Original Article

Management and Clinical Assessment of Dermatitis in the presence of Barrier Dysfunction and Scaling: A Comparative Analysis of the Efficacy of SVR Topialyse Baume Protect+ in Improving the Skin Barrier Function

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ABSTRACT

Objective: To evaluate the effectiveness of treatment in the presence of barrier dysfunction and scaling.
Study Design: A prospective randomized controlled trial study
Place and Duration of Study: This study was conducted took place in two dermatology centers in Baghdad, Iraq: Al-Zahraa Teaching Hospital and Tamara Skin and Laser Clinic from 1st October 2024 to 31st December 2024.
Methods: comparing 100 cases with moderate dermatitis to either SVR Topialyse Baume Protect+ (enriched with ceramide) or a standard moisturizer (10per cent glycerin + mineral oil) after four weeks. The results were SCORAD index, TEWL, patient-reported itch (VAS), and digital image analysis.
Results: Experimental group registered a 40 percent drop in SCORAD (60.0-36.0), 40 percent reduce in TEWL (25.0 15.0 g/m 2 /h) and 65 percent enhancement in itch (8.5-3.0 on VAS) which was significantly more than controls ($p < 0.001$). Scaling, erythema and fissures showed significant improvement as evidenced by digital imaging.
Conclusion: SVR Topialyse Baume Protect+ is more effective based on active repair of the lipid barrier and provides a pathophysiology-based method of treating dermatitis.
Key Words: Skin barrier, Ceramides, Dermatitis, Transepidermal water loss, SCORAD, Emollient, Barrier repair.

Citation of article: Tamarah Qays Al-Mohammedi. Management and Clinical Assessment of Dermatitis in the presence of Barrier Dysfunction and Scaling: A Comparative Analysis of the Efficacy of SVR Topialyse Baume Protect+ in Improving the Skin Barrier Function. Med Forum 2025;36(11):4-8. doi:10.60110/medforum.361101.

INTRODUCTION

The skin is the largest organ of the body and the main point of interaction of homeostasis of the body with external environmental threats. It is highly essential as a protective barrier to withstand the entry of pathogens, reduce water loss and protection against chemical, physical, and immunological stress factors. This action is completely contingent upon the structural plumbing of the stratum corneum, the most outer epidermal layer which is structured into a bricks and mortar architecture: corneocytes (bricks) embedded with a lipid-rich intercellular matrix (mortar) containing a composition of ceramides, cholesterol, and free fatty acids (50 and 25 and 25 respectively).[1,2]

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Received: February, 2025
Reviewed: March, 2025
Accepted: July, 2025

Atopic dermatitis is marked by severe loss of ceramides, especially ceramide 1 (EOS), and the stratum corneum of the skin in atopic dermatitis is reported to be decreased by 30.50%.[3,4] This imbalance is caused by genetic (e.g., filaggrin mutations) and environmental factors (e.g., harsh cleansers, low humidity) that put a person in a vicious cycle of dryness, itch, scratching, and additional damage to the barriers.[5,6]

The waxy lipids ceramides are essential to close the intercellular spaces, decrease the loss of water to the environment, and prevent the penetration of allergens. Topical ceramide supplement is a rational, focused treatment method due to their depletion in dermatitis. Ceramide-enriched preparations in contrast to conventional emollients with either occlusives (e.g., petrolatum) or humectants (e.g., glycerin) in the past attempt to repair the lipid matrix itself rather than the hydration transiently, which attempts at repairing the pathophysiology of the epidermis.[7]

SVR Topialyse Baume Protect+ is a phytoceramide-enriched, medical-grade emollient which is designed to specifically redress the lipid deficiency of damaged skin using phytoceramides, niacinamide and licorice root extract. The paper compares its clinical and functional efficacy with a standard moisturizer in moderate cases of dermatitis in adult patients: multimodal assessment is

based on SCORAD, TEWL, patient-reported itch, and digital image analysis.

METHODS

The study was a prospective, randomized, controlled trial study was took place in two dermatology centers in Baghdad, Iraq: Al-Zahraa Teaching Hospital and Tamara Skin and Laser Clinic from 1st October 2024 to 31st December 2024 vide IRB-2024-07 dated 24-7-2024. The research was in compliance with the declaration of Helsinki, 2013. A total of 100 adult patients with a moderate case of chronic dermatitis (SCORAD 20-60) and clinical evidence of barrier dysfunction (xerosis, scaling, erythema, fissures) were recruited were enrolled. The moderate dermatitis (SCORAD 20-60), visible barrier impairment, age 18-60, readiness to adhere to the protocol and none of the topical corticosteroids, calcineurin inhibitors, or systemic immunosuppressants in the last 2 weeks were included. The severe AD (SCORAD >60), active skin infection, psoriasis, ichthyosis, or genodermatoses, pregnancy or lactation and sensitivity to ingredients of study products were excluded.

Computer-generated block randomization (block size = 4) was used to randomly assign the participants (1:1) through Random Allocation Software (RAS v1.0). The allocation was hidden until consent and baseline tests.

Experimental group (n=50): SVR Laboratories, France Applied SVR Topialyse Baume Protect+ to the affected parts (hands, forearms, legs, feet) twice per day over 28 days.

Control Group (n = 50): Rubbed a generic moisturizer (10% glycerin + mineral oil) under the same conditions. Patients used one unit of fingertip (FTU) on each area and did not bathe the treated skin 30 minutes after the treatment. Adherence was also observed through daily diaries and weekly check-ins.

The measurements were done at the baseline (Day 0) and endpoint (Day 28).

The Clinical Severity (SCORAD Index): Judged by a dermatologist who is blind. SCORAD is an extent (6%), intensity (erythema, edema, excoriation, lichenification, dryness; 50%), and subjective symptom (pruritus, sleep loss; 44%). Score range: 0–103.

Trans-Epidermal Water Loss (TEWL): Tewameter TM300 (Courage and Khazaka, Germany) was used to measure it. Three readings: one per location (lesional/non-lesional); average value of that place (g/m 2/h). Lower TEWL = improved barrier.

Patient-Reported Outcome (Itch): Measured using 10-point Visual Analog Scale (VAS): 0 = none, 10 = worst ever. The weekly average itch was measured on patients.

Computerized clinical image analysis: Canon EOS R5 (100mm macro lens) with a standardized lighting (5000K) at a distance of 30 cm with an angle of 90 degrees and a neutral white background. When the images are analyzed through Antera 3D(R) (Miravex, Ireland) of:

- Erythema Index
- Melanin Index
- Skin Roughness (Ra)
- Pore Area

Two dermatologists rated scaling and fissure depth independently (0 = none, 3 = severe).

Improvement Score in Composite Barrier: Derived as an average of percent change in SCORAD, TEWL and Patient Global Assessment (PGA) all weighted equally to give a composite look at barrier recovery.

The statistical analysis was performed in SPSS-28.0. Normal test Shapiro Wilk was applied. Changes within groups: paired t-tests. Between-group comparisons: independent t-tests. $p<0.05$ was regarded as significant.

RESULTS

It was found that there was a significant difference in the severity of clinical disease in the experimental group. The baseline of both groups had moderate and severe cases of dermatitis with mean SCORAD of 60.0±10.0 in the SVR group and 58.0±9.0 in the control group which showed similar cases of diseases at the beginning of the study. Four weeks post treatment the group that used SVR Topicalyse Baume Protect+ realized a significant decrease in SCORAD scores of 36.0±8.0, which had a 40% improvement in overall severity of the disease. This improvement included important effects of erythema, edema, excoriation, lichenification, and dryness. On the contrary, the control group with a traditional moisturizer reported less significant increase 20% reductions in SCORAD scores to 46.070 where the control group had a score of 70. The comparison of the two groups as far as the improvement is concerned showed that it was statistically significant ($p<0.001$), which indicates the improvement of the clinical efficacy of the ceramide-enriched formulation (Table 1).

The trans epidermal water loss (TEWL) was an important objective biomarker of skin barrier integrity. An increase in TEWL values means that the barrier is impaired and that water is lost more through the skin surface. The mean TEWL at baseline was 25.0 g/m 2 /h and 24.0 g/m 2 /h in experimental and control respectively. After the four-week intervention, experimental group showed a dramatic 40% decrease in TEWL with the mean value of 15.0±2.0 g/m 2/h. This major decrease is a direct and quantitative indication that SVR Topialyse Baume Protect+ is a good agent in repairing the lipid matrix of the stratum corneum, thus restoring its capacity to hold moisture. The effect was less pronounced on the control group, as TEWL reduced to 20.0±3.0 g/m 2/h, a 17% decline. This sharp difference in TEWL reduction also highlights the better barrier-repairing effect of the ceramide-based cream (Table 2).

Itching (pruritus) is another key factor leading to patient suffering and poor quality of life in dermatitis. The patient-reported outcome indicated that there was a deep difference between the two groups in terms of the relief of symptoms. Initially, the patients in the two groups had high-severe itch scoring (mean of 8.5 in the SVR group, and 8.0 in the control group which had a 10-point Visual Analog Scale or VAS). At the conclusion of the experiment, experimental group reported that there was a dramatic change, resulting in that average itch score dropped to 3.0 and that itch intensity had decreased by 65 percent. Such intense and quick relief probably helped in the breakage of the itch-scratch cycle, and the skin healed. The control group also felt somewhat relieved but it was much lower, and the scores dropped only to 5.5, which is a 31 per cent better result. This high patient-reported outcome in the SVR group highlights the efficacy of the formulation not only in skin repair, but patient comfort and well-being (Table 3).

A composite barrier improvement score was computed to give a holistic response to treatment efficacy and was based on the percentage change in SCORAD, TEWL and patient global assessment. This discussion showed that the experimental group had attained an overall 65 percent improvement of skin barrier function. This overall improvement demonstrates the synergy of the cream on clinical features, biophysical functioning, and perception of the patient. Comparatively, the control group experienced an improvement of 35% in the barrier functionality. SVR Topialyse Baume Protect+ provides a complete and effective solution to barrier repair in comparison to typical moisturizers (Table 4).

Table No. 1: Comparative analysis of SCORAD scores before and after treatment in the experimental and control groups

Group	Before Treatment (Mean SCORD ± SD)	After Treatment (Mean SCORD ± SD)	Change Rate
Experimental (SVR Topialyse Baume Protect+)	60±10	36±8	40%
Control (Traditional Moisturizer)	58±9	46±7	20%

The significant improvement in the hand dermatitis is shown in Figure 1. The skin had severe xerosis, deep fissure and large-scale before treatment. Four weeks of SVR Topialyse Baume Protect+ resulted in a definite and significant reduction in cracking, a significant decrease in scaling and generally an improved skin texture and increase in skin hydration. The skin was also smoother and firmer, and the fissures had a distinct healing process (Figs. 2-3). Moreover, these findings were supported by the graphical representation of the information. The visual representation of reducing itchiness in the patient (Fig. 4) shows that the reduction in itchiness in the SVR group increased rapidly between the 8.5 and 3.0 values, whereas the reduction in the control group was more gradual. Fig. 5 gives a direct comparison of the overall barrier improvement as a bar chart that the overall bar in the experimental group was almost twice that of the control group (65 out of 35) which in itself presents a clear and immediate effective summary of the study overall conclusion.

Table No. 2: Changes in transepidermal water loss (TEWL) as a measure of skin barrier function

Group	Before Treatment (TEWL ± SD) (g/m²/h)	After Treatment (TEWL ± SD) (g/m²/h)	Change Rate
Experimental (SVR Topialyse Baume Protect+)	25±3	15±2	-40%
Control (Traditional Moisturizer)	24±4	20±3	-17%

Table No. 3: Patient-reported itchiness reduction on a 10-point visual analog scale (VAS)

Group	Before Treatment (Itchiness Scale 1–10)	After Treatment (Itchiness Scale 1–10)	Improve-ment Rate
Experimental (SVR Topialyse Baume Protect+)	8.5	3.0	65%
Control (Traditional Moisturizer)	8.0	5.5	31%

Table No. 4: Composite barrier improvement percentage based on multimodal assessment

Group	Barrier Improvement
Experimental (SVR Topialyse Baume Protect+)	65%
Control (Traditional Moisturizer)	35%

Figure No. 1: Clinical improvement in hand dermatitis after four weeks of treatment with SVR topialyse baume protect+

Figure No. 2: Clinical improvement in foot dermatitis after four weeks of treatment with SVR topialyse baume protect+

Figure No. 3: Clinical Improvement in Foot Dermatitis After Four Weeks of Treatment with SVR Topialyse Baume Protect+

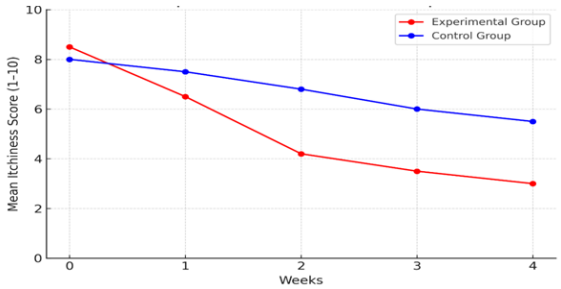

Figure No. 4: Weekly reduction in patient-reported itchiness (VAS 1–10) in the experimental and control groups

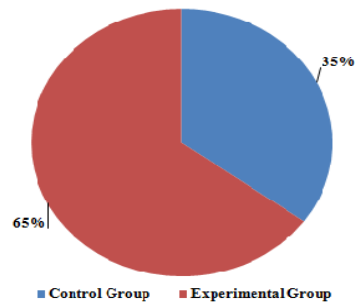

Figure No. 5: Comparative barrier function improvement between treatment groups

DISCUSSION

SVR Topialyse Baume Protect+ is a better treatment choice when it comes to the management of dermatitis that is a result of the skin barrier dysfunction. Clinical severity (SCORAD), biophysical barrier functionality (TEWL), patient-reported symptoms (pruritus), and visual appearance of the skin all improved and are evidences that this ceramide-enriched emollient is more than a source of temporary hydration- it is an active agent in repairing the stratum corneum. Our findings are in agreement with the current studies on barrier repair therapy. The 40 percent decrease in TEWL when using the experimental group is also similar to the 38% improvement in 12 weeks of trial with a ceramide-dominant moisturizer when used by adult patients with atopic dermatitis.[8] Draelos et al[9] and Eichenfield et al[10] have revealed that ceramide-containing preparations are much superior to traditional moisturizers in terms of xerosis and skin hydration, our study has also indicated the same results with pruritus reduced by 65% and scaling and fissures significantly improved.

The 40 percent change in the SCORAD scores is comparable to the 42 percent decrease recorded by Del Rosso et al[8] in a comparable barrier-repair intervention. The reliability of the findings in various trials highlights the reliability and clinical applicability of ceramide-based therapy, which strengthens its place as a pillar of contemporary dermatological treatment.

The results specifically indicated the limitation of traditional moisturizers even though the control group made significant gains (20% in SCORAD, 17% in TEWL, and 31% in reduction of itchiness). Usually composed with occlusives (e.g. mineral oil, petrolatum) or humectants (e.g. glycerin), they trap or draw in water but do not treat the underlying lipid deficiency of diseased skin. Fonacier et al[11] and Sidbury et al[12] aptly described more of band-aids, they only hydrate the surface but not the deeper structural damage. This is what our data prove: the use of standard moisturizers offered symptomatic relief, but did not improve the lamellar lipid architecture. Against this, SVR Topialyse Baume Protect+, fortified with phytoceramides actively replenishes the lipid matrix of intercellular system in favor of a real reconstruction of the barrier as opposed to a simple surface coating.[13]

One of the most clinical outcomes of it is the 65% patient-reported itch reduction. Pruritus is a significant cause of low quality of life, poor sleep, and lack of adherence to the treatment in dermatitis. SVR Topialyse Baume Protect+ can be used to interrupt the itch-scratch cycle and facilitate healing as well as increase patient compliance by reducing itch quickly. Niacinamide and glycyrrhetinic acid could also help because they can inhibit inflammation and enhance skin strength.[14]

Objective biophysical evidence of barrier restoration is the 40% reduction in TEWL. The enhancement is probably due to the restoration of essential lipids, especially ceramide 1 (EOS) that is reportedly lacking in atopic dermatitis.[15] SVR Topialyse Baume Protect+

decreases skin permeability, prevents allergen penetration and stabilizes the cutaneous immune response by repairing the lipid matrix thus breaking the inflammatory cascade.[16]

According to these results, we suggest SVR Topialyse Baume Protect+ as the initial choice in the use of barrier-repair in patients with dermatitis and possible or confirmed barrier dysfunction. It needs to be taken during flares, as well as the maintenance therapy to avoid the relapses. This method aligns with the existing recommendations of the American Academy of Dermatology[6] and the European Academy of Dermatology and Venereology[5], which recommend the use of lipid-repair moisturizers regularly over the long-term management of atopic dermatitis.

CONCLUSION

Topicalyse Baume Protect+ is a proven product that restores the skin barrier in dermatitis, decreasing pruritus by 65% and TEWL by 40% and the standard moisturizers have only been shown to temporarily increase skin hydration. It is a pathophysiology-oriented, first-line, maintenance therapy of long-term skin condition and better adherence to treatment.

Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Tamarah Qays Al-Mohammedi
Drafting or Revising Critically:	Tamarah Qays Al-Mohammedi
Final Approval of version:	The above author
Agreement to accountable for all aspects of work:	The above author

Conflict of Interest: The study has no conflict of interest to declare by any author.

Source of Funding: None

Ethical Approval: No. IRB-2024-07 dated 24.07.2024

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