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# Randomized clinical trial on a hydrating intimate cleanser as an adjuvant in vulvar dermatosis therapy

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ABSTRACT

**Objective:** Vulvar dermatoses are characterized by dehydration leading to symptoms as itching and burning. Topical corticosteroids and lanolin cream are the standard therapy. A new non-irritant cleanser based on soft natural surfactants (Saugella idraSerum, a product by Rottapharm\Madaus) (SiS) exhibited interesting clinical properties. Purpose of the study was to compare the activity of SiS in vulvar dermatoses versus a common reference cleanser (Aveeno intimo) (Ref). **Methods:** In a controlled randomized clinical study 32 patients with vulvar dermatosis received Mometasone 2 applications weekly and lanolin cream 1 application daily for 7 days followed by 1 application as needed. To one half of the patients SiS and to half of patients Ref were recommended as daily cleanser bid for 1 month. Any onset of symptoms was checked before and after treatment. **Results:** Burning improved after SiS treatment vs Ref in a significantly higher rate (respectively 80% *vs* 25%, $P<0.05$). Dryness improvement was superior with SiS (81.1% *vs* 50.0%, $P=0.10$) though the Ref group applied a significantly higher number of doses of emollient cream as needed. **Conclusion:** This new-generation intimate cleanser was effective in reducing burning and the concomitant emollient treatment in vulvar dermatoses.

## 1. Introduction

Vulvar dermatoses are diseases occurring on an immune base which are frequently found in a center for the treatment of vulvar diseases. Lichen sclerosus, lichen planus and lichen simplex chronicus are three of the most common vulvar dermatoses [1]. Lichen sclerosus is characterized by intensive vulvar itching and can affect men and women of all ages, but it appears most commonly in post-menopausal women. Lichen planus is an inflammatory auto-immune disorder that can affect the vulva and vagina. Its peak incidence is between the ages of 30 and 60 years. There are three clinical variants of lichen planus affecting the vulva: erosive, papulosquamous and hypertrophic [2]. Lichen simplex chronicus is caused by a persistent itching and scratching of vulvar skin, which results in a thickened, leathery appearance. It is thought to be an atopic disorder in many cases and may arise in normal skin as a result of psychological stress or environmental factors. The primary lesions of vulvar dermatosis are white and red, flat and/or thickened areas. There may be erosions and fissurations. The main symptom is severe itching and burning, in case of erosions or fissures. Some patients experience dyspareunia, especially those with erosive lichen planus. The clinical and histological alterations of vulvar dermatoses are responsible for changes in vulvar skin barrier function that enhance the symptoms (dehydration and impaired lipid skin film). The treatment of all the three disorders should begin with corticosteroid ointments or creams of varying potency [2-4]. It is also recommended to use emollient creams with the aim of restoring the protective skin barrier. It is crucial to adopt products for personal hygiene.

A new non-irritant cleanser based on soft natural surfactants (Saugella idraSerum Rottapharm\Madaus) (SiS) exhibited hydrating and emollient properties.

The purpose of our study was to compare the activity of SiS in vulvar dermatoses versus a common reference

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cleanser (Aveeno intimo).

## 2. Materials and Methods

The experimental design was a controlled, randomized, clinical study in which 32 patients with vulvar dermatoses were recruited. The diagnosis was of vulvar dermatosis. Each patient received Mometasone furoate in the form of 0.1% cream. The treatment was intensive during the first month: ½ fingertip unit (FTU), namely the amount of topical steroid (Mometasone furoate) that is squeezed out from a standard tube on the fingertip of an adult (about the same as 0.5g of topical steroid) once a day for four weeks, then twice a week for other four weeks plus lanolin cream 1 application daily for 7 days, and thereafter lanolin cream was applied only when needed as a rescue treatment. The patients were prescribed to apply a cleanser b.i.d. namely Saugella idraSerum (Rottapharm|Madaus) (SiS) or a common reference cleanser (Aveeno intimo) (Ref) according to the randomization list.

Each woman was unaware whichever was the new cleanser (SiS) compared to the common reference one (Ref). For the above consideration the study can be considered a patient-blind controlled trial.

The parameters evaluated for efficacy were the following: amount of the rescue cream used, burning, dryness, rubbing, applicability and pleasantness of the product. Each descriptor was ranked on a 4-point intensity scale (0=none, 1=mild, 2=moderate and 3=severe).

The signs and symptoms were classified before and after treatment.

A statistical analysis for the comparison of the two treatments was carried out by applying the chi-square test ( $\chi^2$) (improved vs impaired/unchanged versus baseline) and Student's t test (amount of rescue cream employed).

## 3. Results

The characteristics of the study population are summarized in Table 1. The women in the two groups were similar for age and diagnosis.

**Table 1**
Characteristics of the study populations

| SiS group | | Ref group | P value |
|---|---|---|---|
| Number of cases | 16 | 16 | |
| Age (years, mean and range) | 52 (32-73) | 56 (34-69) | NS |
| Diagnosis | 9 LS | 11 LS | NS |
| | 4 LSy | 3 LSy | NS |
| | 3 Derm | 2 Derm | NS |

LS=lichen sclerosus ; LSy=lichen simplex ; Derm=other dermatoses

Burning improved after SiS treatment vs Ref in a significantly higher rate (respectively 80% vs 25%, $P<0.05$). Dryness improvement was better with SiS (81.1% vs 50.0%, $P=0.10$) though the Ref group applied a significantly higher number of doses of emollient cream as needed.

The use as needed of the emollient lanolin cream was significantly superior in a total number of doses in Ref group versus SiS group: 10.1±1.0 vs 6.8 ± 0.7 ($P< 0.01$). (Fig. 1)

The differences between the treatments for rubbing, applicability and pleasantness of the product were statistically non-significant, respectively 36.4% vs 60.0%, 50.0% vs 43.8%, 56.3% vs 62.5%.

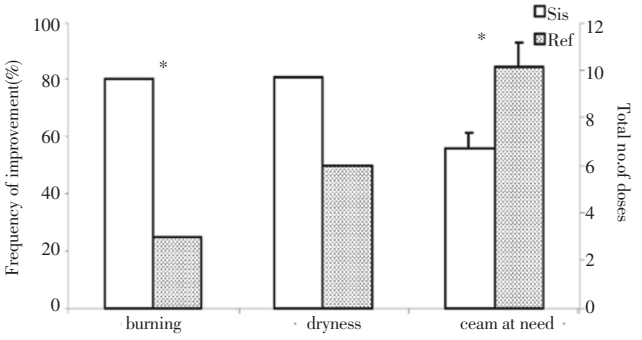


**Figure 1.** Improvement of symptoms and spare in cream requirement after using a cleanser b.i.d. for 1 month in vulvar dermatosis. (*$P<$ 0.05)

## 4. Discussion

Vulvar dermatoses are mainly treated with potent topical steroids to relieve the symptoms, to prevent structural damages and to reverse histologic changes.

The recommended regimen of lichen sclerosus, which is the most frequent vulvar dermatosis, begins with a high-potency corticosteroid used daily until all the active lesions have resolved (usually in two to three months), then tapered to once or twice per week [3-5]. The rationale for once daily application is based on pharmacodynamic studies showing that an ultrapotent corticosteroid needs only a once a day application [5]. A gradual dose reduction enables the majority of patients to remain in asymptomatic remission and to minimize steroid exposure [5]. The use of potent corticosteroids, such as clobetosol or Mometasone cream, achieved a symptoms remission rate ranging from 77% to 98% [6,7]. This outcome also applies to other vulvar dermatoses, obviously with some differences related to the specific characteristics of the different vulvar diseases. Patients with erosive vaginal lichen planus, for example, can also be treated with a steroid foam that affords a greater adhesion of the drug [8]. In our study we obtained a high

remission rate of symptoms, pruritus first of all, with the use of Mometasone furoate cream, but vulvar dermatosis can also have problems related to the damage of the barrier function of vulvar skin. The skin barrier depends on the degree of hydration, the presence of a horny layer and an intact surface. Transepidermal water loss (TEWL) is an indicator of the skin barrier function; it is minimal in the genital area [9] and even more in the presence of a vulvar dermatosis.

The surface lipid film is the main vulvar skin protective factor. It consists of a hydrophilic component (Natural Moisturizing Factor = NMF) and a soluble fraction, mainly consisting of sebum (95% of total).

Treatment of vulvar dermatoses should restore the lipid film surface to protect the vulvar skin; this requires the need of using emollient preparations in addition to topical steroid therapy.

The use of emollient preparations also reduces the onset of burning, which takes to the frequent occurrence of erosions and/or ulcers, as well to the possible iatrogenic effect of topical steroids.

In our study we used a new non-irritant cleanser based on soft natural surfactants (SiS).

This product contains a natural pool of surfactants consisting of Cocoyl Wheat Amino Acids (coconut derivatives and wheat's amino acids), associated with a set of high power moisturizing and emollient substances (Maltodextrins, Aveena sativa, Caprylic Glycol, etc.). SiS also contains extracts of Calendula officinalis and Salvia officinalis (antimicrobial, anti-inflammatory, itching relieving and re-epithelising agents) and components of the active vehicle assuring hydrating and emollient properties, higher adhesion to the mucous membrane and a longer permanence of the hydrating active ingredients.

SiS required lower doses of emollient cream thus taking to a significant spare in cost and time. The higher improvement of dryness which occurred with SiS had only a borderline significance, but this difference in favor of SiS is clinically important, because it was achieved though the Ref group applied a significantly higher number of doses of emollient cream as needed.

A proper hygiene with the use of an appropriate intimate detergent agent is mandatory.

The two most important components of an intimate detergent agent are surfactant and emollient moisturizing agents. Surfactants are substances that can lower the liquid surface tension, facilitating the wetting action to emulsify the dirt, so achieving an appropriate skin washing.

SiS formulation through the percentage of naturally occurring surfactants (coconut derivatives and wheat's amino acids) provides gentle cleansing and a particularly prolonged hydration.

This new-generation intimate cleanser was effective in reducing burning and the concomitant emollient treatment in vulvar dermatoses.

In our case series we did not find differences in rubbing, applicability and pleasantness in Ref group versus SiS group. Again we stress the need for a proper hygiene with selected products that meet the vulvar skin requirements.

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