propionate: 6 71.4 5 X
- Mometasone furoate: 6 X 5 X

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.

### Table 4  Clinical Trials Evaluating the Therapeutic Efficacy of Vitamin D Analogs Compared to Other Treatments and Placebo

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Design</th>
<th>Severity</th>
<th>Dose Regimen</th>
<th>Pharmaceutical Preparation</th>
<th>No. of Patients</th>
<th>Study Duration</th>
<th>% of Response</th>
<th>Overall Efficacy</th>
<th>Evidence Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison with Vehicle</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Green et al43</td>
<td>db, r, plac</td>
<td>M/M</td>
<td>Cal bid Tac qd</td>
<td>Solution Emulsion</td>
<td>25/24 273</td>
<td>4 wks</td>
<td>60 vs 17</td>
<td>&gt; plac</td>
<td>1(+)</td>
</tr>
<tr>
<td>Ruzicka et al48</td>
<td>db, r, plac</td>
<td>M/M</td>
<td>Cal bid Tac qd</td>
<td>Emulsion</td>
<td>8 wks</td>
<td>53 vs 30</td>
<td>&gt; plac</td>
<td>1(+)</td>
<td></td>
</tr>
</tbody>
</table>

Comparison with other drugs

| Reygagne et al34           | Ib, r        | M/S      | Cal bid Clob (0.05%) | Solution Emulsion          | 76 75           | 4 wks         | 50 vs 28        | > plac          | 1(+)           |
| Klaber et al35             | db, r        | M/M/S    | Cal bid Bet val (0.1%) | Emulsion                   | 236 232         | 4 wks         | 59 vs 75        | > bet           | 1(+)           |
| Klaber-McKinnon et al44    | op, r        | M/M/S    | Cal bid Clob         | Emulsion                   | 238            | 16 wks        | Wk 24: −63%     | VitD > coal tar | 1(+)           |
| Klaber-McKinnon et al44 (follow-up) | op, nr | M/M/S | Capasal qd Cal bid | Solution Emulsion          | 237 166         | 4 wks         | 73 vs 72        | VitD = bet      | 1(+)           |
| Duweb et al45              | op, r        | ND       | Cal bid Bet val (1%) | Solution Emulsion          | 24 18           | 6 wks         | 73 vs 72        | VitD = bet sal  | 1(+)           |
| Emaitig et al46            | op, r        | M/M/S    | Cal bid Bet dip      | Solution Emulsion          | 72 12 wks       | 97 vs 95       | VitD = bet sal  | 1(+)           |
| Barret et al47             | op, r        | ND       | Cal bid Plac + cal bid | Solution Emulsion          | ND 8 wks        | 56 vs 52       | VitD = vitD + tar | 1(+)           |
| Faergemann et al48         | db, r        | M/M      | Cal + tar Itra + cal bid | Solution + shampoo Oral + solution | 67 6 wks | 70 vs 63 | Itra + vitD = vitD Itra + vitD > vitD | 1(+)           |
latter produced significantly better results at 4 weeks. The effect of the calcipotriol solution increased after 8 to 12 weeks, when no differences were observed with respect to corticosteroids. It should be noted, however, that all of the trials lacked sufficient statistical power. The most interesting of the uncontrolled trials was one by Thaçi et al, who assessed the efficacy and tolerability of calcipotriol solution applied during an 8-week period alone or in combination with other products in 3396 patients with mild to moderate psoriasis of the scalp. This treatment achieved a reduction in the PSSI from 18.4 to 5.6 (\(P < .001\)) and an improvement in the investigator’s global assessment in 79.8% of patients.

In a randomized, double blind, multicenter trial, Ruzicka and Trompke compared treatment with talcalcitol emulsion (4 µg/g) to placebo for 8 weeks in 273 patients with mild to moderate scalp psoriasis. They observed a greater reduction in the global severity score with tacalcitol than with placebo (58% and 30% respectively, \(P < .001\)). No trials have compared talcalcitol with other drugs used to treat scalp psoriasis.

### Safety

The most common adverse event associated with calcipotriol solution is irritation, usually observed at the start of treatment. In an observational study of a calcipotriol solution in over 3000 patients, adverse events were recorded in only 2.4% of patients after 8 weeks of treatment. In a 52-week observational study enrolling 202 patients, 18 adverse events were observed during the first 2 weeks, but after that the frequency of events gradually declined until only a single event occurred between weeks 28 and 52. In the randomized controlled trials that compared calcipotriol to topical corticosteroids, more adverse events were associated with calcipotriol than with the corticosteroids. In a study by Klaber et al in 474 patients, adverse events were reported for 87 patients in the calcipotriol group and 31 patients in the betamethasone group, leading to withdrawal of treatment in 4.6% and 0.9% of patients, respectively (\(P = .017\)).

It is possible that cutaneous irritation could be attenuated by the administration of oral itraconazole. One trial showed that application of calcipotriol by patients pretreated with itraconazole to reduce or eliminate colonies of *Malassezia furfur* was associated with less irritation than its application in a control group pretreated with placebo (19.4% versus 47.1%, \(P < .001\)). The therapeutic effect on the scalp lesions was similar in both groups.

### Summary of the Review

Vitamin D analogs are a safe and effective alternative for the treatment of psoriasis of the scalp. In 2 double blind comparative trials calcipotriol was less effective than topical corticosteroids. In another 2 trials, neither of which had a sufficient sample size, no differences were observed between the treatment groups even though the treatments were administered for more than 4 weeks. Long-term treatment with vitamin D derivatives, at least in psoriasis affecting other parts of the body, maintains its efficacy and is not associated with tachyphylaxis. The most common adverse event is irritation, especially on the face. The adverse effects can be attenuated by reducing the frequency of application or by adding other treatments, such as topical corticosteroids. The frequency of adverse events also tends to decrease over time.

Table 5 summarizes the responses of the expert panel and the members of the psoriasis group.

### Recommendation of the Expert Panel

Vitamin D analogs are second-line treatments in psoriasis of the scalp and have a good safety profile.

Grade of recommendation: B.

### Combination Therapy With Vitamin D and Corticosteroids

Treatments combining 2 or more active ingredients are widely used in medicine because they can offer advantages over single-drug therapy, especially in terms of increased efficacy.

### Table 5 Positive or Negative Consensus on Treatment With Vitamin D Analogs

<table>
<thead>
<tr>
<th>Consensus of the Expert Panel</th>
<th>Consensus of the Psoriasis Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Med</td>
<td>Pos</td>
</tr>
<tr>
<td><strong>General considerations</strong></td>
<td></td>
</tr>
<tr>
<td>Vitamin D analogs have an excellent safety profile.</td>
<td>6</td>
</tr>
<tr>
<td><strong>Which vitamin D Analog should be considered a first-line treatment.</strong></td>
<td></td>
</tr>
<tr>
<td>Calcitriol</td>
<td>3</td>
</tr>
<tr>
<td>Calcipotriol</td>
<td>4</td>
</tr>
<tr>
<td>Tacalcitol</td>
<td>2</td>
</tr>
</tbody>
</table>

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.
efficacy and reductions in adverse events. The use of drugs that act in different ways on the same disease can result in a synergistic effect offering a good level of efficacy while also reducing the adverse effects of both drugs. Combination therapy is very common in the management of psoriasis. In the treatment of psoriatic scalp lesions, the combination of a topical corticosteroid and a topical vitamin D analog can reduce the irritation produced by the vitamin D and minimize the amount of topical corticosteroid required, thereby improving the safety profile of the treatment.52 However, a certain chemical incompatibility exists when the combination involves 2 products that are stable at different pH levels, such as a vitamin D analog and a corticosteroid. There is evidence that this combination in the form of an ointment has an acceptable safety and efficacy profile and is well accepted by patients in the treatment of psoriasis.53 However, an ointment is not an acceptable treatment for use on the scalp because it is greasy and difficult to apply and clean. Gel is the most appropriate vehicle for this drug combination in the treatment of psoriatic lesions on the scalp.

**Efficacy**

In initial open-label studies involving small samples and no comparator, an ointment containing calcipotriol and betamethasone improved symptoms and was associated with almost no adverse effects.54-57 To improve cosmetic acceptability, a new gel formulation of the calcipotriol/betamethasone combination for once daily application has been developed. Several randomized trials that compared this 2-compound product with each of its components in monotherapy have been published in recent years.57-60 During the clinical development phase, the combination was studied in 4479 patients with mild, moderate, or severe scalp psoriasis, 313 in comparison with placebo and the rest in comparison with calcipotriol or betamethasone separately as monotherapy (Table 6).

In several 8-week controlled and double blind clinical trials, the combination of calcipotriol and betamethasone in gel applied once daily produced significantly better results than betamethasone dipropionate, calcipotriol, or its own vehicle when these were administered alone.57-60 Treatment efficacy was defined as clearance or an excellent response as assessed by the investigator or as the proportion of patients who presented with “absent” or “very mild disease” in the global assessment of the investigator.

Another study evaluated the effect on quality of life of once daily application of the 2-compound gel (calcipotriol 50 µg/g plus betamethasone dipropionate 0.5 mg/g) compared to that of twice daily application of a calcipotriol solution (50 µg/mL); quality of life was measured using the SF-36 and the more specific Skindex-16 questionnaire.61 Skindex-16 scores demonstrated a statistically significant difference in favor of the 2-compound therapy from week 2.

Table 6 Clinical Trials Evaluating the Treatment Efficacy of Calcipotriol and Betamethasone in Gel Compared to Either Component Alone, Other Drugs, or Placebo

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Design</th>
<th>Severity Dose</th>
<th>Vehicle</th>
<th>No. of Patients</th>
<th>Study Duration</th>
<th>% Response</th>
<th>Overall Efficacy</th>
<th>Evidence Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compared to Placebo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tyring50</td>
<td>db, r, 3:1</td>
<td>ND</td>
<td>Cal/bet/plac Gel</td>
<td>135/42</td>
<td>8 wks</td>
<td>72 vs 40a</td>
<td>Combi &gt; plac</td>
<td>1(++)</td>
</tr>
<tr>
<td>Buckley57</td>
<td>db, r</td>
<td>M/M/S</td>
<td>Cal/bet qd Gel</td>
<td>108</td>
<td>8 wks</td>
<td>83a</td>
<td>Combi &gt; bet</td>
<td>1(++)</td>
</tr>
<tr>
<td>Jemec58</td>
<td>db, r</td>
<td>M/M/S</td>
<td>Cal/bet qd Gel</td>
<td>541</td>
<td>8 wks</td>
<td>71,2a</td>
<td>Combi &gt; bet</td>
<td>1(++)</td>
</tr>
<tr>
<td>Van der Kerkhof59</td>
<td>db, r (1:1:2)</td>
<td>M/M/S</td>
<td>Cal qd Gel</td>
<td>272</td>
<td>8 wks</td>
<td>43.4</td>
<td>Combi &gt; cal</td>
<td></td>
</tr>
<tr>
<td>Kragballe62</td>
<td>ib, r (2:1)</td>
<td>M/M/S</td>
<td>Cal/bet qd Gel</td>
<td>568</td>
<td>8 wks</td>
<td>61</td>
<td>Combi = bet</td>
<td></td>
</tr>
<tr>
<td>Lugers63</td>
<td>db, r</td>
<td>M/M/S</td>
<td>Cal qd Gel</td>
<td>563</td>
<td>8 wks</td>
<td>69a</td>
<td>Combi &gt; cal</td>
<td>1(++)</td>
</tr>
<tr>
<td>Abbreviations: bid, twice daily; bet, betamethasone; dip, dipropionate; cal, calcipotriol; combi, combination calcipotriol/betamethasone dipropionate; db, double blind; ib, investigator blinded; M/M/S, mild, moderate and severe; plac, placebo; qd, once daily; r, randomized.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>aPhysician’s global assessment: excellent response or cleared.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
onwards. The SF-36 results showed significant improvement from baseline in the group receiving the 2-compound gel formulation in both mental (weeks 2, 4, and 8, \( P<.05 \)) and physical components (week 8, \( P=.005 \)), while in the group treated with calcipotriol solution significant improvement was observed only in the mental component scores (week 8, \( P=0.04 \)). In the same randomized, single blind study, fewer patients were symptomatic at week 8 in the group on the 2-compound gel than in the group on the vitamin D analog alone (69% were symptom-free or had minimal disease in the former group versus 31% in the latter, \( P<.001 \)). The efficacy observed in the white patients has also been demonstrated in black and Hispanic patients with moderate to severe psoriasis of the scalp. Finally, in a randomized long-term (52-week) trial that compared the effect of a single daily application of a gel formulation containing calcipotriol (50 µg/g) plus betamethasone dipropionate (0.5 mg/g) to calcipotriol monotherapy in 869 patients with moderate to severe scalp psoriasis, Luger et al\textsuperscript{63} found that the combination provided satisfactory control without prior application of keratolytic agents at 92.3% of the follow-up visits in the 2-compound group versus 80% in the calcipotriol group (\( P<.001 \)).

**Safety**

The tolerability of these 2-compound formulations is similar to that of monotherapy with the corticosteroid, as the combination has been shown to attenuate the adverse effects associated with vitamin D monotherapy. In all the studies, the percentage of patients who reported a treatment-related adverse event was around 5% in both the 2-compound formulation group and the betamethasone group; in contrast, 13% in the group of patients who used calcipotriol and the placebo vehicle experienced adverse effects. Long-term use of the 2-compound formulation containing calcipotriol and betamethasone has been shown to be safe, with a 2.6% annual rate of adverse events possibly associated with treatment.\textsuperscript{64}

**Summary of the Review**

Topical treatment combining a corticosteroid and a vitamin D analog (calcipotriol and betamethasone in gel) offers advantages over monotherapy with either of the components because it is more effective and minimizes the adverse effects. In 3 randomized trials, the 2-compound formulation was shown to be more effective than the topical corticosteroid alone and to have a similar or better safety profile in the treatment of exacerbations of scalp psoriasis (once daily application for 4 weeks). Once remission of the exacerbation has been achieved, intermittent regimens can be used (daily application 2 to 3 times a week) to control the disease. Topical corticosteroids are a first-line short term treatment of psoriasis of the scalp and, based on the available evidence, the 2-compound formulation with calcipotriol is more effective than monotherapy with either of the components and in many cases is an ideal treatment for mild, moderate or severe scalp involvement.

Table 7 summarizes the responses of the expert panel and the members of the psoriasis group.

**Recommendation of the Expert Panel**

The combination of corticosteroids and vitamin D analogs is more effective than single-drug therapy with either component and has fewer adverse effects than monotherapy with vitamin D. The 2-compound therapy combining a corticosteroid and a vitamin D analog is a first-line treatment for psoriasis of the scalp.

Grade of recommendation: A.

**Other Topical Treatments**

The older treatments for psoriasis of the scalp are currently less well accepted by patients, and their efficacy is based more on experience and expert opinion than on controlled clinical trials.

---

**Table 7** Positive or Negative Consensus on Treatment With a Combination of Vitamin D and Topical Corticosteroid in Gel

<table>
<thead>
<tr>
<th>Consensus of the Expert Panel</th>
<th>Consensus of the Psoriasis Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General considerations about vitamin D and topical corticosteroid combination in a gel</strong></td>
<td>Med</td>
</tr>
<tr>
<td>This combination is the short-term first line treatment.</td>
<td>6</td>
</tr>
<tr>
<td>This combination is the most effective treatment for psoriasis of the scalp.</td>
<td>6</td>
</tr>
<tr>
<td>This combination treatment can improve efficacy and reduce adverse effects.</td>
<td>6</td>
</tr>
</tbody>
</table>

**Should this combination be considered a first-line treatment?**

Calcipotriol and betamethasone in gel. | 7 | 100 | | | 6 | | 71.4 | |

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.
Topical Vitamin A Derivatives

Keratolytic agents

The following agents have been used for their keratolytic properties: salicylic acid, alpha-hydroxy acids, and resorcinols. The penetration of other topical treatments appears to be enhanced by keratolytics, which usually eliminate hyperkeratotic scales and are, therefore, used prior to the application of other products. There are hardly any controlled trials of these products. The most widely used keratolytic agent is salicylic acid, which reduces desquamation by interacting with the desmosomes of the stratum corneum.44 Salicylic acid, typically used at concentrations between 5% and 10%, is usually formulated in a solution, gel, ointment, or petroleum jelly. Some of these vehicles are rejected by patients as cosmetically unacceptable, which limits their use and reduces adherence to treatment. In an uncontrolled study that enrolled 30 patients with moderate to severe scalp psoriasis who applied a 6% salicylic acid gel, improvement was observed in most patients 3 to 6 weeks after start of treatment.65 However, as this was an open-label study with a small sample and no comparison group, the conclusions should be interpreted with caution (evidence level 3).

Dithranol and Tar Derivatives

Coal tars have anti-inflammatory and antipruritic effects and inhibit epidermal proliferation. While their mechanism of action is poorly understood, they have been used for decades. Very few trials have been undertaken, but in an uncontrolled study of a coal-tar gel used by 112 patients, improvement was observed in 83% of patients, with remission persisting at 13 months in 30% of patients (evidence level 3).46 In a randomized, investigator-blinded study, Griffiths et al48 compared a 1% tar-blend shampoo (1%) with a 0.05% clobetasol propionate shampoo in 162 patients with moderate to severe scalp psoriasis. The corticosteroid shampoo was more effective than the tar product on all the scales evaluated (total and global severity score, \(P<.001\)) (see the section on topical corticosteroids).

Dithranol (anthralin) has also been used effectively for decades in the treatment of psoriasis of the scalp. Although the mechanism of action remains unclear, it appears that anthralin induces the formation of free radicals directed against mitochondrial toxicity.55 Wulff-Woesten et al49 randomized 64 patients to receive dithranol in 1 of 3 formulations: an easily washed emulsifying oil base, a cream, or a combination of both cream and oil. Using a modified PASI assessment, they observed improvement in symptoms with the washable emulsifying oil base formulation after 1 and 2 weeks (34% and 57% reduction in PASI, respectively). By day 18, the psoriasis lesions had been reduced by 50% in the patients treated with the oil base formulation and by only 20% in those treated with the cream formulations (\(P<.05\)) (evidence level 1–).

Antifungal agents

When psoriasis presents on the scalp in the form of scales, erythema, and pruritus, it is difficult to differentiate clinically or histologically between this entity and seborrheic dermatitis. Both entities have been associated with yeast infections caused by Malassezia globosa, Malassezia restricta, and Malassezia furfur. In fact, Malassezia yeasts are among the normal flora of human skin and, in the presence of certain predisposing factors, they can cause diseases such as pityriasis versicolor, Malassezia species folliculitis, seborrheic dermatitis, some forms of atrophic, reticulate papillomatosis, and systemic infections.70 This pathogenic potential is the basis for the use of antifungal agents.71 The following preparations have been used: 2% ketoconazole, 1.5% ciclopirox olamine, 2% clotrimazole and itraconazole (200 mg/d). Shemer et al72 evaluated the efficacy of an ointment containing 40% urea and 1% bifonazole as the antifungal agent applied at night in 52 patients with psoriasis of the scalp and 17 patients with seborrheic dermatitis in an open-label trial. The ointment was applied once daily for 7 days (or 14 if no response was observed) and then once a week for 3 weeks. At the end of treatment, an improvement was observed in 24.6% of the patients with psoriasis of the scalp and 42.1% of the patients with seborrheic dermatitis (evidence level 2+). In a randomized placebo-controlled trial, Jury et al73 studied the antifungal agent itraconazole (200 mg/d taken orally) in 28 patients with psoriasis of the scalp. After 2 weeks of treatment, no differences in PASI scores were observed between the group taking the oral antifungal agent and the controls. Sample size, study duration, and the use of oral treatment may all have contributed to the lack of any appreciable difference between the groups (evidence level 1–).

The question of whether pretreatment with an antifungal agent could reduce the local irritation caused by calcipotriol has also been studied. More abundant colonization with Malassezia yeasts has been observed in the areas where irritation occurred following treatment with calcipotriol solution. Starting from the hypothesis that Malassezia yeast species could interfere with topical calcipotriol therapy, Faergermann et al74 undertook an 8-week double blind clinical trial in which 137 patients with psoriatic scalp lesions were randomized to pretreatment with either itraconazole or placebo. After 2 weeks of pretreatment, calcipotriol solution was applied daily for 6 weeks in both groups. The percentage of patients who presented local irritation was lower in the group treated with itraconazole than in the control group (19.4% and 47.1% respectively, \(P<.001\)). Skin irritation caused by calcipotriol was also less evident in the patients with lower-grade Malassezia yeast colonization (\(P=.017\)) (evidence level 1++).
Safety

No large controlled trials have been carried out with dithranol because of the reddish brown stains it leaves and the irritation it causes in some patients. Moreover, all the formulations of dithranol are difficult to wash off the scalp, which limits its use to specialized dermatology clinics and selected patients.

For some time, the safety of tars and their derivatives has been questioned because of their mutagenic potential\(^7^5\) and because their use has been associated with nonmelanoma skin cancers.\(^7^6\) The disagreeable smell and staining associated with the use of tar are other factors that have relegated these treatments to a minor role. New tar formulations that do not discolor the skin are currently being investigated.\(^7^7\) Tazarotene has not been used on the scalp, but it can irritate the skin, causing associated adverse effects such as erythema, a burning sensation, and pruritus.\(^7^8\)

Summary of the Review

The use of the topical treatments discussed in this section is based on many decades of clinical experience, but there is a paucity of rigorously designed controlled trials. Furthermore, the use of this very heterogeneous group of compounds is limited by their adverse effects. Owing to its unfavorable cosmetic characteristics and weak effect compared to topical corticosteroids, coal tar is being displaced by other therapies. Anthralin causes skin irritation. While there is broad clinical experience with tazarotene, no controlled trials have specifically studied its application in scalp psoriasis, although it is considered more effective than its vehicle in cream or gel formulations.\(^7^9\) Owing to its potent keratolytic action, salicylic acid enhances the action of certain topical corticosteroids.

Table 8 summarizes the responses of the expert panel and the members of the psoriasis group on this section of the questionnaire.

Recommendation of the Expert Panel

The topical therapies other than the corticosteroids and vitamin D derivatives can be used when first-line treatments are contraindicated or fail to produce any response.

Grade of recommendation: C-D.

Physical therapy

Phototherapy and Grenz Ray Therapy

Efficacy

Phototherapy is a classic treatment for psoriasis, although few studies have been carried out. Both psoralen plus UV-A (PUVA) and narrow-band UV-B (311 nm) phototherapies have been used. However, the application of UV radiation on the scalp is difficult because hair blocks the penetration of the rays. Combs that emit UV-B radiation (308 nm) have recently been designed for use on thick hair. Used in conjunction with a scalp heater, they achieve better penetration.\(^8^0\) The very few controlled trials carried out specifically on psoriasis affecting the scalp have low statistical power. When phototherapy was compared with the application of betamethasone valerate lotion in 44 patients, no differences were observed between the 2 treatments although in the post-treatment follow-up the percentage of recurrence was lower in the group treated with phototherapy.\(^8^1\) No trials have compared Grenz rays with placebo. Grenz rays emit electromagnetic radiation that penetrates more superficially than normal x-rays. The

<table>
<thead>
<tr>
<th>Table 8</th>
<th>Positive or Negative Consensus on Topical Treatments Other than Vitamin D Derivatives and Corticosteroids</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consensus of the Expert Panel</td>
</tr>
<tr>
<td></td>
<td>Med</td>
</tr>
<tr>
<td>General considerations</td>
<td></td>
</tr>
<tr>
<td>Products derived from tar and coal tar are the treatments best accepted by patients.</td>
<td>2</td>
</tr>
<tr>
<td>Vitamin A derivatives are the first-line treatment for psoriasis of the scalp.</td>
<td>2</td>
</tr>
<tr>
<td>Vitamin A derivatives are the most effective treatment for psoriasis of the scalp.</td>
<td>2</td>
</tr>
<tr>
<td>Which of the following should be considered first-line treatments?</td>
<td></td>
</tr>
<tr>
<td>Dithranol</td>
<td>2</td>
</tr>
<tr>
<td>Salicylate in petrolatum</td>
<td>2</td>
</tr>
<tr>
<td>Coal tar</td>
<td>2</td>
</tr>
<tr>
<td>Tazarotene</td>
<td>2</td>
</tr>
<tr>
<td>Antifungal agents</td>
<td>3</td>
</tr>
<tr>
<td>Phototherapy</td>
<td>3</td>
</tr>
</tbody>
</table>

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.
combination of Grenz rays with corticosteroids has been shown to offer only marginal benefits in psoriasis of the scalp.82

Safety

The treatment of the scalp with UV-B radiation (308 nm) produces erythematic lesions and intense heat in all patients.

Summary of the Review

Phototherapy is difficult to use on the scalp and should be considered a second-line treatment.

Recommendation of the Expert Panel

There is insufficient evidence to support a recommendation.

Systemic Therapies

Systemic therapies are limited to patients with scalp psoriasis that has not responded to topical treatment and to patients with lesions in other areas of the body that have failed to respond to less aggressive therapies. Systemic therapies may be conventional ones (methotrexate, ciclosporin, acitretin, and fumaric acid esters) or biologic agents (etanercept, infliximab, adalimumab, alefacept, and ustekinumab). While there is a paucity of studies with a high level of scientific evidence dealing specifically with the topical treatment of scalp lesions, there are simply no trials in the literature specifically designed to evaluate the effect of systemic therapies on scalp psoriasis. However, clinical experience suggests that when a patient’s psoriasis responds to systemic treatment, scalp lesions improve at least as much as those in other areas and such treatment sometimes achieves complete clearance of the scalp.83

Efficacy

- Classic Systemic Therapies
  Methotrexate has traditionally been used to treat moderate to severe cases of psoriasis that respond poorly or not at all to topical treatment. Methotrexate is a folic acid analog that reduces DNA and RNA synthesis by inhibiting purine synthesis. In patients with conventional psoriasis, there is evidence that methotrexate is effective because of its anti-inflammatory and antiproliferative properties.2 In a study with evidence level A, methotrexate produced a remission in 40% of patients (>90% reduction in PASI).84 Comparative trials have shown methotrexate to be less effective than either ciclosporin or adalimumab.85,86 No studies have specifically evaluated methotrexate in scalp psoriasis.
  Ciclosporin, a cyclic peptide composed of 11 amino acids, is isolated from the spores of the fungus Tolypocladium inflatum Gams. It has been widely used as an immunosuppressant to prevent the rejection of organ transplants, and its mechanism of action in plaque psoriasis remains unclear. In several trials that have evaluated systemic treatment of psoriasis with ciclosporin alone, PASI 75 response rates have been observed in 50% to 70% of patients, depending on the dose used.87,88 The systemic retinoid acitretin, an active metabolite of etretinate that inhibits keratinocyte proliferation, is used in cases of severe psoriasis that have failed to respond to topical treatment. The use of acitretin in the treatment of severe psoriasis has been studied89 but not its specific use in the treatment of scalp lesions. Positive results are usually observed only after 24 weeks of treatment.90
  The use of fumaric acid esters, which act by interacting with glutathione, has been evaluated in 2 studies, neither of which dealt with psoriasis of the scalp.91,92

Biologic Systemic Therapies

Adalimumab, a recombinant, humanized, monoclonal antibody, is an immunoglobulin-G that inhibits tumor necrosis factor alpha (TNF-α) and reduces the expression of other inflammation markers. Its efficacy in moderate to severe plaque psoriasis has been demonstrated in 2 placebo-controlled randomized trials,93,94 but the results relating to scalp psoriasis have only been presented in the form of a poster. In the BELIEVE study, the scalp was affected in 90% of the patients and the active treatment reduced the PSSI from 17.9 at baseline (n = 663) to 3.5 at week 8 (n = 640).95 Etanercept, a fusion protein that includes the soluble TNF-α receptor and neutralizes this cytokine, has been evaluated in a number of randomized trials involving patients with moderate to severe plaque psoriasis.96-99 In a 54-week open study, 711 patients with scalp psoriasis were randomized to either a continuous or an intermittent treatment regimen. Severity as measured by the PSSI improved significantly from a mean baseline score of 2.78 in both regimens, although the improvement was greater in the patients receiving continuous treatment (final follow-up PSSI, 0.89) than in those treated intermittently (final follow-up PSSI, 1.28).100
  Infliximab is a monoclonal antibody against TNF-α with proven efficacy in psoriasis.101,102 However, its use in the treatment of psoriatic plaques on the scalp has not been specifically evaluated.
  Alefacept is a recombinant human fusion protein with immunoglobulin-G that inhibits the activation of T-cells by binding to the CD2 receptor. Alefacept has been shown to be effective in certain subgroups of psoriatic patients.103,104 In a 16-week open trial, alefacept therapy (15 mg/wk by intramuscular injection) was evaluated in 30 patients with psoriatic plaques on the scalp.105 Response was measured by evaluating the percentage of patients with a “clear” or “almost clear” assessment, a result reported in 16.7% of cases at the 6-week follow-up. Alefacept is not available in Spain.
  Ustekinumab is a human monoclonal antibody that binds to the p40 protein subunit of interleukins 12 and 23. In 2 studies involving over 2000 patients with psoriasis, at week 12 improvement was observed in the PASI of at least 75%
in 66% to 76% of patients with ustekinumab and in only 3% to 5% of patients receiving placebo.\textsuperscript{106,107} The improvement was observed throughout the follow-up period (52–76 weeks). Psoriasis of the scalp was not specifically studied.

Safety

The limitations affecting the use of methotrexate are related to its many adverse effects, which include hematopoietic suppression, liver abnormalities, gastrointestinal symptoms, and in some cases hair loss. The chief adverse events associated with ciclosporin are hypertension and increased serum creatinine, making continuous monitoring of renal function essential; this drug is also associated with an increase in the development of nonmelanoma skin cancer. Oral retinoids have mucocutaneous and musculoskeletal adverse effects, in particular cheilitis and dryness of the skin and mucosal surfaces. The high teratogenicity of acitretin makes strict contraceptive measures necessary during treatment and for years after its completion. Retinoids also alter liver function and the lipid profile. The safety profile of fumaric acid esters is characterized by the frequent development of gastrointestinal disorders and flushing. The adverse events most often reported for adalimumab are upper respiratory tract infections and local reactions at the injection site. However, severe psoriasis of the scalp with diffuse alopecia induced during adalimumab treatment has recently been reported.\textsuperscript{108} In the PHOENIX 1 and 2 studies, ustekinumab was associated with a rate of adverse events similar to that of placebo.\textsuperscript{106,107} However, the long-term safety profile of this drug with respect to infections and neoplasms is not yet completely clear.\textsuperscript{109}

Table 9 summarizes the responses of the expert panel and the members of the psoriasis group with regard to systemic treatments.

Table 9  Positive or Negative Consensus on Systemic Treatments

<table>
<thead>
<tr>
<th></th>
<th>Consensus of the Expert Panel</th>
<th>Consensus of the Psoriasis Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Med</td>
<td>Pos</td>
</tr>
<tr>
<td><strong>General considerations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic treatments should be used when other options have failed.</td>
<td>6</td>
<td>71.4</td>
</tr>
<tr>
<td>Systemic treatments have the best safety profile.</td>
<td>2</td>
<td>71.4</td>
</tr>
<tr>
<td><strong>Which systemic drug should be considered a first-line treatment?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Ciclosporin</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Acitretin</td>
<td>2</td>
<td>70.1</td>
</tr>
<tr>
<td>Fumaric acid esters</td>
<td>2</td>
<td>85.7</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>2</td>
<td>71.4</td>
</tr>
<tr>
<td>Etanercept</td>
<td>2</td>
<td>71.4</td>
</tr>
<tr>
<td>Infliximab</td>
<td>2</td>
<td>71.4</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>2</td>
<td>85.7</td>
</tr>
</tbody>
</table>

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.

Recommendation of the Expert Panel

Systemic treatments are used to treat very severe psoriasis of the scalp or patients with moderate to severe psoriasis in other sites that requires systemic treatment (Table 9).

Grade of recommendation: D.

Conclusion

The main recommendations concerning the treatment of psoriasis of the scalp obtained from the Delphi process are shown below and in Tables 10-12.

1. In the topical treatment of psoriasis of the scalp, the vehicle is of utmost importance. Lotions, shampoos, and gels are associated with the best rates of adherence and are the preparations preferred by dermatologists.
2. Although the patient’s emotional well-being and quality of life can be affected by the presence of psoriatic scalp lesions, dermatologists rarely make use of instruments that analyze these aspects.
3. Potent topical corticosteroids are the first-line treatment for acute flares of psoriasis on the scalp.
4. Vitamin D analogs are a second-line treatment with a very good safety profile.
5. Two-compound formulations that combine calcipotriol and betamethasone in gel are, together with topical corticosteroids, the most effective first-line treatments for psoriatic scalp lesions.
6. Systemic agents are an alternative for use when other treatments have failed and should not be considered first-line treatments for scalp psoriasis.
7. Treatment of scalp psoriasis requires a 2-phase regimen: induction therapy until improvement or remission is achieved followed by maintenance treatment.
### Table 10  Treatment Regimens for Psoriasis of the Scalp

<table>
<thead>
<tr>
<th></th>
<th>Consensus of the Expert Panel</th>
<th>Consensus of the Psoriasis Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Med</td>
<td>Pos</td>
</tr>
<tr>
<td><strong>General considerations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A 2-phase regimen is required (induction until</td>
<td>6</td>
<td>85.7</td>
</tr>
<tr>
<td>improvement or remission is achieved,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>followed by maintenance treatment).</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Preferred induction treatments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antifungal shampoo</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Corticosteroids in solution</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Combination of vitamin D + corticosteroids</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td><strong>Usual duration of induction therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 1 week</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>From 2 to 3 weeks</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Case by case basis</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Usual frequency of induction treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 application daily</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Weekly (1-2 days a week)</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.

### Table 11  There is Evidence Supporting a 2-Phase Regimen in the Following Treatments

<table>
<thead>
<tr>
<th></th>
<th>Consensus of the Expert Panel</th>
<th>Consensus of the Psoriasis Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Med</td>
<td>Pos</td>
</tr>
<tr>
<td><strong>Antifungal shampoo</strong></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Tar-based shampoo</strong></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Keratolytic agents</strong></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Combination of vitamin D + corticosteroids</strong></td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.

### Table 12  Treatment Regimens During the Maintenance Phase in Psoriasis of the Scalp

<table>
<thead>
<tr>
<th></th>
<th>Consensus of the Expert Panel</th>
<th>Consensus of the Psoriasis Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Med</td>
<td>Pos</td>
</tr>
<tr>
<td><strong>Preferred treatments during the maintenance phase</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination of vitamin D + corticosteroids</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Vitamin D analogs</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td><strong>Usual duration of treatment during the maintenance phase</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 1 week</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Case by case depending on response</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>The usual frequency of maintenance treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two applications daily</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Weekly (1-2 days a week)</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: med, median; neg, negative consensus; pos, positive consensus.
8. The preferred treatments for the induction phase are corticosteroid solutions and combination formulations containing calcipotriol and betamethasone administered once daily for 3 weeks.

9. The preferred maintenance treatments are vitamin D analogs and combination formulations containing calcipotriol and betamethasone.

10. The fixed-dose combination of betamethasone and calcipotriol produces better results in terms of efficacy and safety during the induction phase than monotherapy with either of the 2 components and also reduces the quantity of corticosteroid required.

11. Maintenance therapy with the fixed dose combination of betamethasone and calcipotriol is as safe as vitamin D analogs and more effective.

The GRADE recommendations of the expert panel on the topical treatment of psoriasis of the scalp during

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**Table 13**  GRADE Recommendations of the Expert Panel for the Topical Treatment of Psoriasis on the Scalp During the Acute Phase or From Induction to Remission*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Evidence Level</th>
<th>Balance of Desirable and Undesirable Effects</th>
<th>Resource Utilization</th>
<th>Patient Comfort</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids (lotion)</td>
<td>High</td>
<td>Good</td>
<td>High</td>
<td>Moderate</td>
<td>A</td>
</tr>
<tr>
<td>Corticosteroids (shampoo)</td>
<td>High</td>
<td>Good</td>
<td>Moderate</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>Corticosteroids (foam)</td>
<td>Moderate</td>
<td>Good</td>
<td>Moderate</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Vitamin D analogs</td>
<td>High</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Topical retinoids</td>
<td>Very low</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>Combination of corticosteroids and calcipotriol</td>
<td>High</td>
<td>Good</td>
<td>Moderate</td>
<td>Moderate</td>
<td>A</td>
</tr>
<tr>
<td>Combination corticosteroids and salicylates</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
<td>Moderate</td>
<td>C</td>
</tr>
<tr>
<td>Coal tar</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Poor</td>
<td>C</td>
</tr>
<tr>
<td>Salicylates</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
<td>Moderate</td>
<td>C</td>
</tr>
<tr>
<td>Antifungal agents</td>
<td>Very low</td>
<td>Poor</td>
<td>Moderate</td>
<td>Moderate</td>
<td>D</td>
</tr>
<tr>
<td>Phototherapy</td>
<td>Low</td>
<td>Moderate</td>
<td>Low</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>Systemic agents</td>
<td>Low</td>
<td>Moderate</td>
<td>Very low</td>
<td>Moderate</td>
<td>D</td>
</tr>
</tbody>
</table>

*Five levels of evidence and 4 grades of recommendation (A to D) were defined.

Grade A (highly recommended), based on level 1 studies. Grade B (favorable recommendation), based on level 2 or 3 studies or extrapolations from level 1 studies. Grade C (inconclusive favorable recommendation), based on level 4 studies. Grade D, which implies neither recommendation or disapproval of the intervention, based on level 5 studies.

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**Table 14**  GRADE Recommendations of the Panel of Experts for the Topical Treatment of Psoriasis of the Scalp During the Maintenance Phase*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Evidence Level</th>
<th>Balance of Desirable and Undesirable Effects</th>
<th>Resource Utilization</th>
<th>Patient Comfort</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids (lotion)</td>
<td>Very low</td>
<td>Unknown</td>
<td>Moderate</td>
<td>Moderate</td>
<td>D</td>
</tr>
<tr>
<td>Corticosteroids (shampoo)</td>
<td>Very low</td>
<td>Unknown</td>
<td>Moderate</td>
<td>High</td>
<td>D</td>
</tr>
<tr>
<td>Corticosteroids (foam)</td>
<td>Very low</td>
<td>Unknown</td>
<td>Moderate</td>
<td>Moderate</td>
<td>D</td>
</tr>
<tr>
<td>Vitamin D analogs</td>
<td>High</td>
<td>Good</td>
<td>Moderate</td>
<td>Moderate</td>
<td>D</td>
</tr>
<tr>
<td>Topical retinoids</td>
<td>Very low</td>
<td>Unknown</td>
<td>Moderate</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>Combination of corticosteroids and calcipotriol</td>
<td>High</td>
<td>Good</td>
<td>Moderate</td>
<td>Moderate</td>
<td>A</td>
</tr>
<tr>
<td>Combination corticosteroids and salicylates</td>
<td>Low</td>
<td>Unknown</td>
<td>Moderate</td>
<td>Moderate</td>
<td>D</td>
</tr>
<tr>
<td>Coal tar</td>
<td>Low</td>
<td>Poor</td>
<td>Moderate</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>Salicylates</td>
<td>Low</td>
<td>Unknown</td>
<td>Moderate</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>Antifungal agents</td>
<td>Very low</td>
<td>Poor</td>
<td>Moderate</td>
<td>Moderate</td>
<td>D</td>
</tr>
<tr>
<td>Phototherapy</td>
<td>Very low</td>
<td>Moderate</td>
<td>Low</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>Systemic agents</td>
<td>Low</td>
<td>Moderate</td>
<td>Very low</td>
<td>Moderate</td>
<td>D</td>
</tr>
</tbody>
</table>

*Five levels of evidence and 4 grades of recommendation (A to D) were defined.

Grade A (highly recommended), based on level 1 studies. Grade B (favorable recommendation), based on level 2 or 3 studies or extrapolations from level 1 studies. Grade C (inconclusive favorable recommendation), based on level 4 studies. Grade D, which implies neither recommendation or disapproval of the intervention, based on level 5 studies.
induction and maintenance are shown are Tables 13 and 14, respectively.

**Conflict of Interest**

Dr Luis Puig has received consulting and speaking fees and has participated in clinical trials sponsored by Leo Pharma and Galderma.

Dr Miquel Ribera has received consulting and speaking fees and has participated in clinical trials sponsored by Leo Pharma, Galderma, Abbott, Janssen-Cilag, Merck-Serono, Novartis, Pfizer, Schering-Plough, and Wyeth.

Dr José M. Hernández has received consulting and speaking fees and has participated in clinical trials sponsored by Leo Pharma, Abbott, Janssen, Leo Pharma, Merck-Serono, Novartis, Pfizer, Schering-Plough, and Wyeth.

Dr Isabel Belinchón has received consulting and speaking fees and has participated in clinical trials sponsored by Leo Pharma, Abbott, Janssen, Leo Pharma, Merck-Serono, Novartis, Pfizer, Schering-Plough, and Wyeth.

Dr Esteve Colomé and Dr Gloria Caballé are employees of Leo Pharma España, a company that sponsored the meetings and teleconferences of this group without in any way interfering in those meetings.

The remaining authors declare no conflicts of interest.

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54. Taylor CR, Racette AL. A 308-nm excimer laser for the
53. Dotterud LK, Braun R. UV-B comb versus betamethasone
solution in scalp psoriasis. Tidskr Nor Laegeforen. 2000;
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51. García Diez A. Tratamiento sistémico de la psoriasis del cuero
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et al. A study of the safety of efficacy of calcipotriol and
betamethasone dipropionate scalp formulation in the
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cuo cabelludo del adulto. Monogr Dermatol. 2009;22:
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solution for psoriasis does not discolor naturally light or color-
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29. Dotterud LK, Braun R. UV-B comb versus betamethasone
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Grenz rays or topical corticosteroid combined with Grenz
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23. Reynolds NJ. The anti-psoriatic drug anthralin accumulates in
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et al. A study of the safety of efficacy of calcipotriol and
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cuo cabelludo del adulto. Monogr Dermatol. 2009;22:
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