A SPECIAL PILL-MASK TO RE-HYDRATE THE SKIN AFFECTED BY ATOPIC DERMATITIS

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Received: November 2003. Presented at the Personal Care Ingredients Conference, 19-21 March 2002, Shanghai - China

Key words: Atopic dermatitis; Chitosan; Triamcinolone; Pill-mask; Lamellar emulsion;

Summary

Atopic dermatitis (AD) is a common condition affecting the 10% of infants, whose problematic cutaneous cell-mediated immunity, make them prone to skin infection by viruses, bacteria and fungi. We aimed to investigate the efficacy of an innovative self-preserving polysaccharide-based lamellar emulsion enriched with a chitosan-derived moisturizing and anti-inflammatory compound as an alternative treatment for AD.

The study was an 8-week prospective, randomized, open, parallel-group trial with 36 children. 15 (group A) and 12 subjects (group B), pre-washed by a bath oil, were applied twice a day within 3 minutes with 5 mg/g of a chitosan-derived compound solubilized in a lamellar active emulsion by a special imbibed pill-mask (group A), or a carrier emulsion (group B). A third group C of 9 children was treated with a petrolatum ointment for the same period. After one week of cosmetic treatment, all the groups were treated, once a day, with triamcinolone 0.1% ointment.

A clinical score assessing erythema, scaling, crusting and pruritus was performed at baseline and every 2 weeks thereafter on a visual analogue scale. After 4 weeks from the starting point, a major improvement averaging of 58% was observed in the group A versus group C; 82% of group A vs. group B and 64% of group C vs. group B. This novel cosmetic therapy used in AD, seems useful to reduce corticosteroids dosage avoiding their side effects, and to improve skin hydration decreasing skin dryness also in people with sensitive skin.

Riassunto

La dermatite atopica (DA) è una condizione patologica comune che interessa il 10% dei bambini la cui compromessa immunità cellulare li rende predisposti ad infezioni cutanee causate da virus, bat-
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teri e funghi.
Come trattamento alternativo in caso di DA, si è voluta controllare l'efficacia di un'emulsione lamellare innovativa autopreservabile a base di polisaccaridi, arricchita con un composto derivato dal chitosano ad attività idratante ed antinfiammatoria.
36 bambini divisi in 2 gruppi, A (formato da 15 soggetti) e B (formato da 12 soggetti), sono stati sottoposti ad uno studio di 8 settimane consistente in pretrattamento con un olio e successiva applicazione (2 volte al giorno) di 5mg/g del composto in studio applicato mediante una speciale compresa di tessuto denominata "pill-mask" (gruppo A) o del solo veicolo (gruppo B: di controllo).
Un terzo gruppo, C, formato da 9 bambini, è stato trattato con olio di vasellina per lo stesso periodo. Dopo una settimana di trattamento cosmetico, a tutti i gruppi è stato applicato, una volta al giorno, un unguento a base di triamicinolone allo 0,1%.
Tutti i bambini sono stati valutati clinicamente, al giorno iniziale e alle successive 2 settimane, controllando i parametri clinici di intensità dell'eritema, desquamazione, numero delle lesioni eczematosi e prurito.
Dopo 4 settimane dall'inizio del trattamento è stato riscontrato un miglioramento del 58% nel gruppo A rispetto al gruppo C; dell'82% del gruppo A rispetto al gruppo B e del 64% del gruppo C (vasellina) rispetto al gruppo B (veicolo).
Questa innovativa terapia cosmetica della DA sembra rappresentare una valida alternativa per ridurre sia il dosaggio che gli effetti collaterali propri dei corticosteroidi.
Infatti, l'emulsione lamellare utilizzata sembra essere anche in grado di aumentare l'idratazione cutanea riducendo lo stato di xerosi presente spesso nei soggetti con cute cosiddetta "sensibile".
Atopic dermatitis (AD), a common skin disease affecting from 10 to 15% of children in many parts of the world, accounts for 4% of pediatric emergency care visits and its prevalence is rapidly increasing (1-9).

This inflammatory disease, displaying mainly pruritic eczema and dry skin, may be accompanied by dyshydrotic hand and foot eczema, abnormalities in keratinization including follicular keratosis, and a tendency to develop microbial infections of the skin, which include impetigo, folliculitis, furuncles, and an increased frequency of viral infections (10).

Although no one would disagree that eczema results in interactions between genes and environment, the relative contributions seems to be about 50% each one (11).

Finally in AD, there is a marked disease in water-holding and barrier functions, accompanied to a subjective sensation of itch, which leads to a desire to scratch (12-14). Until now therapy is highly unsatisfactory. The used topical and systemic corticosteroids retards inflammation but the benefit-risks relationship is far from satisfactory. Therefore in large part because of this lack of effective and safe therapy, most patients with AD don’t seek medical care, but “get by” with a multitude of non-prescription remedies.

**AIM**

The aim of this study was to investigate the efficacy of an innovative cosmetic treatment on patients affected by AD with the objective of restore the disrupted barrier re-hydrating the skin at a normal level, and reducing the use of corticosteroids and their consequent negative side effects.

**MATERIAL AND METHODS**

**For cleansing:**


**For treatment:**

2. Pill-mask: pre-imbibed tissue
3. Pill-mask solution (active A): tocotrienols, hyaluronic acid and ATOBIOL®
4. Lamellar Gel (active B): Aqua (Water), Hydrogenated Polydecene, Propylene Glycol, Atobiol, Pentylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Tocotrienols
5. Petrolatum ointment (control)
6. Triamcinolone 0.1% ointment

As it is known, bathing enhances the effects of moisturizers and topical steroids. But it is fundamental to apply the cream within 3 minutes to prevent evaporation from the stratum corneum. As a matter of fact the skin of patients AD affected, rapidly dehydrates and the barrier cracks. Therefore the 3 minute rule is very important.

**TREATMENT METHODOLOGY**

The study was an 8-week prospective, randomized, open parallel-group trial with 36 children, divided in three sub-groups: 15 subjects (group A), 12 (group B) and 9 (group C) all pre-washed by a bath-oil.

Within 3 minutes from washing, was applied twice a day a special pill-mask (ACTIVE A) imbibed with an aqueous active solution of tocotrienols, hyaluronic acid (HA) and 5 mg/g of a patented chitosan-based anti-inflammatory compound named ATOBIOL® (Group A), and soon after the lamellar Gel B or only the lamellar gel enriched with ATOBIOL (5 mg/g) (ACTIVE B, Group B).
A third group of 9 children was treated with a petrolatum ointment for the same period (group C - control). After 8 days of cosmetic treatment, all the groups were treated, two times a week, with triamcinolone 0,1% ointment, continuing the treatment at home applying the sole lamellar gel twice a day.

**METHODOLOGICAL SCHEME**

**FOR THE FIRST 8 DAYS**

1. Phase: - to clean the treated face by the bath oil
2. Phase: - to apply within 3 minutes on wet skin the imbibed pill-mask (ACTIVE A) for at least 15 minutes + ACTIVE B gently massaging (group A)
   - to apply the lamellar gel (ACTIVE B) on wet face gently massaging until absorbing (group B)
   - to apply the petrolatum ointment gently massaging (group C - control)

**CLINICAL EVALUATION**

A clinical score assessing erythema, scaling, crusting, and pruritus was performed, always by the same dermatologist, at baseline (day 1), at day 8th and every 2 weeks thereafter on a visual analogue scale (0 = absent; 1 = mild; 2 = moderate; 3 = severe (Tab. II)).

No patients used other topical treatments within the 2 months of the study period, or systemic drug or diet supplements within also the 4 weeks before starting the study.

The obtained results are reported on Fig. 1 and 2.

<table>
<thead>
<tr>
<th>ERYTHEMA</th>
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<tbody>
<tr>
<td>0 = absent</td>
</tr>
<tr>
<td>1 = mild (&lt;10% surface area)</td>
</tr>
<tr>
<td>2 = moderate (erythema in macules and patches)</td>
</tr>
<tr>
<td>3 = severe (generalized erythema &gt; 50% surface area)</td>
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<table>
<thead>
<tr>
<th>PRURITUS, SCALING, CRUSTING</th>
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<tbody>
<tr>
<td>0 = absent</td>
</tr>
<tr>
<td>1 = mild occasional scratching and scaling</td>
</tr>
<tr>
<td>2 = moderate scratching continuously and some scaling and crusting</td>
</tr>
<tr>
<td>3 = severe hard continuously scratching – excoriation, scaling crusting.</td>
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**TAB. I**

**TAB. II**
Erythema evaluation on patients affected by atopic dermatitis treated by a lamellar gel and special PILL MASK both enriched by a new chitosan-based anti-inflammatory compound for two months

\( n = 36 \cdot t = 22^\circ C \cdot RH = 50\% \)

![Graph](image1)

**Fig. 1**

All p values are highly significant \((p < 0.005)\) as baseline and as to groups

Pruritus scaling and curing evaluation on patients affected by atopic dermatitis treated by a lamellar gel and special PILL MASK both enriched by a new chitosan-based anti-inflammatory compound for two months

\( n = 36 \cdot t = 22^\circ C \cdot RH = 50\% \)

![Graph](image2)

**Fig. 2**

All p values are highly significant \((p < 0.005)\) as baseline and as to groups
A special pill-mask to re-hydrate the skin affected by atopic dermatitis

BIOPHYSICAL EVALUATIONS: 3C SYSTEM METHODOLOGY

Quantitative measurements of skin hydration, surface lipids and TEWL were performed according to Cardillo and Morganti method (15,16) before the 1st day (baseline), after the first 8 days of pre-treatment (end of treatment) and at 15 and 60 days of treatment, always in the morning from 8 and 11 a.m. on skin cleansed the night before.

This computerized methodology collects up to 10/15 measurements over 25 second sampling period and records the mean values, automatically standardizing the environmental conditions (RH = 50%, t = 22°C).

To alleviate the possibility of the patient physiology state, the other major factor-influencing rate of water loss, it was asked to rest in the testing room for 30 minutes before measurements.

Possible site-to-site variation was eliminated by random selection of treated sites.

Skin hydration was assessed by measuring total capacitance of the horny layer and the values are expressed in 3C arbitrary units; skin lipids, observed by a special frosted plastic foil, are measured photometrically and expressed as µg/cm²; TEWL was measured by a special 3C probe. It consists of a cylindrical open chamber measuring system, diameter 14 mm., height 10 mm. and two sensor units, containing a thin capacitance film transducer placed at 3 and 7 mm. distance from the skin.

TEWL is calculated digitally as g/m² h.

The instrument probe was always held perpendicular to the skin surface and allowed to equilibrate for 20 seconds.

All the obtained results are expressed as mean values of the measurements performed on four different right or left skin areas (cheek, forehead, chin and nose).

The obtained results are reported on Fig. 3, 4 and 5.
Skin hydration increase on patients affected by atopic dermatitis treated by a lamellar gel and special PILL MASK both enriched by a new chitosan-based anti-inflammatory compound for two months

\[ n = 36 - t = 22 \, ^\circ\text{C} - \text{RH} = 50\% \]

ALL \( p \) VALUES ARE HIGHLY SIGNIFICANT \((p<0.005)\) AS BASELINE AND AS TO GROUPS

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TEWL decrease on patients affected by atopic dermatitis treated by a lamellar gel and special PILL MASK both enriched by a new chitosan-based anti-inflammatory compound for two months

\[ n = 36 - t = 22 \, ^\circ\text{C} - \text{RH} = 50\% \]

ALL \( p \) VALUES ARE HIGHLY SIGNIFICANT \((p<0.005)\) AS BASELINE AND AS TO GROUPS
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PILL-MASK APPLICATION

The pre-imbibed pill-mask is applied on the entire cleansed face for 15 minutes. The complete imbibition period of the dry pill requires 1 minute of time operating (Fig. 6).

STATISTICS

The Chi-square test and the Fisher exact test were used for statistical analyses. AP value less that 0.05 was considered significant. The Bonferroni correction was made when appropriate.

DISCUSSION

Both the gel and the pill-mask proved a strong anti-inflammatory and re-hydrating activity on atopy affected subjects treated following the methodology above described.

In fact, while the active principle used performed completely its activity, as reported also in one of our previous studies (17), the methodology used for pill-mask contributed remarkably in decreasing many symptoms usually accompanying AD.

As clearly shown on Fig. 1 and 2, the treatment with the sole gel or in combine with PILL-MASK/gel decreased the erythema appearance (Fig.1) from 59 to 65%, and the pruritus-crusting from 66 to 64% (Fig. 2) after 60 days therapy, differently from the usual petrolatum treatment which improves of about 30% only. The use of this special cosmetic therapy gave results higher of above 25%. Why? Probably that is due to the intense anti-inflammatory and reparatory activity performed by the new active principles used, and to the high rehydrating activity performed both by pill-mask and by the constant use of the lamellar gel.

As observed, the treatment with pill-mask only, during the first 8 days of therapy (that is to say before using corticosteroid) improved the erythema appearance from 35 to 44% and pruritus/crusting from 24 to 52%, providing a high capacity in restoring the barrier activity.

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Comparing figure 3 to 5, it can be observed a remarkable increase in hydration (+ 85%) and in surface skin lipids (+ 88%) with a consequent decrease in TEWL (- 40%).

Continuing the cosmetic therapy together with the bi-weekly use of corticosteroid, skin hydration values increase up to 98% using pill-mask/gel, and up to 80% using the sole gel,
while surface skin lipids increase respectively of about 97% in both treatments, and the high values of TEWL recorded in patients affected by AD decreases of about 50%.

In this case also, the control treatment by petrolatum recorded values lower from 30 to 40%.

In conclusion, we deem important to underline the surprising results obtained using corticosteroid only twice a week.

CONCLUSION

This novel cosmetic therapy used in AD, seems useful to reduce corticosteroids dosage avoiding their side effects, and to improve skin hydration decreasing skin dryness also in people with sensitive skin.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the financial support of this study and the cosmetic samples given by Mavi Sud S.r.l.
References

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