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

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A B S T R A C T

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 cumin, 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.

1. Introduction

Psoriasis affects 2–3% of the European populations, and less commonly other populations of other countries, i.e. Far East and China.1,2 To date, there is no doubt that psoriasis is an immune-mediated disorder as reflected by T cell hyperactivity and the production of multiple pro-inflammatory cytokines, such as tumour necrosis factor alpha (TNF-α) and Interleukin (IL)-2, IL-12, IL-17, IL-22 or IL-23.3–5 Nevertheless, all available treatment options remain largely unspecific, and many patients do not achieve the desired outcome.6,7 Topical agents including corticosteroids, vitamin D analogues, Tazarotene, coal tar, and dithranol are predominantly used for mild disease, and systemic agents including phototherapy, methotrexate, ciclosporin, retinoids, fumarates, and biological agents are used for severe disease.6,8 None of these treatment options has fully met the needs of affected patients.6,7 The question whether a combination therapy of biologic and systemic agents may improve treatment outcome is yet unclear.6,7 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.10–12

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 cumin as the main component, and olive oil, tea tree oil, cocoa butter, vitamin A and vitamin B12 as further components.
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 \(\geq 3\) 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 \(<50\%\) 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 \((n=12)\) 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 | Systemic | Affected area | Baseline PASI score |
|---------------|-----|------------|-------------|-------------|--------------------|----------|---------------|---------------------|
| 1             | M   | 42         | 88          | 185         | Corticosteroids    | Phototherapy | Scalp, abdomen, upper & lower extremities, back, genitals | 24.6 |
| 2             | M   | 32         | 89          | 180         | Fumaric acid       | Psorcutan ointment | Cetrizin | Scalp, abdomen, upper & lower extremities, back | 47.4 |
| 3             | M   | 34         | 90          | 180         | Corticosteroids    | Psorcutan ointment | Lower extremities | 8 |
| 4             | F   | 43         | 52          | 169         | Coal tar           | Keto med-shampoo | Upper & lower extremities | 7.2 |
| 5             | M   | 42         | 78          | 187         | Corticosteroids    | Tea tree oil      | Trunk, back, upper extremities | 23.1 |
| 6             | F   | 18         | 67          | 169         | None               | None                | Scalp | 4.4 |
| 7             | M   | 21         | 78          | 176         | Corticosteroids    | None                | Back, upper & lower extremities | 28.1 |
| 8             | M   | 33         | 79          | 185         | Corticosteroids    | None                | Upper & lower extremities | 21.6 |
| 9             | F   | 34         | 60          | 161         | Corticosteroids    | None                | Upper & lower extremities | 23.2 |
| 10            | M   | 46         | 70          | 175         | Corticosteroids    | Tacalitol          | Upper & lower extremities, genitals | 19.6 |
| 11            | M   | 33         | 73          | 175         | Corticosteroids    | Corticosteroids    | Upper & lower extremities | 6.6 |
| 12            | F   | 86         | 90          | 180         | Corticosteroids    | Phototherapy       | Upper & lower extremities, back | 8.4 |
thereafter. Some of the patients complained about the fatty character-
istic 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 for-

tula, 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 intrig-
ugingly, psoriasis signs not only improved but completely dis-
appeared 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, and that oxidative stress is playing a
key role in this process, it seems likely that anti-oxidative
products, such several food constituents, 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 cumin 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.
Similarly, olive oil contains a high concentration of polyphenols which have by large similar effects as thymoquinones
from Nigella Sativa.

Tea tree oil is obtained from leaves of Melalenca alternifolia
which has anti-oxidative, anti-inflammatory, anti-bacterial, anti-
viral, and anti-fungal activities.

Cocoa butter is extracted from cocoa beans which also contain
various antioxidants, i.e. catechines, epicatechines, procyanidines,
and polyphenols. Vitamin B12 is involved in blood production,
DIVA synthesis and regulation.

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-
flammatory, 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 observa-
tion 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. 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 cur-
rent existing preclinical and botanical research data of the com-
ponents of the preparation, no specific safety concerns are

### Table 2

| 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).

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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