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Scalp Psoriasis: Systematic Review Comparing Topical Treatments and Placebo

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Abstract

Patients with scalp psoriasis suffered from a lower quality of life relating to the highly visible site of their psoriatic lesions. In consequence this fact stimulates investigations involving treatments of this dermatologic disease. The aim of this review is to evaluate the topical treatments for scalp psoriasis compared with placebos. Methods: A systematic review was performed using searches in the database LILACS, MEDLINE, Cochrane Library, and Embase. As selection criteria were chosen eligible publications involving randomized controlled trials, patients with scalp psoriasis diagnosed clinically or by biopsy, interventions with topical treatments for scalp psoriasis compared with placebo. Outcome related to the reduction in severity of psoriasis of the scalp, assessed by physicians and patients, and assessment of adverse effects that required discontinuation of treatment. The results have shown that the patients were aged 12 to 97 years, including 3441 patients. Ten of the fifteen studies included reported gender data. Patients were mostly female. Twelve studies were about psoriasis's severity. These studies in which the severity has been described, the classification of severity was mild (0 study), mild to moderate (1 study), moderate to severe (11 studies) and severe (0 study). In conclusion, topical corticosteroids, calcipotriol, ciclopirox olamine and associations between them are effective in the treatment of scalp psoriasis. Clobetasol propionate (0.05%) was the most effective active ingredient in several vehicles in the induction treatment of scalp psoriasis.

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Keywords

Scalp Psoriasis, Topical Treatments, Placebo, Topical Corticosteroids

1. Introduction

Psoriasis is a hereditary disorder that affects 3% of the population worldwide [1]-[3]. There are two common ages for the onset of psoriasis. The first is around 21 years and the second at approximately 50 years [4] [5]. The most frequent type is psoriasis vulgaris, which appears as chronic, erythematous (reddish), and scaling skin lesions [6]. Clinical presentation varies from those with only a few localized lesions to those with generalized skin involvement [4].

There is evidence indicating that interaction between genes and certain environmental factors is an important cause of this disease [7]. Inflammatory cytokines such as tumor necrosis factor alpha, interferon gamma, and other type 1 cytokines also play an important role in the pathogenesis of psoriasis [8]. Many drugs that are used to treat other clinical conditions have also been reported to be responsible for the onset or exacerbation of psoriasis [9]. Among these drugs are lithium salts, antimalarials, beta-blocking agents, non-steroidal anti-inflammatory drugs (NSAIDS), angiotensin-converting enzyme (ACE) inhibitors, and the withdrawal of corticosteroids [10] [11].

Many clinical variants to the psoriasis are described, such as psoriasis vulgaris, guttate psoriasis (drops psoriasis), erythrodermic psoriasis (red psoriasis) and pustular psoriasis [11] [12]. The scalp is one of the most commonly affected parts of the body in people with psoriasis, and the frequency of involvement increases with the duration of the disease [13]. It may be part of generalized psoriasis or coexist with isolated plaques, or the scalp may be the only site involved. Signs and symptoms of scalp psoriasis vary significantly in different people, but pruritus, scaling and cosmetic embarrassment are often present [14] [15]. Because sensitive facial skin is so near the scalp, the use of potentially irritating topical treatments may be limited. Even so, the specific challenges of scalp psoriasis are often neglected in treatment guidelines [15] [16].

Scalp psoriasis can occasionally be confused with seborrhoeic dermatitis affecting the scalp [17]. Seborrhoeic dermatitis is another inflammatory condition which commonly affects the whole of the scalp resulting in mild inflammation and dandruff [17]. Psoriasis on the other hand is usually well-demarcated and has a coarser scale, but early diffuse psoriasis of the scalp can sometimes look very similar to seborrhoeic dermatitis. Sometimes a scalp biopsy may help [18] [19]. Those with psoriasis may also suffer from psychological distress, especially as a result of stigmatization and self-consciousness, so relatively high rates of depression have been reported [20].

The Psoriasis Area and Severity Index (PASI) is one of the most frequently used instruments to evaluate the severity of the disease and its response to different treatments, and its use is based on the extension and severity of the impact on the skin's surface [21] [22].

Relevant aspects of psoriasis that affect the person with this disease are evaluated using a variety of instruments, including the Psoriasis Disability Index (PDI) [23], Dermatology Quality of Life Index (DLQI) [24], the Psoriasis Symptom Assessment [25], and the Itching Scale [26]. The Physician Global Assessment is a tool to evaluate the psoriatic plaques [27]. This is a seven-point scale, with 7 being clear and 6 almost clear, 5 mild, 4 mild to moderate, 3 moderate, 2 moderately severe and 1 being severe psoriasis.

The aim of this review is to evaluate the topical treatments for scalp psoriasis compared with placebos.

2. Material and Methods

2.1. Keywords and Searches in the Databases

The keywords, psoriasis, scalp psoriasis and topical treatment were searched. The searches for identification of the publications used in this study were in Pubmed, Embase, The Cochrane Skin Group Specialised Register and in The Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library. PubMed was searched from 2005 to august 2011. EMBASE, searched from 2010 to August 2011, LILACS (Latin American and Caribbean Health Science Information database, from 1982 to August 2011. The Salford Database of Psoriasis trials was searched up to August 2011.

2.2. Inclusion Criteria to Select Publications in This Investigation

Concerning to the types of studies, only randomised controlled trials (RCTs) were included. The Participants of these studies had the diagnosis of scalp psoriasis, according to clinical or biopsy findings used by authors of primary studies, for example: the classical history, symptoms and signs and typical histopathologic features. The types of interventions were any comparisons of local therapies for scalp psoriasis and placebo, such as, Corticosteroids plus calcipotriol versus placebo, Calcipotriol versus placebo, Corticosteroids versus placebo, Ciclopirox olamine versus placebo, among others. In the studies the outcome measures were Primary outcomes (Reduction in clinician-assessed severity, Improvement in quality of life, Adverse events requiring withdrawal of the treatment such as serious allergic reactions) and Secondary outcomes (Subjective reduction in severity of psoriasis, Minor adverse events not requiring withdrawal of the treatment like rash, itching, Time free of disease, duration of response, measured by the proportion of participants relapsing to baseline scores during continued treatment or following discontinuation of treatment.

2.3. Exclusion Criteria to Select Publications in This Investigation

Quasi-randomized studies were not considered for inclusion. Papers published in other languages than in English were excluded.

2.4. PRISMA Flowchart Involving the Steps in Selecting Full

A flowchart, based in the PRISMA analysis [28], was done to show the steps in the selection of the full papers analyzed in this revision.

2.5. Data Analysis

Data was not comparable and therefore statistical pooling not appropriate with the result that the findings of this review were summarized in a narrative form.

3. Results

The electronic search found in PubMed 239 articles, in Embase, 39 articles and in the Cochrane Library, 125 articles. No article was found in the search of LILACS. Fifteen placebo-controlled studies were selected. The flowchart used in the selection of the papers discussed in this review is show in **Figure 1**.

The 15 studies included 3441 patients. The patient age was between 12 and 97 years old. Gender data were mentioned in 10 of the 15 studies included (66%). Patients were mostly female (1934 women and 1691 men). Twelve studies have discussed about the severity of psoriasis. In these studies that the severity has been described, the classification of severity was mild (0 study), mild to moderate (one study), moderate to severe (11 studies) and severe (0 trial). However, four studies did not provide sufficient information to assess the clinical severity. The evaluation score most widely used to assess the clinical severity was the GSS-TSS (global-total severity score). Quality of life was also mentioned.

The duration of treatment ranged from two weeks to two months. The evaluation included Individual signs (erythema, scaling, and thickening) and Total score or global severity (TSS or GSS).

Concerning to the randomized controlled trials, among the fifteen selected publications, 8 studies (53%) reported clearly the method used for randomization and 3 studies (20%) used the computer randomization. Related to the anthropometric characteristics of participants used in the studies selected, as the age and gender, six studies (40%) provided data regarding age, gender and characteristics of clinical patients. Eight studies (53%) provided incomplete data. Eight studies were excluded. One study was not considered due to it did not provide data properly. Seven studies were excluded because there was no comparison with placebo.

In **Table 1** are shown the selected publications, the treatments suggested involving medication and placebo, and the conclusion of the studies.

4. Discussion

Van Voorhees and Fried, 2009 [44] have pointed out that the involvement of the scalp in patient with psoriasis is frequent. Due to the greater exposure to the environmental, it has a considerable effect on the quality of life of

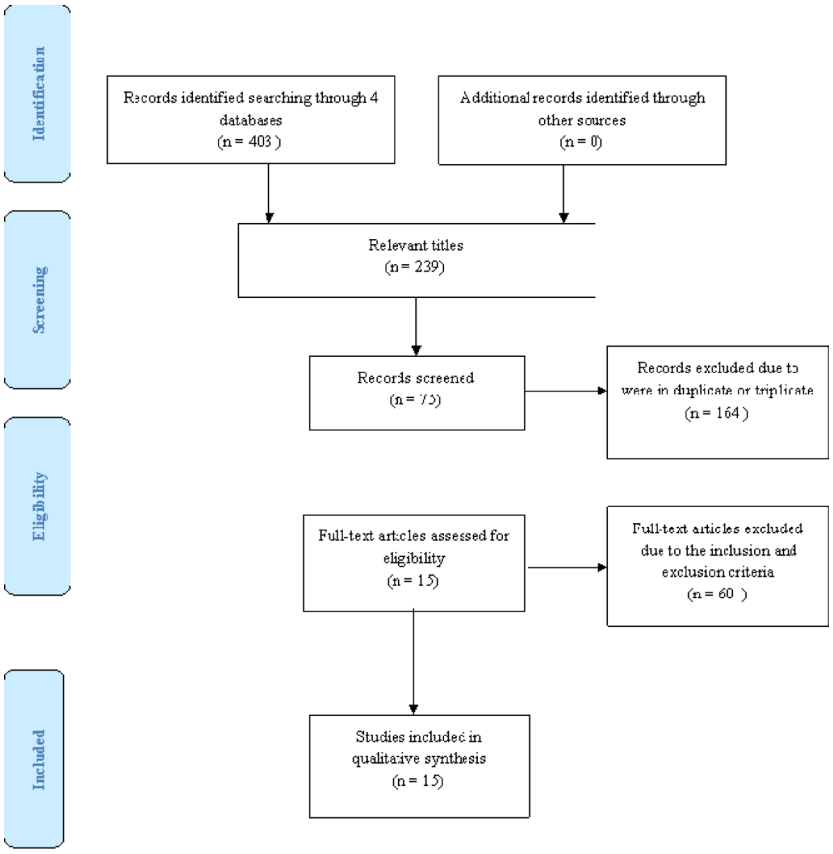

Figure 1. Flowchart indicating the steps to select the papers analyzed in this revision.

the patient. In this case, nevertheless, this fact must be discussed, due to the published studies rarely use tools to address these issues. Zampieron *et al.*, 2015 [45] have also reported that patients with scalp psoriasis suffered from a lower quality of life relating to the highly visible site of their psoriatic lesions. In consequence this fact stimulates investigations with this dermatologic disease, as it is presented in our work.

Firstly 403 papers were found in the databases that were searched. However, the analysis of the available papers used in this review included only 15 randomized controlled trials (see flowchart in **Figure 1**) due to the inclusion and exclusion criteria use.

The number of participants with scalp psoriasis with topical treatment in the publications is more than three thousand. The selected papers involve a total of 3 441 patients. Each of the studies utilized a comparison with a placebo, and the results of active ingredients were found to be more statistically significant than the placebos.

Many topical treatments, such as corticosteroids, calcipotriol, coal tar, salicylic acid are used for scalp psoriasis [46]. But, it is necessary to verify that there are few adequately controlled investigations that support the effectiveness of the suggested topical managements.

On the basis of the findings of this review, it was found that the best results were obtained with the use of clobetasol propionate in different vehicles (solution, foam and lotion) [29] [30]. When the placebo was compared to calcipotriol, there were better results with calcipotriol [47]-[49]; however, the magnitude of the effect was lower than in relation to clobetasol and It was similar to other corticosteroids, such as valerate of betamethasone, ancinonide, halcinonide, and fluocinolone acetonide. The opposite was observed for psoriasis on the body, which is described a greater efficiency in the association between calcipotriol and betamethasone dipropionate [50]. This study found no effect in terms of the overall gain in response to treatment in cases of psoriasis of the scalp. In **Table 1**, it is possible finding suitable information about the different formulations used to treat scalp psoriasis and the type of vehicle.

Characteristically, psoriasis is recurrent over years, and maintenance of the controlled disease, is a clinical challenge [51]. This fact is also true for scalp psoriasis. In this study, Meredith and Ormerod, 2012 [51] reported

Table 1. Selected publications, the treatments and conclusion of the studies.

References	Type of application	Treatment	Conclusion
Sofen *et al.*, 2011 [29]	Spray	Clobetasol propionate and placebo	Treatment for up to four weeks is effective and well tolerated for moderate-to-severe plaque psoriasis of the scalp.
Olsen *et al.*, 1991 [30]	Ointment	Clobetasol propionate and placebo	Clobetasol propionate 0.05% scalp application appears to be a safe and an effective treatment for scalp psoriasis.
Jarratt *et al.*, 2004 [31]	Shampoo	Clobetasol propionate and placebo	The shampoo formulation of clobetasol propionate is convenient and efficacious and minimizes systemic exposure while being efficient, safe and well-tolerated in the treatment of moderate to severe scalp psoriasis.
Franz *et al.*, 2000 [32]	Foam	Clobetasol propionate and placebo	The results of the studies demonstrate that the enhancement of absorption induced by the foam vehicle also leads to an increase in efficacy. Data from 188 subjects show that those treated with clobetasol propionate (CP) foam experienced greater psoriatic improvement than subjects treated with a currently marketed solution product. For each of the signs and symptoms of psoriasis, as well as for the investigator's global assessment, CP foam was found to be superior to CP solution.
Reygagne *et al.*, 2002 [33]	Shampoo or gel	Clobetasol propionate and placebo	After 4 weeks of treatment, clobetasol proprionate 0.05%, shampoo was at least equivalent to the gel form and superior to its vehicle. The two active treatments were found to be equivalent safe.
Franz *et al.*, 1999 [34]	Foam	Betamethasone valerate and placebo	This formulation has increased efficacy in the treatment of scalp psoriasis without an associated increase in toxicity.
Medansky and Handler, 1974 [35]	Lotion	Betamethasone valerate and placebo Betamethasone valerate and placebo	The lotion with betamethasone was more them the vehicle.
Tyring *et al.*, 2010 [36]	Ointment	Calcipotriol and betamethasone dipropionate with placebo	Calcipotriol and betamethasone dipropionate was significantly superior to placebo. 71.9% of patients had cleared ou minimal disease after 8 weeks of treatment.
Harris, 1972 [37]	Lotion (alcoholic)	Valerate betamethasone with placebo	Significant differences were found to exist in favor of betamethasone valerate lotion 0.1% in lichenification, excoriation, inflammation, scaling and pruritus than vehicle group.
Jemec *et al.*, 2008 [38]	(*)	Two active ingredients (calcipotriol and betamethasone dipropionate) with each one active ingredients separately and with placebo	The two active ingredients formula was superior to placebo and both of the active ingredients separately. Adverse effects were similar in the two compound group and betamethasone group and significantly smaller than calcipotriol group and placebo group.
Green *et al.*, 1994 [39]	Solution	Calcipotriol with placebo	Calcipotriol was significantly superior to placebo in reducing redness, thickness, scaliness and extent of psoriasis, and in the patients' assessment in reducing scalp flaking and itching. No statistically significant changes in blood biochemistry were detected during the study, and the solution was generally well tolerated.
Pauporte *et al.*, 2004 [40]	Topical oil	Fluocinolone acetonide with placebo	It is shown that fluocinolone acetonide (FA) in an oil base that aids in the softening of the skin and allows penetration of the steroid into the stratum corneum, is an effective treatment for psoriasis of the scalp. This study also showed that the vehicle alone causes an improvement in the signs of psoriasis, but that the addition of 0.1% of the low potency steroid, FA leads to a significantly better improvement.

Continued

Lepaw, 1978 [41]	Solution of edetate disodium, polyethylene glycol 300, purified water and butylated hydroxytoluene.	Halcinonide solution with placebo	The treatment was excellent in sixteen patients treated with halcinonide and in one patient treated with placebo. In the comparative evaluation halcinonide was superior in twenty-two patients, the placebo was superior in four patients, and both drugs were equally effective in one patient. There were no adverse reactions due to halcinonide, but one patient experienced pruritus with the placebo solution.
Ellis *et al.*, 1988 [42]	Lotion	Amcinonide with placebo	Among the patients, overall improvements in psoriatic lesions was seen in 78% amcinonide group and 27% of the placebo group. There was no serious side effects attributtabe to this study.
Shuttleworth *et al.*, 1998 [43]	Shampoo	Ciclopirox olamine and placebo	For ciclopirox olamine only, there was significant ($P < 0.05$) improvement over baseline for clinical assessment of overall scalp psoriasis (day 29) and degree of scaling (days 8, 15 and 29) and for patients' self-assessments of overall scalp psoriasis (days 15 and 29) and scalp itching (day 15), but differences from placebo were not significant. Ciclopirox olamine tolerability and acceptability were good.

that it was not possible to assess recurrence rates because there was only a short period of follow up.

It is important to state that is often necessary to combine oral treatments and topicals, especially in severe cases of scalp psoriasis, there are, extensive or resistant to topical treatments. In these cases, some authors have pointed out the importance of medications, such as methotrexate, cyclosporine, acitretin, and treatment involving psoralen plus ultraviolet A (PUVA) [52]-[55].

Vergou *et al.*, 2011 [56] have also suggested immunobiologicals, including infliximab, adalimumab and the etarnecept to be administered. For this class of drugs, a complete healing of the lesions and maintenance of the healing period of three years for adalimumab treatment has been described [57].

Psoriasis of the scalp, especially those cases classified as moderate to severe is associated with emotional and social disorders that affect the well-being of patients [58]. Despite this, few studies evaluate the emotional repercussions of this type of psoriasis patients. The National Psoriasis Foundation 2006 Benchmark Survey estimates that psoriasis has a moderate to large negative impact on quality of life (QoL) in approximately 75% of affected patients [59]. It is also noted that those patients are more likely to commit suicide when compared to those who do not have the disease [20] [60].

Adverse effects were found in 9 of 15 studies. Studies generally omit reporting adverse events. Due to the small sample of studies and the short follow-up period, ranging from two weeks to two months, the possibility of not detecting more serious adverse events or consequence of the chronic use of medications may be higher than they would be under other conditions.

5. Conclusion

In conclusion, this investigation demonstrates the efficacy of topical treatments for scalp psoriasis, such as corticosteroids, calcipotriol, ciclopirox olamine, and associations, when compared with placebos. Clobetasol propionate (0.05%) was the most active ingredient, in various vehicles, in terms of the induction treatment of psoriasis of the scalp. However, due to the small clinical follow-up time of the studies, it was not possible to obtain data concerning the maintenance of the outcome or recurrence rates, so more research is needed in this area. It is important to consider that among the active principles used for the topical treatment of scalp psoriasis and compared with placebo, clobetasol propionate was the most effective, in all types of vehicle.

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Conflict of Interest

There is no conflict of interest in this paper.

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