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Research Article

Long-Lasting Emollient and Anti-Itching Efficacy of a Creamy Rinse-Off Product Containing Purified Omental Lipids and A 3-Calm Anti-Itching Complex In The Treatment Of Xerosis: A Real-Life Trial on 171 Subjects

Alfano S[1], Milani M[1*], Di Guida A[2#], Maiorino A[3#], Cotellessa C[4#], Gaspardini F[4#], Bianchini G[5#], De Marco I[6#], Bortoli J[7#], De Felice C[4#], Giura MT[8#], Cuconato M[9#], Gravante M[10#], De Tommaso S[11#], Gianfaldoni S[12#], De Blasio S[13#], Iannazzi S[14#], Balice Y[15#], Bono R[16#], Longo V[17#], Fonte L[18#]

[1]Cantabria Labs Medical Department, Caronno P. 20142 (VA), Italy

[2]Dermatologists, Outpatient private clinic, Napoli (NA), Italy

[3]Dermatologists, Outpatient private clinic, Salerno (SA), Italy

[4]Dermatologists, Outpatient private clinic, Roma (RM), Italy

[5]Dermatologists, Outpatient private clinic, Firenze (FI), Italy

[6]Dermatologists, Outpatient private clinic, Noci (BA), Italy

[7]Dermatologists, Outpatient private clinic, Modena (MO), Italy

[8]Dermatologists, Outpatient private clinic, Asti (AT), Italy

[9]Dermatologists, Outpatient private clinic, Cosenza (CS), Italy

[10]Dermatologists, Outpatient private clinic, Poggiardo (LE), Italy

[11]Dermatologists, Outpatient private clinic, Cento (FE), Italy

[12]Dermatologists, Outpatient private clinic, Pontedera (PI), Italy

[13]Dermatologists, Outpatient private clinic, Ancona (AN), Italy

[14]Dermatologists, Outpatient private clinic, Brescia (BS), Italy

[15]Dermatologists, Outpatient private clinic, Lissone (MB), Italy

[16]Dermatologists, Outpatient private clinic, Sciacca (AG), Italy

[17]Dermatologists, Outpatient private clinic, Catania (CT), Italy

[18]Dermatologists, Outpatient private clinic, Padua, Italy

The POLARIS Investigators' Group

***Corresponding author**: Massimo Milani, Cantabria Labs Difa Cooper. Caronno P. Italy.

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Abstract

Background: Xerosis is caused by several diseases, including atopic dermatitis, and is characterized by a damaged skin barrier, leading to dryness, flakiness, and increased susceptibility to irritation but it's also related to drastically changes in keratinization and skin lipid content [1,2]. A common symptom in xerosis patients is the development of pruritus, characterized by itching areas of dry skin. Numerous conventional detergents used in everyday life, are formulated with harsh chemicals and synthetic additives that can disrupt the skin's natural barrier, leading to increased dryness and irritation, predisposing to develop conditions such as xerosis [3]. **Study Aim:** In this Real-Life study we wanted to evaluate the efficacy of a detergent (*POL Calm detergente Cantabria Labs Difa Cooper, Caronno P, Italy)* containing Purified Omental Lipids, lipoprotein-based surfactants, Trealix and 3-Calm anti-itching Complex, to hydrate and reduce the itching in patients with xerosis. Pure Omental Lipids have been proved to have emollient and moisturizing actions on skin, in addition it exerts angiogenic properties due to its richness in VEGF (Vascular Endothelial Growth Factor). **Study design:** We performed a multicentric, real-life open prospective 4-weeks clinical trial. **Subjects and Methods:** A total of 171 patients (102 women and 69 men, mean age 56 ± 21 years) were enrolled and instructed to apply the POL detergent once daily for the entire duration of the trial (4 weeks). **Results:** At baseline, the xerosis score for the upper body parts was recorded at 2.22 ± 1.02. After 4 weeks of treatment with POL Calm detergent, this score decreased significantly to 0.51 ± 0.66, reflecting a reduction of 76.8%. Similarly, the xerosis score for the lower body parts decreased from 2.56 ± 0.98 at baseline to 0.67 ± 0.68 after treatment, indicating a reduction of 74%. The pruritus intensity score for the upper body parts demonstrated a baseline value of 2.16 ± 1.17, which decreased to 0.43 ± 0.61 after 4 weeks, representing a substantial reduction of 80.2%. Similar reduction of itch score was observed for the lower body parts. The product was very well tolerated. **Conclusion:** In this real-life study conducted in a large sample of subjects with severe xerosis, the use of a creamy rinse-off detergent containing purified omental lipids and anti-itching complex has demonstrated potent emollient and anti-itching effects.

Keywords: Xerosis; Itch; Purified Omental lipids; Real-life Study.

Introduction

Xerosis, or abnormally dry skin, and pruritus, or chronic itching, are common skin conditions that can significantly impact an individual's quality of life [1]. These conditions can be challenging to manage, and traditional treatments, such as emollients and topical corticosteroids, may not always provide adequate relief [1]. Xerosis is caused by several diseases, including atopic dermatitis, and is characterized by a damaged skin barrier, leading to dryness, flakiness, and increased susceptibility to irritation [2], but it's also related to drastically changes in keratinization and skin lipid content [4]. A common symptom in xerosis patients is the development of Pruritus, characterized by itching areas of dry skin [4]. Pruritus can be a symptom of various underlying dermatological, systemic, or neurological disorders, and understanding the underlying cause is crucial for effective management [5]. Loss of autonomic nerve function disrupts sweat production (anhidrosis), which in turn leads to xerosis due to insufficient moisture retention, reduced nutrient delivery, and diminished natural oil production from sudoriferous glands. The feet are particularly vulnerable due to their distal location and limited capacity for self-repair, but they are not the only location in which ulceration is developed. As the skin becomes dry and fragile, cracks and fissures can develop, creating entry points for infection. These structural changes, compromise the skin's protective function and can make wounds more resistant to healing, ultimately increasing the risk of chronic ulceration [6]. The interplay of underlying pathophysiology, disease progression, coexisting comorbidities, and medications contributes to a heightened risk of itch, a condition characterized as an unpleasant sensation that often prompts individuals to scratch intensively, decreasing the quality of life (QoL) of an affected patient [7]. All those conditions highlight the importance of a correct skin care, in order to reduce the risk of diabetic patients' ulcer development and progression and to improve their QoL [8]. The effectiveness of management of xerosis conditions involves wound care, but also the hydration maintenance to reduce any further complications that could potentially emerge and worsening the patients' condition [9]. In the worst-case scenario, after the development of skin xerosis, patients are treated with a combination of emollients and

moisturizers, such as urea, for the long-term [10]. A recent clinical trial evaluated the effectiveness of POL-P cream, which contains urea, Pure Omental Lipids (POL), carnosine, and panthenol, in diabetic patients. The results showed a remarkable 74% reduction in the Dry Area Severity Index (DASI) among the participants [11]. Additionally, another clinical trial confirmed the emollient and hydrating properties of POL-P cream, demonstrating that its efficacy is comparable to that of a glycerol-based emollient cream. Notably, patients using POL-P cream experienced an 80% reduction in itching, compared to a 50% reduction for those using the glycerol-based cream [12]. Detergents are surfactants widely used in households and personal care products to clean and remove dirt, oil, and impurities. They play a vital role in maintaining hygiene and sanitation, which is crucial for preventing the spread of pathogens. However, many conventional detergents contain harsh chemicals and synthetic additives that can compromise the skin's natural barrier, leading to dryness and irritation [3]. To use a detergent that do not have a negative impact on the sensitive skin of patients, such as xerosis patients' skin, is fundamental in order to not worsen the already existing condition.

Study Objective

In this Real-Life study we wanted to evaluate the efficacy of a detergent *(POL Calm detergente; Cantabria Labs Difa Cooper, Caronno P., Italy)* containing Purified Omental Lipids, lipoprotein-based surfactants, Trealix and 3-Calm anti-itching Complex, to hydrate and reduce the itching in patients with xerosis. Pure Omental Lipids have been proved to have emollient and moisturizing actions on skin, in addition it exerts angiogenic properties due to its richness in VEGF (Vascular Endothelial Growth Factor) [13].

Study design

We performed a multicentric, real-life open prospective 4-weeks clinical trial.

Inclusion criteria

To be eligible for participation in this study, individuals must meet the following criteria:

1. Adults, males and females, aged 18 years or older at the time of enrollment.
2. Clinically confirmed diagnosis of xerosis with clinically relevant pruritus localized to the arms or legs at the time of screening
3. Ability to provide written informed consent and willingness to adhere to all study procedures.

Exclusion criteria

Individuals were excluded from the study if they met any of the following conditions:

1. Presence of active skin diseases, such as psoriasis, urticaria, or other dermatological conditions that could have interfered with study assessments.
2. Current or recent use of medications that could have affected itch perception or treatment, including antihistamines, corticosteroids (topical or systemic), or other drugs indicated for pruritus management.
3. Known allergy or hypersensitivity to any of the active ingredients contained in the study products.
4. Pregnant or breastfeeding individuals at the time of enrollment or during the study period.

Materials and methods

The clinical trial was conducted between June 2024 and February 2025, adhering to the principles of the Helsinki Declaration and complying with Good Clinical Practice (GCP) regulatory requirements. All participants provided signed informed consent prior to enrollment. At the conclusion of the enrollment period, a total of 171 patients (102 women and 69 men, mean age 56 ± 21 years) were enrolled and instructed to apply the POL detergent once daily for the entire duration of the trial (4 weeks). The detergent used in this trial is commercially available and marketed by Cantabria Labs Difa Cooper (POL Calm Detergente, Caronno Pertusella, Italy). This rinse-off cleanser is specifically formulated to gently cleanse sensitive and fragile skin, effectively removing impurities while providing a soothing and hydrating effect. Due to its mild formulation, rinsing, could be not necessary ensuring cleanliness and comfort for delicate skin. However, in the present trial the product was use as a rinse-off detergent.

Study Outcomes

The efficacy of the treatment was evaluated through clinical assessments of xerosis and pruritus in the upper (arms and hands) and lower (legs and feet) parts of the body at baseline (V0) and after a 4-week follow-up (V1). The minimal xerosis score ranged from 0 (absence of xerosis) to 5 (severe signs of xerosis). Similarly, the pruritus score was assessed, with a minimum score of 0 (absence of pruritus) and a maximum of 5 (severe symptomatology). After 4 weeks of treatment, patients responded to four questions regarding their assessment of skin dryness and pruritus levels. Additionally, evaluations of the product's tolerability, potential side effects, and overall efficacy were conducted.

Statistical Analysis

Statistical analysis was conducted using GraphPad Prism statistical software version 9.0 (GraphPad Software Inc., La Jolla, CA, USA). A parametric - T test was used to compare data at the baseline (V0) and after the 4-weeks treatment (V1). Data is expressed in mean ± standard deviation (SD) and was considered significant a p-value <0.05.

Results

In this study, we evaluated the effects of POL Calm detergent on xerosis and pruritus intensity in both upper and lower body parts over a 4-week treatment period. A total of 171 participants were enrolled in this study and all the subjects completed the treatment period (Figure 1).

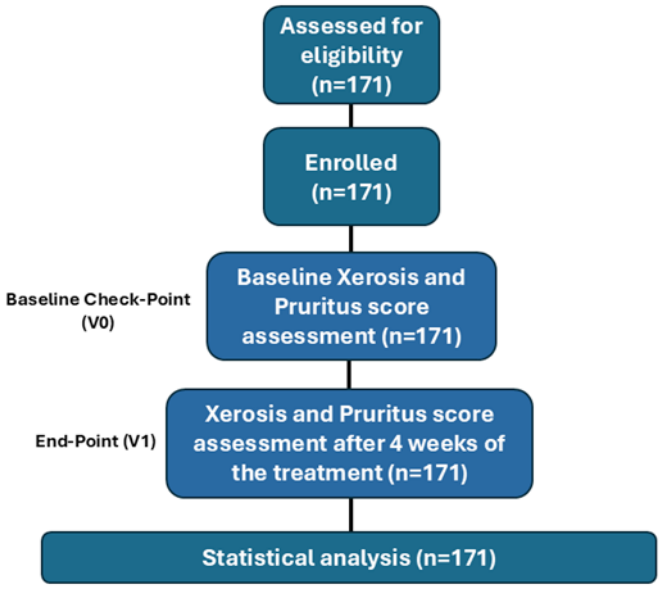

Figure 1: Study workflow.

The results indicate a significant reduction in the scores of all assessed parameters following the intervention. At baseline, the xerosis score for the upper body parts was recorded at 2.22 ± 1.02. After 4 weeks of treatment with POL Calm detergent, this score decreased significantly to 0.51 ± 0.66, reflecting a reduction of 76.8% (Figure 2).

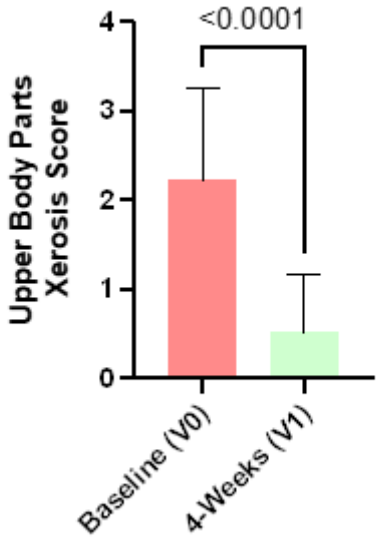

Figure 2: Upper body parts Xerosis score.

Similarly, the xerosis score for the lower body parts decreased from 2.56 ± 0.98 at baseline to 0.67 ± 0.68 after treatment, indicating a reduction of 74% (Figure 3).

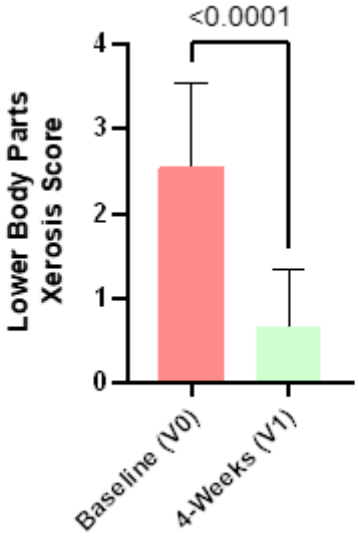

Figure 3: Lower body parts Xerosis score.

Furthermore, the pruritus intensity score for the upper body parts demonstrated a baseline value of 2.16 ± 1.17, which decreased to 0.43 ± 0.61 after 4 weeks, representing a substantial reduction of 80.2% (Figure 4).

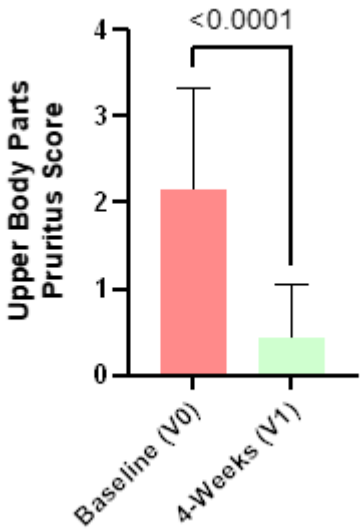

Figure 4: Upper body parts Pruritus score.

Likewise, the pruritus intensity score for the lower body parts declined from 2.53 ± 1.13 at baseline to 0.54 ± 0.69 following the treatment, corresponding to a reduction of 78.5% (Figure 5).

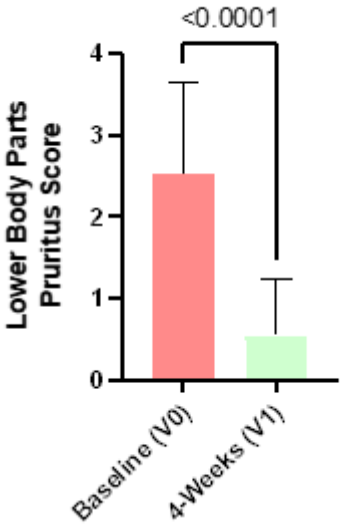

Figure 5: Lower body parts Pruritus score.

These findings suggest that treatment with POL Calm detergent effectively alleviates xerosis and pruritus in affected areas, supporting its use as a therapeutic option in managing these conditions.

Discussion

In the last years, especially in what experts call "post-COVID-19 Era", we are assisting in an increase in the number of people suffering of dermatological conditions, such as xerosis. The geriatric population, because of the implementation of measures to prevent COVID-19 (frequent handwashing, sheltering in place, etc.) is the most susceptible to dermatologic consequences associated to those [14]. Not only elderly people has a major chance to develop conditions such as xerosis, but also in other susceptible groups such as people undergoing oncological targeted therapies, that are associated with a significant risk of developing xerosis [15].

Although, as amply demonstrated in literature, one of the main causes of developing xerosis, is diabetes. Literature suggest that the type of diabetes influence the development of the xerosis, the prevalence rates range from 45% [16] for patients suffering of type 2 diabetes to 82% [17] for diabetic patients with peripheral neuropathy.

This study evaluated the efficacy of POL Calm detergente, a formulation containing Purified Omental Lipids and other soothing agents, in managing xerosis and associated pruritus in a real-life clinical setting. The findings indicate a significant reduction in both xerosis and pruritus scores after four weeks of treatment, highlighting the potential of this product as an effective therapeutic option for individuals suffering from these challenging skin conditions. The results demonstrated a remarkable 76.8% reduction in xerosis scores for the upper body and a 74% reduction for the lower body, alongside an 80.2% decrease in pruritus intensity for the upper body and a 78.5% decrease for the lower body.

These outcomes suggest that POL Calm detergent not only improves the hydration of the skin but also effectively alleviates the discomfort associated with chronic itching. The substantial improvements observed in both xerosis and pruritus scores underscore the importance of selecting appropriate skin care products that can provide relief to patients, particularly those with compromised skin barriers due to conditions like diabetes [9].

One of the strengths of this study is its large sample size of 171 participants, which enhances the reliability of the findings and allows for a more comprehensive understanding of the product's efficacy across a diverse patient population. Furthermore, the real-life approach of the study, conducted in a multicentric setting, reflects the practical application of POL Calm detergent in everyday clinical practice. This aspect is crucial, as it ensures that

the results are not only statistically significant but also relevant to patients dealing with xerosis and pruritus in their daily lives. However, there are limitations to consider. The study was an open uncontrolled trial, which may introduce biases in patient-reported outcomes and the assessment of treatment efficacy. The lack of control group limits the ability to attribute improvements solely to intervention, as factors such as natural disease progression or external variables may have influenced the results.

Additionally, the study's duration of four weeks, while sufficient to observe initial changes, may not capture the long-term effects and sustainability of the treatment. Future research with a randomized controlled design and extended follow-up periods would provide more robust data on the efficacy and safety of POL Calm detergent.

In conclusion, despite its limitations, this study provides valuable insights into the effectiveness of POL Calm detergent for managing xerosis and pruritus. The significant improvements in skin hydration and reduction in itching underscore the potential benefits of this formulation for patients suffering from these conditions. As the prevalence of xerosis and pruritus continues to rise, particularly among elderly [14,18] and diabetes suffering population, the development and evaluation of innovative skin care products like POL Calm detergent are essential for improving patient quality of life and managing these common dermatological issues effectively. Further studies are warranted to confirm these findings and explore the long-term benefits of this treatment.

Conclusion

In this real-life study conducted in a large sample of subjects with severe xerosis, the use of a creamy rinse-off detergent containing purified omental lipids and anti-itching complex has demonstrated potent emollient and anti-itching effects in severe xerosis.

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