

Efficacy and Tolerability of an Innovative Detergent on Feminine Hygiene (Saugella Hydraserum) In a Controlled Clinical Study in an Italian Population

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Abstract

Background/Aims: In daily feminine hygiene in women prone to genital dryness, it is rational to use a specific detergent (SH) containing less aggressive natural surfactants which stimulate epidermal renewal of keratinocytes, agents increasing bioadhesiveness of hydrating components; and plant extracts with natural antimicrobial, and anti-inflammatory activity. This study evaluated efficacy and acceptability of SH (Saugella Hydraserum) compared with a standard detergent (C) in women with vaginal dryness.

Methods: Women of childbearing potential with vaginal dryness were randomised to treatment with SH or with C, b.i.d. for 4 weeks in a controlled, balanced, parallel-group study stratified by clinical condition. Clinical evaluations were performed at baseline and every week.

Results: A total of 120 women were treated, 60 per treatment, mean age 32.6 years, with dryness due to hormone deficiency or hypersensitive to normal detergents.

Symptoms severity was significantly reduced in favour of SH for pruritus ($67.4\% \pm 7.4$ vs $-36.8\% \pm 7.5$, $p < 0.01$), burning ($-65.3\% \pm 7.4$ vs $-36.9\% \pm 7.2$, $p < 0.05$), erythema ($-80.3\% \pm 6.6$ vs $-39.2\% \pm 9.8$, $p < 0.05$), dryness ($-52.9\% \pm 7.1$ vs $-16.2\% \pm 5.0$, $p < 0.001$), dyspareunia ($-44.9\% \pm 6.2$ vs $-16.7\% \pm 6.6$, $p < 0.05$).

Conclusions: Saugella Hydraserum showed better clinical efficacy than normal intimate detergent on pruritus, burning, erythema, dryness, and dyspareunia in women with vulvovaginal dryness. This outcome was obtained by the combination of natural surfactants, offering skin protection, and a complex of active substances, aimed both at normal hydration of the external genitalia and prevention of microbial contamination.

Keywords: Vaginal dryness; Feminine hygiene; Plant extracts

Introduction

The use of products for feminine hygiene aimed at the specific pathophysiological condition is able to improve feminine hygiene in a clear and noticeable manner.

Furthermore, it is important to take into account the multifactorial nature and inter individual differences and, given these factors, to follow an organic and systematic approach in feminine hygiene, which has never been done before [1].

To date, detergents containing active substances with proven efficacy and a pH compatible with the intended objective have been available, appropriate for the following categories: pre-pubertal girls, women of childbearing potential, during the menstrual cycle, during pregnancy and in the postpartum period, in situations at risk of bacterial infections (surgical operations, being in situations or places with mixed conditions of hygiene), in active bacterial infections (pruritus and vulvar burning), and also as a co-adjuvant of specific antibacterial and antifungal therapies, during the menopause [2].

Research & Development in the field of cosmetics has made considerable progress in obtaining substances that may extend the objectives of use of detergents and provide clinical solutions for more specific populations such as women of childbearing age who are sensitive to standard detergents containing aggressive surfactants or who are prone to dryness of the genital region or with irritation not due to infection, women of childbearing potential using oral contraceptives in whom the genital mucosa tends to become dry as a result of low levels of ethinyloestradiol, with consequent difficulty during sexual intercourse and an increase in local infections, girls after the menarche

who, because of excessive feminine hygiene, have altered hydration of their mucosa.

A possible solution to the problem of feminine hygiene for these categories of women may be a specific latest-generation detergent (SH) whose formulation is non-irritant due to the fact that it contains surfactants of natural origin (derivatives of coconut and amino acids of wheat), which ensure particularly gentle cleansing with prolonged hydration. In fact, these surfactants stimulate epidermal renewal of keratinocytes and are therefore able to restructure damaged skin and restore the lipid layer of the skin that is removed during normal routine washing. They therefore protect the skin barrier.

The potent hydrating and emollient activity is ensured by the presence of active substances (oat milk, maltodextrins, diglycerol and caprylyl glycol) which contribute to restoring and/or maintaining the right water content and, therefore, physiological skin elasticity in the external genitalia.

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Furthermore, xanthan gum, thanks to its physico-chemical properties and hydrophilic colloid nature, ensures that the hydrating and wetting agents remain in situ for longer, including during and after cleansing. The higher viscosity and ability to adhere to the biological substrate contribute to ensuring that it is not washed away, with lesser removal from the site of application and possibility of prolonging the local protective effect [3].

The formulation includes *Calendula officinalis* extract, which has an effective anti-inflammatory, re-epithelialising and antipruritic action [4-10] and *Salvia officinalis* extract, which has a natural antimicrobial, anti-inflammatory and antioxidant action, helping to prevent the occurrence of bacterial and/or fungal infections without interfering with the vaginal ecosystem. The antimicrobial activity is potentiated by caprylyl glycol, often used as a sebostatic and skin-purifying agent, which has proven action on Gram-positive and Gram-negative micro-organisms and yeasts, which in fact makes it an alternative preservative to traditional cosmetic preservatives [11-16]. The presence of lactic acid and microbiologically pure milk serum helps to maintain the correct physiological pH thereby fighting the development of pathogenic micro-organisms.

The study focus is to observe the answer to an innovative soft cleanser of a sample of women predisposed to develop dryness and/or irritation of genital area with the use of normal detergents. This study was aimed to evaluate the clinical activity and acceptability of this new detergent based on natural extracts in comparison with a standard treatment in women of childbearing potential who had symptoms of vaginal dryness.

Materials and Methods

The experimental design was a controlled, balanced, parallel-group study stratified by clinical condition.

The study enrolled women of childbearing potential who had symptoms of vaginal dryness, selected from among women sensitive to normal detergents and prone to dryness of the genital area or with irritation not due to infection, women who were using oral contraceptives, girls after the menarche with altered hydration of their mucosae and therefore for whom use of a hydrating feminine detergent needed to be recommended.

Subjects were randomly assigned to treatment with SH (Saugella Hydraserum/Idraserum, Rottapharm/Madaus, Patent No. 0001393777 for industrial invention) or a commercially available standard (C, control). The products were used as a normal detergent for feminine hygiene twice daily (morning and evening) for 4 weeks.

On admission, data from each individual patient's history and baseline symptoms were recorded; patients were then given the product specified by the randomisation list and a diary for the daily recording of signs and symptoms. Then, after 4 weeks, each woman re-attended for a check-up, bringing back the completed diary.

An assessment was made of vaginal pH and degree of pruritus, burning, vulvovaginal erythema and oedema, vaginal dryness and dyspareunia using a semi-quantitative score between 0 and 4, where 0=absent, 1=mild, 2=moderate, 3=intense, 4=very intense.

At the end of treatment, the doctor gave a final overall rating of the treatment (0= no effect, 1= poor effect, 2 = reasonable effect, 3 = good effect, 4 = excellent, and of the woman's overall condition compared with pre-treatment: improved, unchanged and deteriorated.

	SH	C
N	60	60
Age (yrs ± SD)	34.4 ± 10.7	30.7 ± 7.6
Ethnic group	Caucasian	Caucasian
Hypersensitive	13	19
Dryness	13	10
	16	12
Post-partum	9	10
Post-antibiotic therapy	9	9
Pruritus	1.85 ± 0.11	2.04 ± 0.16
Burning	1.96 ± 0.14	2.21 ± 0.15
Oedema	1.23 ± 0.12	1.27 ± 0.11
Erythema	1.32 ± 0.15	1.47 ± 0.12
Dryness	2.29 ± 0.15	2.42 ± 0.15
Dyspareunia	2.02 ± 0.18	1.93 ± 0.16

Table 1: Characteristics and severity of symptoms at the start of treatment in the two study groups (mean ± SE).

Statistical analysis was undertaken by analysis of variance for parametric and non-parametric data on absolute changes and the chi-square test for frequency data. The power of the study has been calculated Power of the study calculated on final percent decrease in severity score versus baseline for each symptom [17].

Results

One hundred and twenty women were treated, 60 in each treatment group, mean age (± SD) 32.6 (± 9.4) years, and more specifically 34.4 years (± 10.7) with SH and 30.7 years (± 7.6) with C. The sample was made up of women with dryness as a result of hormone deficiency (post-partum, post-antibiotic therapy) and women who were hypersensitive to normal detergents (68.3% / 31.7% in the SH group and 78.3%/21.7% in group C, respectively). The two groups were homogeneous for initial severity of the assessment parameters (Table 1).

The severity of symptoms gradually fell during the course of the 4 weeks of treatment with a statistically significant difference in favour of Saugella Hydraserum versus the control group for pruritus (SH from 1.85 ± 0.11 to 0.62 ± 0.13 vs C from 2.04 ± 0.16 to 1.26 ± 0.16, p<0.01 between treatments), burning (SH from 1.96 ± 0.14 to 0.66 ± 0.13 vs C from 2.21 ± 0.15 to 1.37 ± 0.16, p<0.05), erythema (SH from 1.32 ± 0.15 to 0.19 ± 0.04 vs C from 1.47 ± 0.12 to 0.91 ± 0.04, p<0.05), dryness (SH from 2.29 ± 0.15 to 0.95 ± 0.13 vs C from 2.42 ± 0.15 to 1.89 ± 0.14, p<0.001) and dyspareunia (SH from 2.02 ± 0.18 to 1.14 ± 0.17 vs C from 1.93 ± 0.16 to 1.58 ± 0.16, p<0.05) (Figure 1). The power of the statistical test was above 80% for all parameters.

The frequency of cases with disappearance of the symptom/sign was significantly greater for the SH group versus controls (p<0.001 for vulvovaginal dryness, p<0.01 for pruritus and burning and p<0.05 for dyspareunia, while it was borderline significant (p=0.065) for oedema) (Figure 2).

Similar to how the symptoms changed, vaginal pH fell significantly with SH compared with controls (p<0.001 difference between treatments) (Figure 3).

The doctor's overall rating was good/excellent in 86.7% of cases with SH versus 21.7% with C (p<0.001) and likewise women rated their final condition compared with before treatment as being improved overall in 90% of cases with SH and in 31.7% with C (p<0.01).

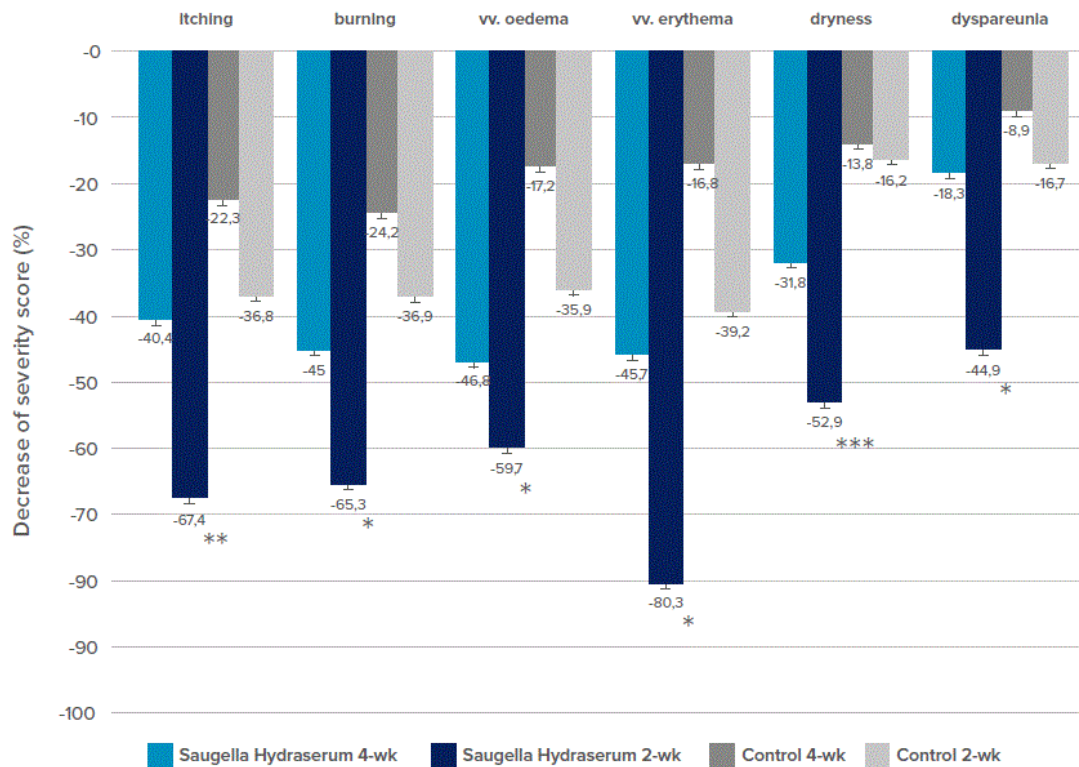


Figure 1: Decrease in symptom score severity after 2 and 4 weeks of treatment with Saugella Hydraserum and control. (Mean \pm SE; * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$ between treatments).

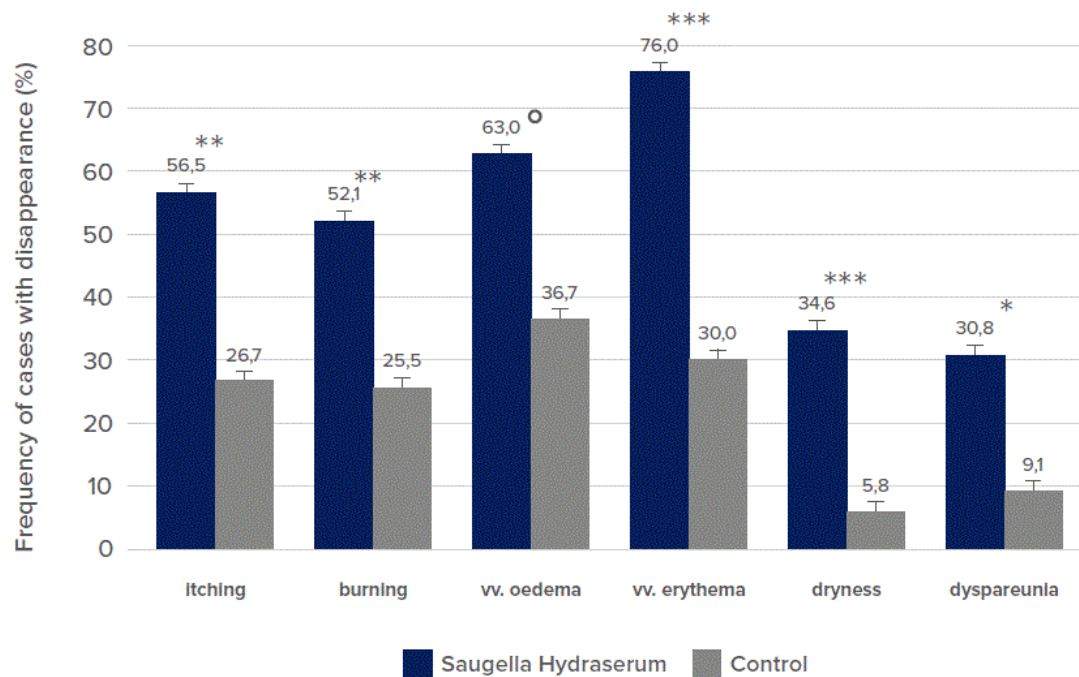


Figure 2: Rate of disappearance of signs and symptoms after 4-week treatment with Saugella Hydraserum and control. (Mean \pm SE; * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, ° $p = 0.065$ between treatments).

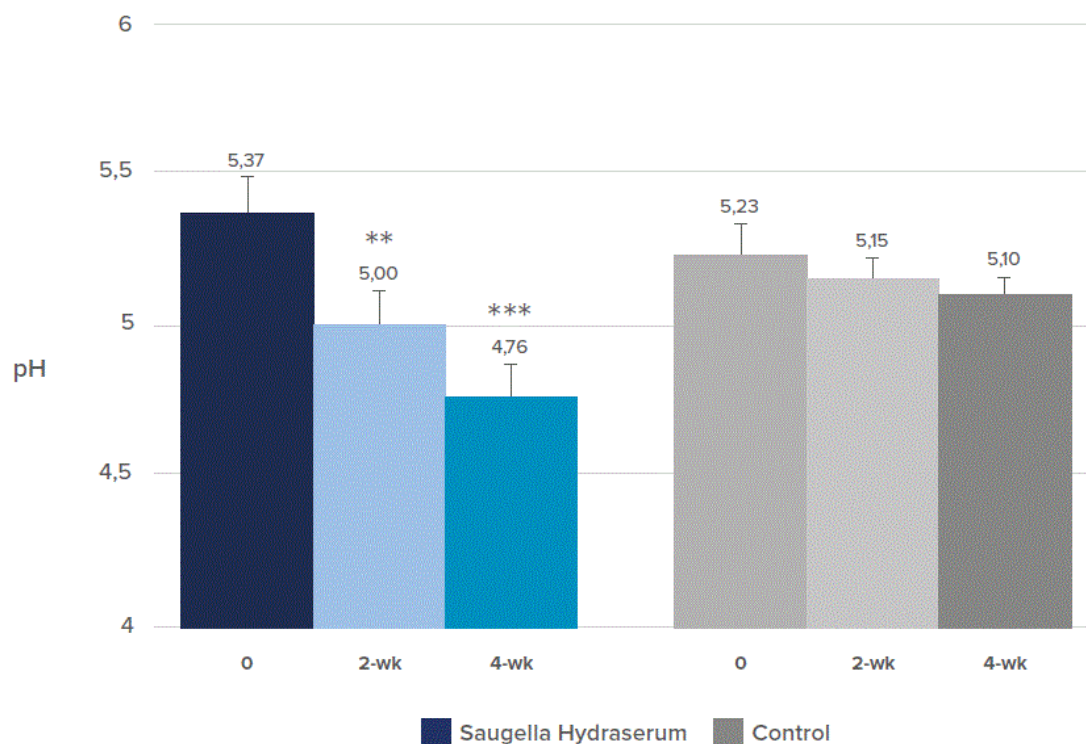


Figure 3: Vaginal pH values before and after treatment with Saugella Hydraserum and control. (Mean \pm SE; ** $p < 0.01$, *** $p < 0.001$ between treatments).

Discussion

To protect/restore the integrity of the vaginal ecosystem, it is first of all advisable to adopt a correct life style including proper nutrition (increased consumption of sugar corresponds to an increase in yeast formation), sexual activity, clothing that avoids the “vulval occlusive” effect, and proper vulvo-perineal hygiene [1].

The second step involves appropriate feminine intimate hygiene, extremely important in preventing the vulvovaginal diseases that only appear to be minor. However, the use of overly aggressive cleansers or those with an inadequate pH level (neutral or alkaline) remove the sebum layer that is essential for the protection of the vulvovaginal mucosa. This exposes the mucosa to inflammation in response to attacks that may be physical (microtraumas), chemical (soaps or other allergens), or infective (bacteria, fungi, parasites, and viruses).

Notwithstanding the wide selection of products for feminine intimate hygiene, it is well recognised today, that many problems complained by women are the result of incorrect use of feminine detergents which, given their composition, should be limited to brief periods. In actual fact, many women continue to use these products without thinking about what they contain, and then they have symptoms from this improper use. The most common conditions include vaginal dryness and consequently dyspareunia that, in part, influences the quality of these women's sex life. The trend is to have products that may be useful as individual treatments or in combination with more specific therapies with the aim of limiting the effects of vaginally administered drugs on the equilibrium of the bacterial flora and the vaginal ecosystem. Our clinical study was conducted using a detergent that had the characteristics as described above. It is worthwhile to specify that to our knowledge there are no clinical trials carried out with randomized controlled design on active cosmetics for

intimate hygiene, and the only study reported in literature adopted an open design [2].

The results of this controlled study have shown, using correct study methodology, that the use of an appropriate detergent in women with vulvovaginal dryness, or who are hypersensitive to normal detergents, results in significantly greater improvement in symptoms and vaginal pH compared with the use of a standard feminine detergent.

This specific detergent may be a good solution to the problem of daily feminine hygiene in women who are sensitive to aggressive detergents, prone to dryness of the genital area or with irritation not due to infection.

The result obtained was due to the greater hydrating potential of Saugella Hydraserum, linked to the presence of natural surfactants, which protect the skin barrier, and a complex of active substances that contribute to restoring correct hydration of the external genitals. Furthermore xanthan gum allows the detergent to remain in situ for longer, particularly the pharmacologically active substances in the *Calendula officinalis* and *Salvia officinalis* extracts, which give the product an effective anti-inflammatory and antimicrobial action that helps to prevent the occurrence of vaginal infections.

Conclusions

Saugella Hydraserum showed better clinical efficacy than normal intimate detergent on pruritus, burning, erythema, dryness, and dyspareunia in women with vulvovaginal dryness or hypersensitive to standard cleansers used in feminine care. This outcome was obtained by the combination of natural surfactants, offering skin protection, and a complex of active substances, aimed both at normal hydration of the external genitalia and prevention of microbial contamination.

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