



Contents lists available at ScienceDirect

Journal of Traditional and Complementary Medicine

journal homepage: <http://www.elsevier.com/locate/jtcm>

Short communication

## A case series of the effects of a novel composition of a traditional natural preparation for the treatment of psoriasis

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## ARTICLE INFO

## Article history:

Received 8 January 2015

Received in revised form

7 June 2015

Accepted 10 August 2015

Available online 19 September 2015

## Keywords:

psoriasis

complementary medicine

traditional

black cumini

topical treatment

## ABSTRACT

The objective of this study was to assess the effectiveness of a specific composition of a traditional herbal preparation (DurrDerma) in adult patients with moderate to severe skin psoriasis. The preparation is a newly developed topical combination containing plant-based extracts traditionally used in skin disease as black cumini, olive oil, tea tree oil, cocoa butter completed by vitamin A and vitamin B12. We documented the effectiveness of the preparation in a first case series. A total of 12 patients (8 males and 4 females, 21–86 y) with manifest and treatment-resistant psoriasis were included and treated for 12 weeks. All patients were assigned to twice-daily treatment with the DurrDerma preparation. Treatment success as determined by the Psoriasis Area and Severity Index (PASI) score, the body surface area, and the dermatology life index was achieved (PASI reduction of >75%) in 10 of the 12 treated patients (83%). The remaining two patients showed a PASI reduction of ≤50%. In 5 of the patients PASI reduction was achieved <12 weeks (between week 3–11). The beneficial effect in responder patients might be explained by a synergistic anti-oxidative and anti-inflammatory activity of all components present in DurrDerma. We conclude that the new preparation using a traditional approach seems to be a promising complementary treatment for psoriasis.

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## 1. Introduction

Psoriasis affects 2–3% of the European populations, and less commonly other populations of other countries, i.e. Far East and China.<sup>1,2</sup> To date, there is no doubt that psoriasis is an immune-mediated disorder as reflected by T cell hyperactivity and the production of multiple proinflammatory cytokines, such as tumour necrosis factor alpha (TNF- $\alpha$ ) and Interleukin (IL)-2, IL-12, IL-17, IL-22 or IL-23.<sup>3–5</sup> Nevertheless, all available treatment options remain largely unspecific, and many patients do not achieve the desired outcome.<sup>6,7</sup> Topical agents including corticosteroids, vitamin D

analogous, Tazarotene, coal tar, and dithranol are predominantly used for mild disease, and systemic agents including photochemotherapy, methotrexate, ciclosporin, retinoids fumarates, and biological agents are used for severe disease.<sup>8,9</sup> None of these treatment options has fully met the needs of affected patients.<sup>6,7</sup> The question whether a combination therapy of biologic and systemic agents may improve treatment outcome is yet unclear.<sup>6,7</sup> Thus, there is a need for alternative and well-tolerable treatment for psoriasis. In fact, many affected patients are using or seeking new therapeutic options, including complementary and alternative medicine.<sup>10–12</sup>

In this observational case series study, we documented the effectiveness and tolerability of DurrDerma in adult patients with active moderate to severe psoriasis vulgaris. The active ingredients of DurrDerma are black cumini as the main component, and olive oil, tea tree oil, cocoa butter, vitamin A and vitamin B12 as further components.

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Peer review under responsibility of The Center for Food and Biomolecules, National Taiwan University.

## 2. Patients and methods

A total of 12 unselected out-patients with moderate ( $n = 6$ ) to severe ( $n = 6$ ) psoriasis as diagnosed by a dermatologist or experienced general practitioner and characterized by a Psoriasis Area and Severity Index (PASI) score of  $\geq 10$  (Table 1) were treated with DurrDerma. Patients had to have a disease endurance of  $>3$  months and at least one conventional previous treatment approach. Patients were informed about the available treatment with the Durrderma preparation. Treatment duration was scheduled for 12 weeks and tubes of 200 g and boxes with 500 g were handed out as anticipated for proper use during the planned 12-week treatment period. Patients were asked to apply the cream twice daily and hereby to cover all skin lesions with a thin layer of cream.

The preparation relates to compositions comprising black cumin oil ( $>10\%$ ), olive oil ( $>10\%$ ), tea tree oil ( $<0,09\%$ ), cocoa butter ( $<4\%$ ), vitamin A ( $<0,05\%$ ) and vitamin B12 ( $<0,05\%$ ). The advantage is the innovative composition itself.

The essential oil components of black cumin oil are thymoquinones which have been shown to have anti-oxidative, anti-inflammatory, anti proliferative, anti-allergic and anti-bacterial activities, as well as immunomodulatory and immunotherapeutic characteristics. Olive oil contains a high concentration of polyphenols, in particular hydroxytyrosol. It has been shown to have anti-oxidative, anti-inflammatory and anti-microbial activities. Tea tree oil is mainly composed of various terpinens. It has anti-oxidative and anti-inflammatory activities.

Cocoa butter is extracted from cocoa beans and contains various anti-oxidants that are related to catechines and epicatechines, as well as others that are related to procyanidines and polyphenols.

Vitamin A has anti-oxidative activity and is one of the cells physiological anti-oxidants.

Vitamin B12 is a water-soluble vitamin with a key role in the normal functioning of the brain and nervous system, as well as for the formation of blood. It affects inter alia DNA synthesis and regulation, fatty acid synthesis and energy production.

All patients were evaluated for 12 weeks and assessments of disease activity with calculation of PASI took place at baseline and at the time points of 2,4, 8 and 12 weeks after initialization of treatment by the treating physician.

In addition, all patients completed a patient's questionnaire assessing satisfaction with treatment and side effects. Furthermore

compliance with the recommended application was asked by interview. Written informed consent was obtained from all patients prior to treatment with DurrDerma. There was no selection of patients by age, gender, localization and severity of disease, or previous treatments.

## 3. Results

Patients were aged from 18 to 86 years and had a confirmed diagnosis of psoriasis for longer than 3 months. The majority of patients had received previous standard topical and/or a systemic therapy but were treatment-resistant. Only two patients had no previous standard treatment (Table 1, nos. 6 and 8).

Initially, the vast majority of patients ( $n = 10$ ) showed a mild to moderate increase of local inflammation with increased reddening of the affected skin area (Table 2) for a short period of time. However, during continuous observation and under sustained treatment a gradual and pronounced clinical improvement became obvious in almost all cases within a few weeks. A PASI reduction of  $>75\%$  was observed in 10 of the 12 treated patients, in 3 patients already before the 12-week assessment, in the other 7 patients after 12 weeks of treatment (Table 2). The remaining two patients showed a PASI reduction of  $\leq 50\%$ , at week 4 and 8. The treatment effects in the early responders was maintained until the 12-week assessment.

One of the non-responder patients (no.12) had autoimmune thrombocytopenia which required continuous treatment with Nplate (thrombopoietin receptor agonist). Whether Nplate would have an impact on psoriasis treatment remains obscure.

Of note, one of the well responding patients had a treatment course of topical tea tree oil (also an ingredient of DurrDerma) before starting the DurrDerma application. This patient reported that the previous use of tea tree oil alone was ineffective but resulted in an exacerbation of the disease and discontinuation of this treatment after two weeks.

### 3.1. Safety

The preparation was well tolerated. There were no relevant adverse events. A mild exacerbation of the skin inflammation was a common initial response (2–4 days after treatment initialization) with a subsequent consistent improvement of the disease state

**Table 1**  
Demographic baseline characteristics of treated patients.

Patient (No.)	Sex	Age (year)	Weight (kg)	Height (cm)	Previous treatment Topical	Systemic	Affected area	Baseline PASI score
1	M	42	88	185	Corticosteroids Phototherapy	Corticosteroids	Scalp, abdomen, upper & lower extremities, back, genitals	24,6
2	M	32	89	180	Fumaric acid Psorcutan ointment Curatoderm ointment Keto med-shampoo	Cetirizin	Scalp, abdomen, upper & lower extremities, back	47,4
3	M	34	90	180	Corticosteroids		Lower extremities	8
4	F	43	52	169	Coal tar Corticosteroids Tea tree oil Phototherapy		Upper & lower extremities	7,2
5	M	42	78	187	Corticosteroids		Trunk, back, upper extremities	23,1
6	F	18	67	169	None		Scalp	4,4
7	M	21	78	176	Corticosteroids		Back, upper & lower extremities	28,1
8	M	33	79	185	None		Upper & lower extremities	21,6
9	F	34	60	161	Corticosteroids		Upper & lower extremities	23,2
10	M	46	70	175	Corticosteroids Tacalcitol		Upper & lower extremities, genitals	19,6
11	M	33	73	175	Corticosteroids		Upper & lower extremities	6,6
12	F	86	90	180	Corticosteroids Phototherapy	Corticosteroids	Upper & lower extremities, back	8,4

**Table 2**  
Outcome of treated patients (Assessment at week 12).

Patient (No.)	Treatment (weeks)	Adverse effects	Week 12 PASI response rate (%)	Baseline PASI score (absolute value)
1	12	ITE	100	24,6
2	12	ITE	90	47,4
3	3	None	90	8
4	12	ITE	100	7,2
5	10	ITE	90	23,1
6	13	None	100	4,4
7	32	ITE	90	28,1
8	12	ITE	90	21,6
9	12	ITE	90	23,2
10	4	ITE	50	19,6
11	8	ITE	100	6,6
12	11	None	50	8,4

PASI = Psoriasis Area Severity Index; ITE = Initially Transitory Exacerbation.

<10% = grade 1 (light).

10–29% = grade 2 (moderate to severe).

30–49% grade 3 (severe).

>49% = grades 4–6 (very severe).

thereafter. Some of the patients complained about the fatty characteristic of the preparation and the related pollution of clothes.

#### 4. Discussion

This case series study was initiated to determine by a first documentation the effectiveness and tolerability of DurrDerma, a traditional herbal preparation in a new specific combination formula, in patients with manifest and treatment-resistant psoriasis. Independent of previous treatment and severity of disease, 10 of the 12 treated patients with the new herbal preparation were well responding and 2 patients moderately responding. Most intriguingly, psoriasis signs not only improved but completely disappeared following treatment in 4 patients and nearly disappeared in further 6 of the patients (Fig. 1). Thus, a clinical meaningful effect of the preparation might be possible and should be tested and evaluated by means of a randomized controlled clinical trial. As treatment options in severe psoriasis are limited and the safety profile, so far, seems good, further research is warranted.

The question by which mechanisms DurrDerma works remains speculative. However, based on the fact that psoriasis is an immune-mediated disease,<sup>3–5</sup> and that oxidative stress is playing a key role in this process,<sup>13–20</sup> it seems likely that anti-oxidative products, such several food constituents,<sup>21,22</sup> may have a positive effect on psoriasis. The DurrDerma composition contains different natural and herbal products which have potential anti-oxidative and/or anti-inflammatory effects. Black cummin oil is obtained from the seeds of *Nigella Sativa* and contains thymoquinones, which have been shown to have anti-oxidative, anti-inflammatory, anti proliferative, anti-allergic and anti-bacterial activities, as well as immunomodulatory and immunotherapeutic characteristics.<sup>23–27</sup> Similarly, olive oil contains a high concentration of polyphenols which have by large similar effects as thymoquinones from *Nigella Sativa*.<sup>28–30</sup>

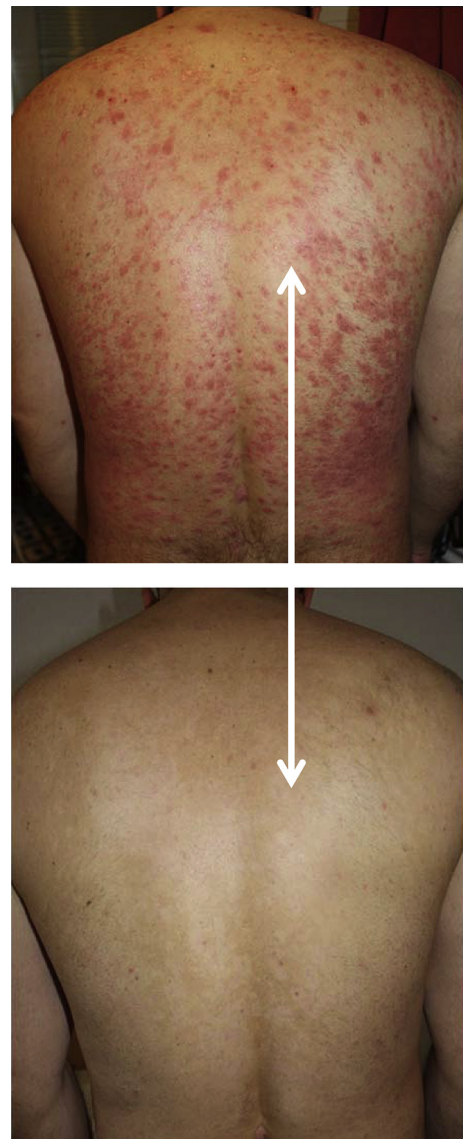
Tea tree oil is obtained from leaves of *Melaleuca alternifolia* which has anti-oxidative, anti-inflammatory, anti-bacterial, antiviral, and anti-fungal activities.<sup>31–33</sup>

Cocoa butter is extracted from cocoa beans which also contain various antioxidants, i.e. catechines, epicatechines, procyanidines, and polyphenols.<sup>34</sup> Vitamin B12 is involved in blood production, DNA synthesis and regulation.<sup>35</sup>

Thus, DurrDerma may provide a therapeutic effect that is not based on an isolated substance, but rather on a synergistic

combination of various prophylactic, therapeutic, anti-inflammatory, immunological and anti-microbial activities. The synergistic effect is supported by the observation that one patient (no. 4), previous to the application of the preparation in this case observation, used tea tree oil which, however, led to continuous worsening of his psoriasis. In addition, there is empirical observation that many such affected patients appear to have used olive oil without effect.

The question why DurrDerma initially induces a transitory negative effect on psoriasis remains obscure. However, some topical drugs, such as coal tar and anthralin have been described also to cause a flare-up (Koebner phenomenon) in patients with active psoriasis.<sup>36,37</sup> We do not know if the initial (mild) aggravation is a precondition for the retarded and lasting treatment effect. Of note, patients need to be informed about this treatment kinetic to ensure compliance. Clearly, the safety of the preparation needs to be assessed in larger studies. However, on the background of current existing preclinical and botanical research data of the components of the preparation, no specific safety concerns are expected.



**Fig. 1.** Skin status of the back of one patient before and after 12 week treatment with the preparation.

## 5. Conclusion

In conclusion, the observations in this case series study point to a promising and clinically relevant beneficial effect of the Durr-Derma preparation in patients with skin psoriasis. Further clinical trials are warranted.

## Conflict of interest

The authors declare no conflict of interests.

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