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CLINICAL EFFECTIVENESS OF A SPECIAL SILK TEXTILE IN THE TREATMENT OF RECURRENT PEDIATRIC INFLAMMATORY VULVITIS: AN OPEN LABEL PILOT STUDY

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Clinical effectiveness of a special silk textile in the treatment of recurrent pediatric inflammatory vulvitis: an open label pilot study

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Aim. **Pediatric inflammatory vulvitis (PIV) is clinically characterized by itching, soreness and inflammation and can be due to both an infective process and a non-specific irritative process, especially in atopic patients. Sometimes these non-specific PIVs, that tend to be recurrent, can be overinfected, with exacerbation of the clinical features. The importance of the cleansers, emollients, and the kind of textiles that enter in direct contact all day long with the inflamed skin, is well known. The study objective is the evaluation of the safety and efficacy of the transpiring, slightly elastic knitted silk briefs, with anti-bacterial and non-irritating properties, registered as Dermasilk®, in recurrent PIV.**

Methods. **The study we conducted was a prospective cohort study of 12 pre-pubertal girls, aged between 2 and 10 years, affected by recurrent PIV, that used Dermasilk® briefs in association to conventional treatments.**

Results. **Dermasilk® briefs have proven to be an effective and safe adjuvant product available for use in association with conventional drugs for the treatment of recurrent PIV.**

Conclusion. **Dermasilk® briefs play an important role in the management of the flares of recurrent PIV, proven by an earlier resolution of symptoms, as well as in the maintenance of the remission and in the prevention of overinfections.**

KEY WORDS: Vulvitis - Child - Silk.

Genital diseases are not as common in young girls as in women, and therefore represent only a small percentage of dermatological consultations. Pediatric inflammatory vulvitis (PIV), the most frequent gynecological problem in prepubertal girls, is clinically characterized by itching, soreness and inflammation, sometimes with discharge, that may be so severe as to interfere with daily activities. Excluding foreign bodies and sexual abuse, many cases of PIV are due to pathogens that are usually involved in infections of the upper respiratory tract such as *Haemophylus influenzae, Streptococcus pyogenes* and *Staphylococcus aureus.*[1, 2] Therefore, a previous infection of the upper respiratory tract that occurred some weeks or months before, frequently represents the main predisposing condition for the development of PIV.[1] However, in some cases, the condition is only a non-specific irritative process,[2, 3] usually not sustained by an infection and with no pathogens isolated, occurring especially in atopic girls. These non specific PIV may be due to poor hygiene, irritant soaps or shampoos, and tight clothing,[2] even though a superinfection, caused by itching, can sometimes exacerbate the clinical features.[1, 4]

These non-specific PIV are typically recurrent and, even if the treatment of the overinfection is appropriate, the symptoms may take a long time to resolve and tend to recur during the follow-up, frequently without complete remission between relapses. Specific treatment mostly depends on the results of microbiological examinations and is based on topical or

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systemic drugs, but the importance of the cleansers, emollients, and the kind of textiles that come into direct contact with the inflamed skin throughout the day, is well known, especially for the non-specific PIV,[5-7] and should be carefully considered. So the choice of appropriate cleansers and suitable fabrics such as cotton briefs is usually recommended.

Materials and methods

Since 2004, in our Dermatological Unit, a new type of silk textile clothing has been recommended to patients suffering from atopic dermatitis. This transpiring and slightly elastic knitted silk, registered as Dermasilk®, has non-irritating properties thanks to its sericin-free composition and is specially designed to avoid skin irritations and allergies that are usually caused by the sericin proteins contained in classic silk textiles. Furthermore, Dermasilk® has antibacterial properties thanks to an exclusive water-resistant treatment with AEM 5772/5 (3-trimethylsilypropyl-dimethyloctadecyl ammonium chloride), also called AEGIS™ (AEGIS Environments, Laboratory and Technical Services, Midland, MI, USA), a durable antimicrobial finish for textile products that prevents smell and odour formations and bacteria survival, including *Staphylococcus aureus*. This AEM 5772/5 antibacterial treatment has already been utilized in the USA in many commercial products. Our patients affected by atopic dermatitis referred a substantial relief in symptoms both during the flares and also in the maintenance periods thanks to the use of these medical grade silk clothes and in the literature many studies confirm these results.[8-15]

The aim of the study, started one year ago, was to determine the clinical effectiveness and the safety of Dermasilk® briefs, in association with the conventional therapy, in pediatric patients suffering from recurrent PIV.

The study we conducted was a prospective cohort study of 12 prepubertal girls, aged between 2 and 10 years, mean age 5.75 years, affected by recurrent PIV. Inclusion criteria were the prepubertal age and the diagnosis of recurrent PIV, defined as recurrent when symptoms persisted more than three months with at least three episodes of acute PIV, alternated with complete or partial remission. In the latter case the young girls presented some acute episodes and, in the pause between flares, some residual low-grade symptoms, such as minor discharge or mild itching or soreness. Exclusion criteria were the following: a diagnosis of *Lichen sclerosus et atrophicus*; immunosuppression, diabetes or insulin-resistance.

We performed a survey directed both at the patients affected by recurrent PIV and at the parents if the patients were too young to answer.

At the baseline visit all patients complained of a history of at least three relapses of PIV during the last three months and at physical examination showed vulvitis characterized by erythema, edema and sometimes fissurations associated with burning and itching. As part of the atopy assessment, all patients and parents were asked whether they had a personal or family history positive for atopy.

Only in cases where a positive personal or family history was present and the investigators suspected an allergic pathogenesis on the basis of the clinical evaluation, a dosage of total IgE, (PRIST), RAST (radio allegro sorbent test) and a skin PRICK test, for immediate type 1 hypersensitivity, were requested. Microbiological investigations were performed before starting the treatment: a standardized cutaneous vulvar swab culture for bacteria and fungi was made.

Results

The main data for our cases are summarized in Table I.

Seven out of the 12 patients had family history positive for atopy. Total IgE was normal in all cases. RAST was positive in one case for egg white. PRICK tests were positive for oat grass, composite and cat hair, in one patient, and positive for oat grass, kiwi and pollen in another.

On the basis of the results of the vulvar swabs, we divided our patients into two groups: the first, including eight patients, characterized by the absence of any isolated micro-organism or the presence of a mixed bacterial growth, and the second, including four patients, with positivity for *Streptococcus pyogenes group A* (1 case), *Streptococcus pyogenes group A* and *Staphylococcus aureus,* (1 case) *Heamophylus influenzae* (1 case) and *Candida albicans* (1 case).

If the microbiological examinations showed the absence of any pathogens, the treatment consisted of washing with an aqueous cream or an emulsifying ointment. On the contrary, if a proven infection was documented by positive results of microbiological

TABLE I.—*Patients' characteristics.*

Patient N.	Age (years)	Symptoms	Family and personal history positive for atopy	RAST	PRICK test	Positivities found by vulvar swabs
1	10	Itching	Present	Negative	Negative	*Candida albicans*
2	7	Itching	Present	Negative	Negative	*Haemophilus influentiae*
3	5	Soreness	absent			*Streptococcus pyogenes group A* Mixed bacterial growth
4	6	Itching	Present	Egg white	Negative	*Staphilococcus aureus*
5	6	Itching	Present	Negative	Negative	*Streptococcus pyogenes group A* and *Staphilococcus aureus*
6	6	Itching	Absent			Mixed bacterial growth
7	5	Soreness Itching	Absent			Negative
8	4	Itching	Present	Negative	Oat grass, kiwi and pollen	Negative
9	8	Itching Soreness	Absent			Negative
10	4	Itching Soreness	Absent			Negative
11	2	Itching	Present	Negative	Negative	Negative
12	6	Itching	Present	Negative	Oat grass, composite and cat hair	Negative

examinations, an appropriate antibiotic or antifungal treatment was prescribed. Patients were treated with topical mupirocine ointment, twice a day for 10-14 days in cases of bacterial infections and with topical econazole cream, twice daily for two weeks in the case of Candida infection. The most inflamed cases of PIV were treated with topical application of mild-potency steroids for 5-7 days in association with aqueous cream or emulsifying ointment.

In addition to the specific treatment mentioned above, all patients received three pairs of Dermasilk® briefs; six different sizes were available to suit the dimension of the pelvis. All patients were volunteers and informed consent was obtained from the parents who were instructed on the use and management of the textile. The briefs needed to be changed daily and washed with shampoo as indicated by the producer. The parents were informed about the importance of daily use of the silk products instead of their own briefs in order to obtain an objective improvement.

The number of episodes of flare pre-treatment and post-treatment with Dermasilk® briefs was compared by applying the χ^2 test, as appropriate. A P value of 0.01 was considered significant.

After 30 days, during the second examination, all the patients suffering from recurrent episodes of PIV reported a significant improvement of symptoms (both soreness and itching) and physical examination revealed a decrease in erythema and inflammation. At the final consultation, three months after the beginning of the study, in 11 out of 12 patients the lesions had totally cleared and no relapse had occurred. The total number of episodes of PIV of the 12 patients passed from a 60 to 3 ($P<0.001$). No local adverse reactions to Dermasilk® briefs were reported.

At the end of the study, six months after the second visit, all parents were contacted by phone and asked to answer a questionnaire to obtain more details about possible relapses and the use of Dermasilk® briefs. None of the 12 parents referred relapses of PIV during the last three months, confirming that the decrease of the flares of PIV was statistically significant, and all parents expressed their intention to continue the daily use of the silk products instead of their own briefs made of other fabrics.

Discussion and conclusions

Our results show that two vulvar swabs were positive for *Streptococcus pyogenes group A* and one for *Heamophilus influenzae*, which are the most frequent pathogens isolated also in the other studies in the literature.[1, 3, 4] Although these two pathogens were successfully treated in these two patients, we cannot demonstrate a causative relationship between *Streptococcus pyogenes group A, Staphylococcus aureus, Heamophylus influenzae* and *Candida albicans*, and

previous episodes of PIV, because during these past episodes patients had not been referred to us for consultation and vulvar swabs had not been performed. *Candida albicans* is a rare finding in vulvar swabs of pediatric patients, as confirmed by the literature data [2, 4] and may be considered both pathogenetic or simply a contaminant. Microbiological investigations should, in fact, always be requested in patients suffering from recurrent PIV, but we suppose that an overinfection may be observed only in a few of the recurrent episodes and in these patients the bacteria or *Candida albicans* may cause an exacerbation of inflammatory vulvitis but are not the causative agent. Probably, as in AD, some flares are overinfected and others not.

On the basis of our data, excellent results were obtained in both groups of patients suffering from recurrent PIV, with and without infections, thanks to the use of Dermasilk® briefs, with statistically significant results in term of reduction of the flares.

Dermasilk® briefs represent an effective and safe adjuvant product available for use in association with conventional drugs for the treatment of recurrent PIV. In patients affected by vulvitis due to an infection, this kind of underwear may contribute to the early resolution of symptoms and also help prevent relapses thanks to its anti-microbial and anti-irritant properties. Moreover, Dermasilk® briefs demonstrated to play an important role in the management of the flares of recurrent PIV, proven by an earlier resolution of symptoms, as well as in the maintenance of the remission and in the prevention of overinfections. In fact, the eradication alone of the infection does not always completely resolve PIV or prevent recurrences.

Riassunto

Efficacia clinica di uno speciale tessuto in seta per il trattamento della vulvite infiammatoria ricorrente in età pediatrica: studio di coorte prospettico

Obiettivo. La vulvite infiammatoria in età pediatrica (VIP) è clinicamente caratterizzata da prurito, bruciore e infiammazione e può essere dovuta sia a processi infettivi sia a processi irritativi aspecifici, soprattutto in pazienti atopici. Talvolta la VIP, che tende ad essere ricorrente, può presentare una sovrainfezione, con esacerbazione dei segni e dei sintomi. L'importanza dei detergenti, degli emollienti e del tipo di tessuto che entra in diretto contatto durante la giornata con la cute infiammata è ben nota. L'obiettivo del nostro studio è la valutazione della sicurezza e dell'efficacia dell'impiego di slip di seta traspiranti ed elastici, con proprietà antibatteriche e non irritanti, registrati in commercio con il nome di Dermasilk®, nella VIP ricorrente.

Metodi. Abbiamo condotto uno studio di coorte prospettico in 12 adolescenti in età prepuberale, di età compresa tra 2 e 10 anni e affette da VIP ricorrente, che hanno utilizzato degli slip Dermasilk® in associazione ai trattamenti convenzionali.

Risultati. Gli slip Dermasilk® si sono dimostrati efficaci e sicuri come trattamento adiuvante ai farmaci convenzionali impiegati nel trattamento della VIP ricorrente.

Conclusioni. Gli slip Dermasilk® hanno giocato un ruolo importante nella gestione delle riacutizzazioni della VIP ricorrente, come dimostrato da una rapida risoluzione dei sintomi, dal mantenimento della remissione e dalla prevenzione di eventuali sovrainfezioni.

Parole chiave: Vulvite - Età pediatrica - Seta.

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