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Solasodine Glycosides from the Eggplant in a Topical Cream Psorend[BEC] Are Effective against Psoriasis

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Abstract

Background: Psoriasis is a chronic disease that can have significant effects on quality of life. **Aim:** To test whether the antineoplastic, antipathogenic plant derived secondary metabolites, solasodine glycosides, can treat psoriasis. **Case Presentation:** We report a case of a 54-year-old French-Vietnamese male who presented with diagnosed erythematous scaly annular recalcitrant psoriasis scattered throughout his body. **Method:** After failing conventional treatment regimens for over 10 years the patient received a trial with a topical cream formulation Psorend[BEC], containing solasodine glycosides, for his psoriasis. **Result:** Topical applications of Psorend[BEC] twice daily resulted in complete resolution of cutaneous lesions after 4 weeks of treatment with no recurrence post 1 year after therapy. **Conclusion:** Topical Psorend[BEC] therapy rapidly removes recalcitrant psoriasis with no apparent side effects.

Keywords

Psoriasis, BEC, Solasodine Glycosides, Psorend[BEC], Eggplant, Devil's Apple, Black Nightshade

1. Introduction

The chronic disease psoriasis is a common skin condition that speeds up the life cycle of skin cells and causes cells to build up rapidly on the surface of the skin. The well-demarcated plaques consist of extra skin cells that form scales and red patches, which are itchy and sometimes painful.

Psoriasis affects people of all ages, and in all countries. The reported prevalence of psoriasis in adults ranges from 0.5% - 11.4% and 0 - 1.4% in children, making psoriasis a serious global problem [1]. According to the International

Federation of Psoriasis Associations (IFPA), around 125 million people have some form of psoriasis.

The exact cause isn't fully understood but it is thought to be the result of several factors, including genetic and environmental conditions [2]. Overactive immune system (T-lymphocytes) that creates inflammation inside the body leading to the symptoms of psoriasis on the skin has been implicated [3]. There is no cure for psoriasis and there is no known way to prevent psoriasis.

People who have psoriasis tend to have a higher risk of developing certain other types of health conditions, called comorbidities [4].

Psoriasis has a profound emotional and social, as well as physical, impact on the affected patients.

A wide variety of psychological effects of psoriasis have been described in a large number of patients ranging from poor esteem, sexual dysfunction, depression and suicidal ideation [5].

There are several ways that lead to some relief from the symptoms of psoriasis. Psoriasis treatments generally reduce inflammation to clear the skin. Treatments can be divided into three main types: topical treatments, light therapy, and systemic medications including biologics. The side effects of these medications range from mild to major. Psoriasis is currently not curable, but it can go in remission.

Topical treatments can effectively treat mild to moderate psoriasis. For severe psoriasis, creams are combined with oral medications, light therapy and/or biologics [6].

There is an increase in prevalence of psoriasis [7]. Therefore, there is a need for more effective therapies with fewer side effects for the treatment of psoriasis in general, and in particular, for moderate to severe psoriasis.

In 1987, it was first reported that BEC and its individual components elicit antineoplastic activities with high therapeutic indices [8]. BEC is a plant extract obtainable from various Solanum species such as *S. linnaeanum* (Devil's Apple), *S. nigrum* (Black nightshade), *S. melongena* (Eggplant) and is composed of solasodine glycosides. BEC consists of 33% solamargine, 33% solasonine and 34% mono-and diglycosides of solasodine [9].

Since then, hundreds of independently published articles have confirmed and elaborated on the original findings, to the extent, that these compounds are the ongoing hope for treating terminal tumours [10]. In addition, currently, there is an established effective topical cream formulation Curaderm for the treatment of skin cancers [10] [11].

BEC glycoalkaloids are also effective against infections of bacteria [12], fungi [13], viruses [14], malaria [15], parasites [16] [17], leishmaniasis [16] [17], and show promise as trypanocidal agents [16] [17].

The antimicrobial mechanisms of action of BEC are similar to the antineoplastic mechanisms of action of BEC with cancer [17].

Pathogenic microbial infections, cancer and psoriasis share an important commonality, in that, there are increases in unchecked cell growths, although

the aetiologies may be different.

Therefore, it not surprising that BEC was tested against psoriasis. Proof of concept studies with an aqueous cream formulation containing BEC with a twice-daily application over the psoriatic lesions resulted in amelioration of symptoms [18].

Subsequently, Phases I/Ila clinical studies of a topical cream containing BEC was carried out in healthy subjects and subjects with mild to moderate psoriasis. The results of these studies determined that the primary endpoints of safety and tolerability were achieved. Unfortunately, the secondary endpoint of efficacy was not achieved. Reportedly, the lack of efficacy was caused by the inappropriate cream formulation used in the clinical studies [18].

2. Psorend^{BEC}, the Natural Novel Topical Treatment Formulation

The importance of cream formulations when using BEC was previously highlighted, and it was shown that at low concentrations of BEC in topical creams, it was essential to choose the appropriate excipients for a specific application to obtain high efficacy.

Excipients were at one time considered to be "inactive" ingredients but presently they are considered to be able to serve as "key determinants of dosage form performance".

In the context of cream compositions, an excipient is a natural or synthetic substance formulated alongside the active ingredient of the medication to confer a therapeutic enhancement on the active ingredient in the final dosage form, such as, facilitating drug interaction with targeted diseased state, solubility and stability of the medication over the expected shelf life [19] [20].

This concept was investigated when BEC was added to various cream formulations, specifically to obtain a possible treatment for psoriasis.

After investigating a wide variety of topical formulations, it was concluded to add BEC to an existing cream formulation that reduces dryness, itching, redness, soreness, and scaling in patients with eczema.

The eczema cream is an oil in water formulation consisting of coal tar as the "active" ingredient.

3. Case Report

A 54-year-old French-Vietnamese male builder was referred to our research facility with well-demarcated erythematous scaly annular plaques, scattered on his torso, legs, arms, face, and scalp, which had not responded to a wide variety of conventional psoriasis treatments. The patient gave his consent for his Case Report to be published.

3.1. History

The initial lesions first appeared on the knees ten years ago and new lesions

gradually appeared over two to three years thereafter. There was no joint pain and/or a history of infections prior to lesions development. His past medical history was significant only for depression. There was no personal or family history of psoriasis or other dermatologic diseases. Prior to the presentation in our research facility, he had skin biopsies and the diagnosis was considered as psoriasis vulgaris (common plaque psoriasis). He was under the care of a general practitioner and dermatologist for 10 years who had treated his psoriasis with oral and topical medications. Topical therapies included Corticosteroids creams, Donovex ointment, Anthranil ointment, Salicylic acid ointment, Coal tar cream, and UV therapy.

However, despite years of follow-ups and treatment adjustments, including Methotrexate 25 mg per week, he not only remained poorly controlled, but his condition worsened and the patient experienced various side effects such as thinning of the skin, erythema, skin irritation, tinnitus, itching of the skin, tiredness, nausea and easily bruising from his medications.

Consequently, therefore, the patient did not persist with any particular treatment. The patient is a non-smoker with no alcohol or illicit drug use.

3.2. Appearance on Admission

Scattered erythematous medium-to-large plaques on the chest, back, arms, lower limbs, thighs, scalp, and face with silvery scales. There were flexural involvements and erythema, scale and induration, which were severe throughout a large body surface area. Some affected areas were quite sore. As the patient was not experiencing efficacy with appropriately administered conventional psoriasis treatments, he decided to stop all treatments and on admission to our research facility, he was off all previous treatments for at least six months.

3.3. Treatment

Psorend^{BEC} cream contains coal tar, zinc oxide, allantoin, vitamin E acetate, vitamin A palmitate and BEC plant extract in an aqueous cream formulation. Psorend^{BEC} was applied twice daily and was gently rubbed onto the psoriatic lesions.

The objective of this communication was to establish whether BEC in a topical cream formulation, Psorend^{BEC}, is effective against a serious case of psoriasis that had not responded to a wide variety of therapies.

4. Results

Before treatment with the Psorend^{BEC} cream, the psoriasis lesions were widespread across his body, some of which were bleeding, caused by scratching the itchy affected areas (**Figures 1-5**).

It was found that the eczema cream formulation without BEC only had a marginal antipruritic effect on psoriasis when applied to the lesions over 4 weeks with twice daily applications. However, when BEC was added to the now modified

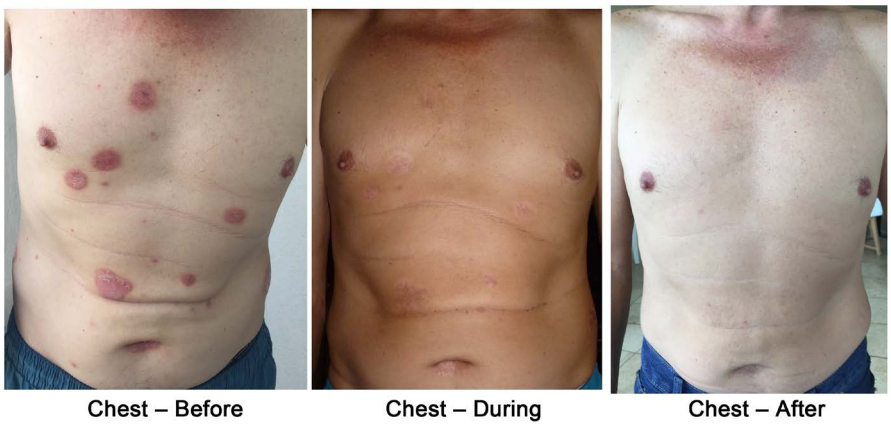

Figure 1. Psoriasis on the chest before, during (2 weeks) and after (4 weeks) of Psorend-[BEC] therapy.

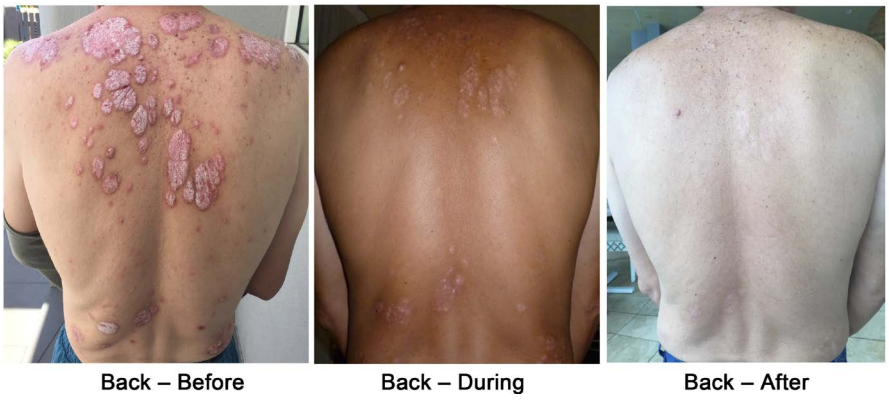

Figure 2. Psoriasis on the back before, during (2 weeks) and after (4 weeks) of Psorend[BEC] therapy.

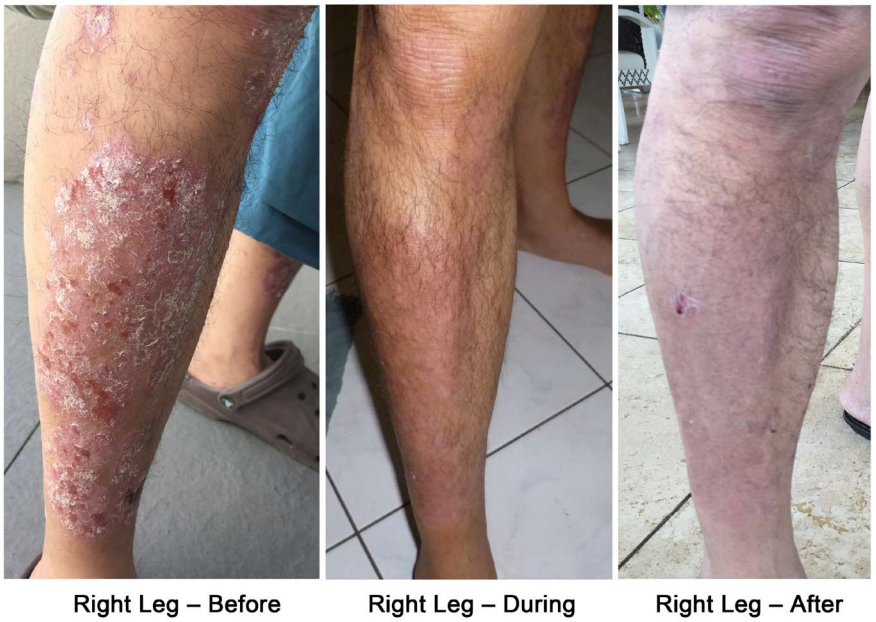

Figure 3. Psoriasis on the right leg before, during (2 weeks) and after (4 weeks) of Psorend[BEC] therapy.

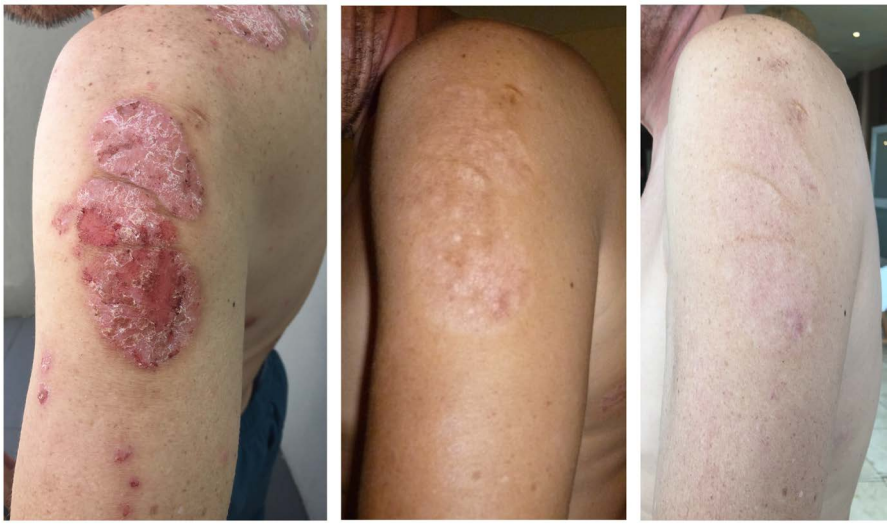

Figure 4. Psoriasis on the left arm before, during (2 weeks) and after (4 weeks) of Psorend[BEC] therapy.

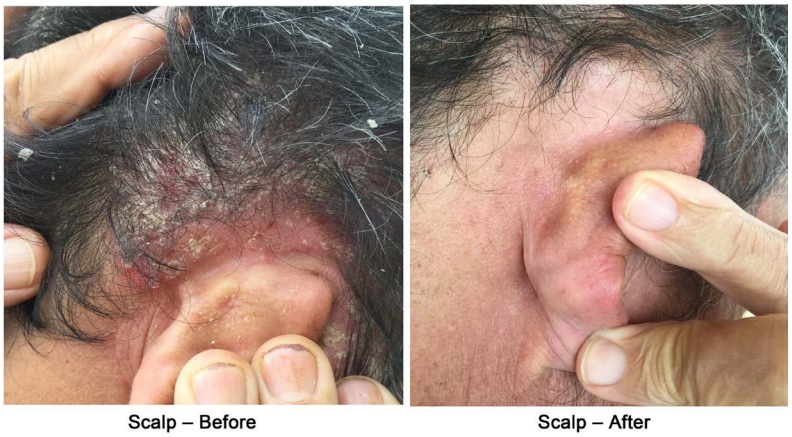

Figure 5. Psoriasis on the scalp before and after (4 weeks) of Psorend[BEC] therapy.

eczema cream (Psorend[BEC]) and then applied twice daily to psoriatic lesions, a rapid positive effect was apparent.

The use of Psorend[BEC] for two days resulted in considerable reduction in itching all over the body where the cream was applied. Continuation of Psorend[BEC] therapy for two weeks resulted in much improvement of the lesions (**Figures 1-4**).

After 4 weeks of Psorend[BEC] treatment, the scaly patches and wounds disappeared and the skin obtained its normal appearance without any blemishes (**Figures 1-5**). Treatment was stopped after the disappearance of the symptoms (4 weeks of treatment).

There have been no recurrences of any lesions to date, which is one year after cessation of Psorend[BEC] therapy. No further treatment has been required to date. This observation is important because retention rates or persistence rates in a given treatment protocol are very useful in assessing the "added value" of ther-

apy in daily clinical practice.

The treatment was well tolerated and no local or systemic side effects were observed.

5. Discussion

Before 2003, dermatologists had limited options to treat psoriasis. Many of those treatments caused side effects and did not always result in satisfactory results.

Since then, biologics have become available that affect the immune system, resulting in the reduction of inflammation and consequently slow down the growth of skin cells. In that context, it is interesting that naturally occurring BEC exerts a positive outcome on the immune system [21] and also affects the proliferation of unwanted cells [10].

A biologic is a pharmaceutical drug product manufactured in, extracted from, or semi-synthesized from biological sources resulting in high treatment costs. The side effects of biologics can be very serious, ranging from suicidal ideation, susceptibility of infection and may even cause cancer [22].

Thus, there is a need for new highly efficacious, safe, low cost treatments for psoriasis.

In 1987 it was first reported that BEC consisted of a mixture of solasodine glycosides, of which solamargine and solasonine are the major components. BEC has high antineoplastic efficacy and low toxicity when treating a wide variety of cancers [10].

Subsequently, it was reported that the BEC glycoalkaloids were effective against bacteria, fungi, viruses, parasites and malaria. These observations supported the accepted understanding that in plants, BEC glycoalkaloids are secondary metabolites, which are regarded as defensive agents against pathogens and predators including fungi, bacteria, viruses, insects and worms.

Here, it is reported for the first time that Psorend^{BEC} may prove to be a good candidate for the treatment of severe psoriasis.

The severity of psoriasis is determined by how much of the body's surface is covered and how much it affects a person's quality of life.

In this case report, a large portion of the patient's body surface was covered with psoriasis at multiple sites.

The quality of life was very poor and the patient had to endure his condition for a decade. This was despite the use of various prescribed medications.

When using Psorend^{BEC} the relief was virtually immediate, the itching had stopped shortly after the application of Psorend^{BEC}. Reduced symptoms of the psoriasis lesions were observed within one week of Psorend^{BEC} treatment. After 2 weeks treatment, striking remission was observed and after 4 weeks treatment the lesions had completely regressed.

Importantly, there was no recurrence after one-year follow-up post treatment and there were no observable side effects.

It is interesting that the solasodine glycosides present in the formulation

Psorend[BEC] was able to eliminate recalcitrant psoriasis. The same solasodine glycosides, but in a different topical cream formulation, Curaderm[BEC5], is effective against a wide variety of non-melanoma skin cancers [10], including recalcitrant basal cell carcinomas [23].

We now show for the first time that BEC in combination with other commonly used substances is highly effective against a serious case of psoriasis.

At this stage, it is not known whether the other components in the cream formulation work synergistically with BEC. Importantly, a cream formulation containing all the other components at identical concentrations, but without BEC, had no effect on psoriasis.

Evidence is now presented that BEC elicits efficacy against another medical condition, psoriasis.

6. Conclusions

Although this is only a case study with unknown modes of action of the treatment medication, the results are nevertheless very rapid, long lasting, and impressive.

Many further studies are required to establish the possible value of Psorend[BEC] as a potential treatment for psoriasis. Such clinical studies are underway.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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