

Dermasilk Briefs in Vulvar Lichen Sclerosus: An Adjuvant Tool

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■ Abstract

Objective. The purpose of our study was to evaluate whether briefs made of Dermasilk fabric could be an adjuvant tool in the management of vulvar lichen sclerosus (LS).

Materials and Methods. A controlled, randomized, double-blind study versus placebo was conducted, comparing Dermasilk versus standard cotton briefs in patients affected by LS during treatment with clobetasol propionate 0.05% ointment and vitamin E moisturizer. For each patient, an evaluation of objective genital signs and subjective symptoms typical of LS was recorded before the start of treatment, after 1 month, and after 6 months of the study. Statistical analysis was performed with SPSS 17.0 for Windows.

Results. Forty-two women affected by LS were recruited and divided into those wearing Dermasilk or cotton briefs. Patients wearing Dermasilk briefs showed a better improvement in the clinical symptoms of burning sensation, skin irritation, and pain (Fisher test, $p < .0001$) compared with the cotton placebo group. The improvement in itching was also faster in the Dermasilk group (Fisher exact test, $p < .05$). Erythema also showed a better improvement in the Dermasilk group (Fisher test, $p < 0.05$).

Conclusions. Dermasilk fabric seems to be a useful adjunct to topical treatment in producing a better and more rapid control of symptoms in patients with LS. ■

Key Words: lichen sclerosus, vulvar, Dermasilk

Vulvar lichen sclerosus (LS) is an inflammatory disease with a chronic relapsing course. The characteristic symptoms, such as vulvar itching and soreness,

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Alpretec, producer of Dermasilk briefs, provided materials required to perform the study.

will frequently adversely affect the quality of life of affected women. Lichen sclerosus, if not treated, may result in permanent scarring, and it is considered a risk factor for vulvar cancer. Its pathogenesis is complex and still not completely understood. A genetic susceptibility, demonstrated by its association with other autoimmune diseases and a frequently positive family history, seems to be present. Sexual hormones, infection, and local trauma could play a role as trigger factors [1–3].

Topical steroids are considered the best treatment of acute flares and maintenance, with complete symptom control reported in 66% to 100% of patients and total remission of clinical signs in 23% to 54% of cases in long-term follow-up studies [4–6]. Some authors have recommended the addition of a topical moisturizer during treatment and as maintenance therapy. In non-responding patients, calcineurin inhibitors [7] and photodynamic therapy [8] have been used with good results. Surgical treatment is indicated for scarring complications [1, 2].

Local trauma and irritation have been reported as aggravating factors of LS, and consequently, clinicians often recommend that patients avoid tight clothes and synthetic underwear. We have hypothesized that the use of a specialist underwear could be helpful in the management of LS.

We decided to evaluate the safety and efficacy of underwear made of Dermasilk fabric (Alpretec, San Donà di Piave, Venice, Italy), a fine-knitted silk fabric made of 100% pure sericin-free fibroin, impregnated with a nonmigrating antimicrobial protection, in patients affected by LS.

A controlled, randomized, double-blind study versus placebo was conducted, comparing Dermasilk versus standardized cotton briefs in patients affected by LS during treatment with clobetasol propionate 0.05%

ointment and vitamin E moisturizer. The purpose of the study was to investigate any difference in signs and symptoms of LS between the 2 groups during a period of 6 months.

PATIENTS AND METHODS

Forty-two women, older than 18 years, affected by LS and attending the dermatological section of our department were recruited. Diagnosis of LS was based on clinical observation of typical signs on the vulvar and perianal mucosa (see Table 1). When the clinical diagnosis was uncertain, a biopsy specimen was taken for histology. None of the patients had been treated with hormone replacement therapy, and none of the patients were affected by genital carcinomas or other dermatological diseases. This study was approved by the ethics committee of the University of Bologna. Informed consent was obtained appropriately from each patient and control.

A 2-week period of washout from any previous treatment was required before starting the study. All the enrolled patients were treated with clobetasol propionate 0.05% ointment and a standard moisturizer containing vitamin E. Patients were advised to apply half a fingertip unit (0.25 g) of clobetasol propionate 0.05% ointment every night and the same dose of moisturizer every morning for 6 months.

Table 1. Prevalence of Signs and Symptoms in the Whole Sample

	All patients (N = 42)	
	At baseline	After 6 mo
Symptoms		
Burning sensation	42 (100)	30 (71.43)
Dryness	42 (100)	39 (92.86)
Soreness	42 (100)	17 (40.48)
Dyspareunia	36 (85.71)	25 (59.52)
Itching	27 (64.29)	4 (9.52)
Urinary problems	24 (57.14)	19 (45.24)
Constipation	1 (2.38)	0 (0)
Clinical signs		
Erythema	42 (100)	28 (66.67)
Atrophy	39 (92.86)	36 (85.71)
Fissures	35 (83.33)	3 (7.14)
Whitening	24 (57.14)	15 (35.71)
Vaginal stenosis	19 (45.24)	19 (45.24)
Telangiectasia	18 (42.86)	15 (35.71)
Erosions	15 (35.71)	0 (0)
Purpura	5 (11.90)	3 (7.14)
Hyperpigmentation	3 (7.14)	3 (7.14)
Bleeding	3 (7.14)	0 (0)

The whole sample is considered (*n* [%]), and the prevalence of signs and symptoms observed in all the patients at baseline and after 6 months is reported. Each sign and symptom is considered as present or absent; severity scores are not considered (*p* values with McNemar χ^2 test).

In addition, a sealed, numbered, and anonymous envelope was given to each patient. Half of the patients received an envelope containing 3 pairs of briefs made of white cotton (CT group), the other half received an envelope with 3 pairs of briefs made of Dermasilk fabric (DS group).

For each patient, an evaluation of subjective symptoms and objective genital signs, identified as typical of LS in previous studies [5], was recorded before the start of treatment, after 1 month, and after 6 months of the study. Both signs and symptoms were evaluated according to an increasing severity score from 0 to 3, in which 0 means absent, 1 means mild, 2 means moderate, and 3 means severe.

Statistical analysis was performed with SPSS 17.0 for Windows (IBM SPSS, Armonk, NY). A type 1 error was accepted at $p < .05$. Nonparametric statistics were performed to summarize data. Pearson χ^2 or Fisher test was performed to compare the effect of Dermasilk and cotton briefs. Mann-Whitney *U* test was performed to compare measures.

RESULTS

Forty-two women affected by LS, aged from 22 to 79 years (median age = 51.5 y, interquartile range [IQR] = 38–67 y), were enrolled in this study. The diagnosis of LS was based on clinical observation of the typical signs. In 32 patients, it was confirmed or had been previously confirmed on histology. Symptoms and/or signs suggestive of LS were reported by patients from 6 months to 12 years before consultation (mean duration = 2.8 y). Many patients had already been treated with different regimens based on topical steroids but without stable results.

No statistically significant difference was found between the patient's age in the 2 groups: median age of the DS group was 49 years (IQR = 34–67 y), whereas median age of the CT group was 53 years (IQR = 44–67 y).

Table 1 shows the prevalence of each symptom and sign in all patients. No statistically significant differences were detected at the beginning of the study between the 2 groups of patients regarding the presence of these symptoms and signs. There were a numerically greater number of patients in the DS group experiencing erosions.

Symptoms

Symptomatic relief in soreness and itching was observed in both groups (McNemar χ^2 , $p < .0001$; see Table 1). Although only 1 patient (2.4%) was completely symptom free at the end of the study, 37 (88.1%) reported a

Table 2. Prevalence of Signs and Symptoms in DS and CT Group

	Comparison of groups						
	Baseline		After 1 mo		After 6 mo		
	DS group (n = 21)	CT group (n = 21)	DS group (n = 21)	CT group (n = 21)	DS group (n = 21)	CT group (n = 21)	
Symptoms							
Burning sensation	21	21	20	21	9	<i>p</i> < .0001	21
Dryness	21	21	21	21	18		21
Soreness	21	21	19	20	0	<i>p</i> < .0001	17
Dyspareunia	20	16	20	16	9		16
Itching	13	14	4	12	0	<i>p</i> < .05	4
Urinary problems	13	11	12	11	8		11
Constipation	1	0	1	0	0		0
Clinical signs							
Erythema	21	21	20	20	9	<i>p</i> < .05	19
Atrophy	20	19	20	18	18		18
Fissures	19	16	8	10	0		3
Whitening	14	10	14	10	5		10
Vaginal stenosis	10	9	10	9	10		9
Telangiectasia	8	10	8	9	6		9
Erosions	11	4	1	1	0		0
Purpura	3	2	1	2	1		2
Hyperpigmentation	1	2	1	2	1		2
Bleeding	1	2	0	0	0		0

The sample is divided into DS and CT groups, and the number of patients presenting each sign and symptom is reported at baseline, after 1 month, and after 6 months in the 2 groups; each sign and symptom is considered as present or absent, severity scores are not considered (*p* values with fisher exact).

good response and 4 (9.5%) reported a poor response (all from the CT group; see Table 3). There was no significant improvement in dryness and urinary symptoms.

Comparing the 2 groups, burning sensation and soreness showed a statistically significant improvement in the DS group (Fisher test, *p* < .0001; see Table 2). The improvement in itching was faster in the DS group with a significantly greater reduction in itching after 1 month (Fisher exact test, *p* < .05; see Table 2). There was a numerically greater reduction in dyspareunia in the DS group, although this did not reach statistical significance (see Table 2).

Clinical Signs

Fissures and erosions were the 2 clinical signs that showed most improvement across both groups of patients.

Table 3. Overall Results at the End of the Study

	All patients, N = 42	DS group, n = 21	CT group, n = 21
Symptoms			
Complete response	1	1	0
Good/partial response	37	20	17
Poor response	4	0	4
Clinical signs			
Complete response	2	2	0
Good/partial response	31	19	12
Poor response	9	0	9

Complete response is defined as an absence of every symptom or sign; poor response is lack of appreciable improvement versus baseline (none or minimal improvement in the severity score).

The prevalence of fissures was significantly diminished (McNemar χ^2 , *p* < .0001; see Table 1). Two DS patients (4.8%) gained a complete clinical remission of disease, 31 (73.8%) achieved a good but partial response, and 9 CT patients (21.4%) a poor response (see Table 3).

Comparing the 2 groups, erythema showed a significantly better improvement in the DS group (Fisher test, *p* < .05; see Table 2), and there was a numerically greater improvement in whitening in the DS group (see Table 2).

Symptoms and Signs Severity Scores

Comparison of the severity scores of symptoms and signs between the 2 groups shows that severity of itching, burning sensation, and fissures have a trend in favor

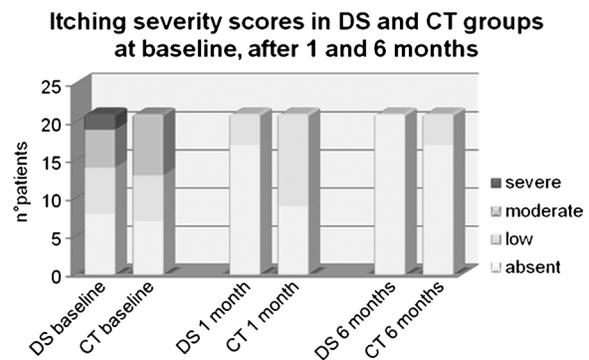


Figure 1. Itching severity scores (according to an increasing severity score from 0 to 3, in which 0 means absent and 3 means severe) in the 2 groups at baseline, after 1 month, and after 6 months.

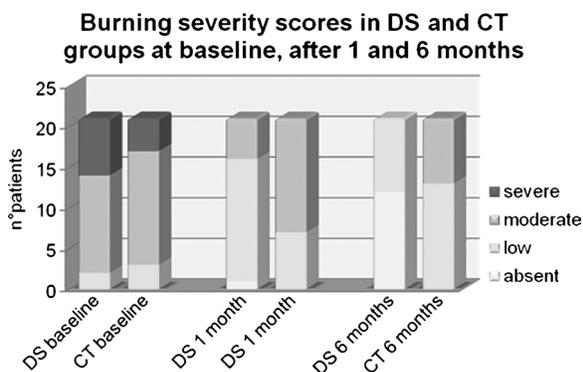


Figure 2. Burning severity scores (according to an increasing severity score from 0 to 3, in which 0 means absent and 3 means severe) in the 2 groups at baseline, after 1 month, and after 6 months.

of the DS group both in overall improvement in score and the speed of reduction at month 1 (see Figures 1–3).

Compliance and Adverse Effects

All patients confirmed that they had applied the ointments and used the underwear assigned as prescribed. None of the patients complained of treatment adverse effects. Four patients, 3 of whom were in the CT group, developed concomitant *Candida* vulvovaginitis that resolved with oral antimicrobics. None of the patients developed squamous cell carcinoma during the study.

DISCUSSION

Vulvar LS is a chronic inflammatory disease that may cause severe scar changes and increase the risk of developing vulvar squamous cell carcinoma. Long-term treatment with high-potency topical steroids is nowadays considered the most effective in preventing disease progression.

External irritation and trauma can be major aggravating factors to the lifestyle of the patient. In our study, we aimed to evaluate the use of Dermasilk briefs in the management of LS. Dermasilk combines the properties of knitted pure silk fibroin, such as softness, high breathability, hygroscopic, and heat-regulating properties, with an antimicrobial agent (AEM 5772/5), and is able to restore the skin barrier function, altered by inflammation, irritation, and infections. The antimicrobial substance that protects Dermasilk has no contraindications or undesired effects because it is fixed permanently on the fiber by covalent bonding and is not released from the fabric, even as a result of machine washing. Moreover, it does not alter the composition of the normal bacterial flora and does not create

microbial resistance [9–11]. Dermasilk is a patented fabric, clinically tested and classified as a class 1 medical device.

Most of the clinical trials concerning Dermasilk underwear have been conducted on children affected by atopic dermatitis with good reduction of signs and symptoms [12–16], and it has recently been included in the European Academy of Dermatovenereology guidelines for atopic dermatitis [17].

In our study, we followed up 42 women affected by LS using conventional treatment with clobetasol propionate 0.05% ointment at night and moisturizer containing vitamin E in the morning for 6 months. At the end of the study, 1 patient reported complete symptoms control and 37 reported a partial but considerable improvement. Considering clinical signs, 2 patients gained complete healing and 31 reported a significant response.

Patients of the DS group reported statistically significant better improvement of burning sensation and soreness, thereby providing a greater impact on quality of life. The improvement of these symptoms may contribute to the diminished prevalence of dyspareunia in patients of DS group, which, although it did not reach statistical significance, is an important goal for women with LS. Patients in the DS group reported a faster response to treatment with a lower severity score of itching and burning sensation after 1 month of treatment compared with those in the CT group. A better trend in DS group was obtained especially for erythema and fissures.

The complete healing rate in our study is lower than reported elsewhere [4–6], probably because we observed our patients for only 6 months, whereas other studies are

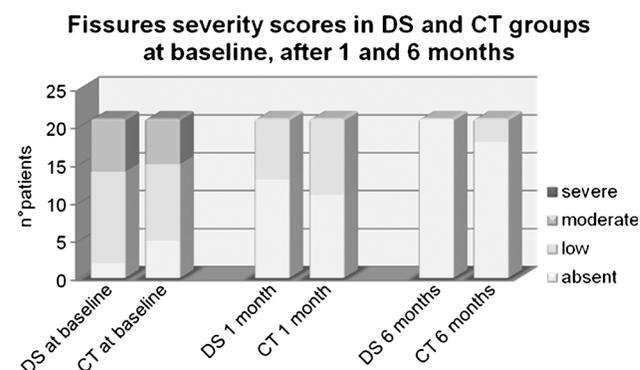


Figure 3. Fissures severity scores (according to an increasing severity score from 0 to 3, in which 0 means absent and 3 means severe) in the 2 groups at baseline, after 1 month, and after 6 months.

often based on longer surveillance times. In addition, many women in our sample were affected by long-standing LS.

The purpose of this study was to evaluate whether the addition of Dermasilk underwear could help the disappearance or the improvement of signs or symptoms of LS, making the treatment of the disease more rapid and efficient. In this study, Dermasilk fabric seemed to be a useful adjunct to topical treatment in producing a better and more rapid control of symptoms in patients with LS. Dermasilk works by minimizing skin and mucosal irritation often induced by other fabrics made of rougher fibers and by maintaining a stable water balance and temperature thanks to its hygroscopic and heat-regulating properties. It is these properties that qualify it to be considered a suitable adjunct in the management of LS.

We appreciate that our study has its limitations. In particular, it is difficult to conceal from the patients if they are using briefs made of silk or of cotton, but they were not aware of the exact composition of their briefs compared with those used in the other arm of the study, so potential bias was minimized.

This study provides evidence that Dermasilk briefs seem to be helpful in relieving the severity of symptoms quickly in patients affected by LS undergoing topical treatment with clobetasol propionate 0.05% ointment and vitamin E moisturizer. Long-term follow-up to investigate whether Dermasilk briefs could have a role in preventing relapses of the disease would be of interest in future studies.

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Use of Dermasilk briefs in recurrent vulvovaginal candidosis: safety and effectiveness

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Summary

Despite the generally excellent results achieved with fluconazole 150 mg weekly in recurrent vulvovaginal candidosis (RVVC), some patients with a long history of disease do not achieve complete resolution of symptoms following antimycotic treatment. It is thought that use of tight synthetic fabric underwear could be a significant factor in causing recurrence. We decided to compare underwear made of Dermasilk[®], a pure fibroin fabric impregnated with a permanent antimicrobial protection, with a cotton placebo to see whether it could be a useful adjunctive tool in the management of RVVC. We recruited 96 women who had a long-term history of RVVC and had not responded to oral antimycotics with complete satisfaction. The patients were randomly divided into two groups and instructed to use either white cotton placebo briefs or Dermasilk[®] briefs. Both groups were treated with fluconazole 150 mg once weekly for 6 months. After 6 months, the Dermasilk group showed a statistically significant greater decrease of itching, burning, erythema and a smaller number of recurrences than the cotton group. Our work suggests that Dermasilk[®] briefs could be a useful adjunctive tool in addition to antimycotic treatment to help relieve the discomfort of recurrent vulvovaginitis.

Key words: Recurrent vulvovaginal candidosis, Dermasilk, antimicrobial textile.

Introduction

Recurrent vulvovaginal candidosis (RVVC), defined as four or more episodes of *Candida* vaginitis in 1 year, affects about 5–8% of adult women.¹ According to the literature, the most effective treatment of RVVC is oral fluconazole 150 mg weekly for at least 6 months during which no recurrences occur in about 90% of cases.² Despite the excellent results achieved with fluconazole, it has been our experience that there is a small, but clinically significant cohort of patients with a long history of RVVC who, despite antimycotic treatment, suffer from persistent symptomatology and may require additional treatments.³

The pathogenesis of vulvovaginal candidosis (VVC) is complex and influenced by many factors.¹ One of the proposed predisposing factors is the popular use of tight synthetic fabric briefs that may help create a favourable environment for *Candida* germination by increasing dampness around the vulvar area.^{4,5} We therefore decided to investigate the comparative influence of two different types of briefs in the long-term management of RVVC. We compared the effect of standard cotton placebo underwear with underwear made of Dermasilk[®] (Alpretec Srl, San Donà di Piave, Venice, Italy) in a group of women suffering from RVVC during treatment with an oral antimycotic. Dermasilk[®] is a pure silk fibroin fabric impregnated with a permanent antimicrobial protection agent (AEM 5772/5) that has been shown to be useful as an adjunct in the treatment of atopic dermatitis^{6–8} and vulval lichen sclerosis.

Subjects and methods

In this 6 months study, we recruited women older than 18 years, attending a Centre for Sexually Transmitted

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Diseases with a history of long-term RVVC (from 1 to 6 years, mean time 2.4 years). All patients had a past history of treatment with weekly oral fluconazole for a period of at least 6 months during which they had continued to experience vulvar irritation that failed to resolve. In addition, many of these patients had also been treated with topical antimycotics, *Lactobacillus* vaginal tablets, topical boric acid and homeopathy without success. Patients affected by the following conditions were not eligible to participate in the study: pregnancy, diabetes mellitus, HIV seropositivity, vulvar dermatological diseases, lichen sclerosus, current use of oral contraceptives and oral antibiotics and oral or topical antimycotic agents during the previous 4 weeks.

At the time of recruitment, eligible patients presented with an episode of acute VVC, a positive culture from vaginal discharge for *Candida* and a vaginitis severity score ≥ 3 as described by Sobel *et al.* [9]. This severity scoring system evaluates symptoms (itching, irritation and burning) and signs (erythema, oedema and excoriations or fissures). The severity of each sign and symptom was scored on a scale of 0 (absent) to 3 (severe). In each patient, bacterial vaginosis was excluded by pH measurement and Gram stain microscopy. The isolation of *Candida* and the identification of the species were obtained by cultures on chromogenic agar (CHROMagar *Candida*, Vacutest Kima, Padova, Italy)¹⁰; when CHROMagar did not allow certain identification of the species, an automated yeast biochemical identification system was used (Vitek card, BioMérieux, Marcy-l'Etoile, France).¹¹

Women who entered the study were treated with fluconazole 150 mg weekly for 6 months. In addition, a sealed anonymous envelope containing either three pairs of white Dermasilk briefs or three pairs of white cotton briefs, was given to each patient. The study was double-blinded and each envelope containing briefs was identified by a progressive number; correspondence between the envelope number and its content was revealed by the producer of briefs only at the end of the study. Patients were asked to wear only these briefs, day and night for the 6 months duration of the study. During the follow-up visits, after 1, 3 and 6 months, cultural examination for *Candida* and scoring of symptoms and signs were repeated. A severity score ≥ 3 with positive culture was considered a recurrence. Considering every single symptom and sign, a lower score at follow-up visit was evaluated as an improvement, a higher score as a worsening.

Statistical analysis was performed with SPSS 17 and Stata 10 for Windows. Data were expressed as ordinal variables, and so they were summarised as prevalence

and frequency; Fisher exact test and Pearson chi square were used to highlight differences between the groups.

Results

One hundred patients with recurrent VVC were recruited, but four were lost during follow-up, and so 96 women completed the study. Ages ranged from 18 to 52 years (median age 30.25). Yeast cultures revealed *Candida albicans* in 82 patients, *Candida glabrata* in 11 and *Candida parapsilosis* in three patients. The patients were randomly divided into two groups: Dermasilk® briefs were given to 48 patients (DS group), whereas cotton briefs were given to the other 48 women (CT group).

No statistically significant difference was found between the age of the two groups: median age of the DS group was 32 years (IQR: 25–39.5 years), whereas that of the CT group was 28.5 years (IQR: 25–37.5 years). Mean duration of recurrent VVC and incidence of symptoms and signs did not statistically differ between the two groups, even though burning and dyspareunia were slightly more frequent in the DS group. No patients reported side effects in either arm of the study.

Both arms of the study showed similar reductions of symptoms and signs within the first month of the study, but after 3 months there appeared to be a divergence developing in favour of the DS group with regard to itching, burning and erythema.

At the 6-month time point, the patients in the DS group showed a significantly greater decrease of itching and erythema (Fisher exact test $P < 0.0001$) and burning (Fisher exact test $P < 0.05$) than the CT patients as shown in Table 1.

Severity scores of symptoms and signs recorded during the follow-up visits showed an improvement after 1 month, whereas after 3 and 6 months, some symptoms and signs worsened, more frequently in CT group (data not shown). A statistically significant different trend between the two groups was gained at the end of the study for erythema with 25/48 (52.08%) patients in DS group, but only 7/48 (14.58%) in CT group showing an improvement in erythema between the 3rd and the 6th month (Pearson Chi square = 16.392; $P < 0.0001$) (Fig. 1).

Eleven of the 48 (22.91%) patients in the DS group did not report any recurrences during the study compared with only four of the 48 (8.3%) patients of the CT group. (Fisher exact test $P = 0.036$). Most patients in the DS group (32/48, 66.7%) had no or one recurrence, whereas in the CT group, most (29/48,

Table 1 Prevalence (in number) of vulvovaginal symptoms and signs in DS (patients wearing Dermasilk® briefs) and CT (patients wearing white cotton briefs) groups at the different checks; severity scores were not considered in this table, all symptoms and signs being considered only as present or absent (Fisher exact test * $P < 0.05$; ** $P < 0.01$, *** $P < 0.0001$).

	Baseline		After 1 month		After 3 months		After 6 months	
	DS	CT	DS	CT	DS	CT	DS	CT
Symptoms								
Itching	48	48	39	42	20	30	6***	28
Burning	38	29	19	19	5	8	1*	8
Skin irritation	42**	28	11	13	3	6	0 $P = 0.056$	5
Clinical signs								
Erythema	48	48	43	44	29	35	6***	38
Oedema	43	39	17	19	1	3	1	3
Excoriations/fissures	23	11	6	6	1	0	0	0

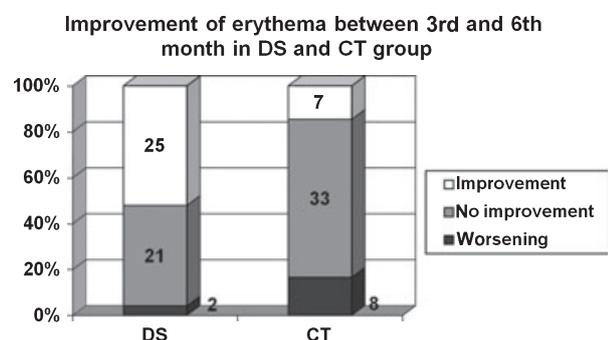


Figure 1 Improvement of erythema at 6 months in DS (patients wearing Dermasilk® briefs) and CT (patients wearing white cotton briefs) groups, calculated on the difference of severity scores between 3rd and 6th month. During the last 3 months of the study, erythema continues to improve in DS group, whereas it remains stable or worsens in CT group.

60.5%) had two or more recurrences (Table 2). Results of mycological cultures are summarised in Table 3. Culture was positive for *C. glabrata* in four women of DS group and seven of CT group; *C. parapsilosis* was found in two women of DS group and one of CT group. In both groups, patients positive for these species were more prone to recurrences.

Discussion

Despite its benign nature, RVVC represents a frequent cause for medical consultation and a significant reduc-

Table 2 Number of patients of DS (patients wearing Dermasilk® briefs) and CT (patients wearing white cotton briefs) groups that developed no, one, two or three recurrences during the whole study (Fisher exact test $P = 0.036^*$).

Recurrences	DS (48 patients)	CT (48 patients)	All patients (96p)
No recurrences	11*	4	15
One recurrence	21	15	36
Two recurrences	14	20	34
Three recurrences	2	9	11

Table 3 Positive results of mycological cultures at baseline, after 1, 3 and 6 months.

	At baseline	After 1 month	After 3 months	After 6 months
<i>Candida albicans</i> (n)	82	47	33	21
<i>Candida glabrata</i> (n)	11	9	10	11
<i>Candida parapsilosis</i> (n)	3	1	3	2
Positive cultures (n)	96	57	46	34

tion in quality of life of the affected women. Usually treatment with fluconazole 150 mg weekly for 6 months is well tolerated and efficacious, but often VVC recurs once therapy is stopped and clear guidelines about the length of treatment are not available. In addition, some patients do not obtain a complete therapeutic and symptomatic resolution during treatment. Several explanations of this phenomenon have been hypothesised. *Candida albicans* seems to develop diminished fluconazole sensitivity after prolonged exposure.^{12,13} Also, other *Candida* species are frequently resistant to fluconazole.^{14,15} The receptivity to yeast of vaginal epithelial cells may be increased by expression of polymorphism of mannose-binding lectine gene, thus making some patients more prone to develop candidosis.¹⁶ Finally, some patients with recurrent VVC seem to develop a vaginal allergic immune response against *Candida*, with the production of *Candida*-specific IgE that impairs T cell immune response and cytokine secretion. This acquired immune defect may alter the integrity of the mucosa and its barrier function, and consequently prolong chronic vaginal symptoms.¹⁷

Although antimycotic therapy is the treatment of first choice, patients with these complicating features may require additional therapeutic measures including advice on appropriate underwear. In the past, doctors have instinctively tended to advise patients to wear cotton underwear because cotton is a natural soft fabric, but there is no clinical evidence to support this practice. Dermasilk® is a high technology fine-knitted natural

fabric made of 100% pure fibroin (medical grade sericin-free silk) impregnated with a non-migrating permanent antimicrobial protection (AEM 5772/5). Its physical properties suggest it could be an ideal fabric for use in RVVC. The removal of sericin minimises the possibility of any contact allergic reaction, and it has extremely low frictional properties due to its long, smooth cylindrical filaments. The protein structure of fibroin is similar to the stratum corneum of the human skin, so that Dermasilk[®] is able to absorb a high percentage of moisture without becoming damp, maintaining a stable heat and humidity balance next to the skin and constant skin temperature.

The antimicrobial AEM 5772/5 (3-trihydroxysilyl propyldimethyloctadecyl ammonium chloride) is a quaternary ammonium compound that is bonded permanently to the fabric and cannot be washed or worn off. This compound kills microorganisms that come into contact with it by puncturing the cell wall and inducing a mechanical cellular lysis. It is not released from the fabric and so does not migrate onto the skin to alter local resident flora, unlike other antimicrobial finishes. AEM5772/5 has been extensively used in hospitals for over three decades and in DermaSilk for nearly 10 years, and has been shown not to irritate human tissues.

Dermasilk[®] has been demonstrated to be significantly more effective than cotton in the management of atopic dermatitis.^{6–8} *In vitro* studies of this textile have demonstrated a significant decrease in *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *C. albicans*.¹⁸ A study conducted in atopic eczema patients over 28 days demonstrated the benefits of Dermasilk vs. identical silk minus the antimicrobial finish.¹⁹ These features have led to the inclusion of Dermasilk fabric into European guidelines for the management of atopic dermatitis.²⁰

The aim of our study was to investigate if Dermasilk[®] underwear may be a useful adjuvant tool in the management of RVVC that had not been completely resolved by antimycotic treatment. In our study, we followed up 96 women affected by recurrent VVC for 6 months; 48 patients used cotton briefs and 48 Dermasilk[®] briefs, in addition to a systemic treatment with fluconazole 150 mg weekly. Strict adherence to wearing briefs assigned during the study was reported in all patients, as they were long-term suffering from VVC and so highly motivated to seek a solution to their problem. All patients showed an improvement after the first month of treatment compared with the previous 4 weeks of wash out. However, signs and symptoms tended to worsen subsequently, also during fluconazole therapy, with a higher statistical frequency in the group

using cotton briefs compared with the Dermasilk group. In fact, at the last follow-up visit, after 6 months, patients using Dermasilk[®] briefs maintained better results compared with women using cotton briefs, with regard to itching, burning and erythema.

The use of Dermasilk[®] briefs seemed to reduce the number of recurrences during antimycotic treatment compared with cotton briefs. The incidence of recurrences in our study is higher than in other reports²¹, but it must be noted that our patients suffered from a particularly persistent form of RVVC and had experienced a high number of VVC episodes during the previous year that had been already treated with long-term antimycotic treatment. Moreover, 11 of our patients had mycological examination positive for *C. glabrata* and three for *C. parapsilosis*; in the literature, these species are often reported to be resistant to a low dose of fluconazole, as also evidenced by the results of our study.

We believe that Dermasilk[®] briefs are helpful in recurrent VVC as a result of the fundamental properties of the fabric. First, the silk fibroin fabric is significantly better than cotton at removing excess moisture and maintaining stable water balance and temperature control, thereby denying the yeast a damp environment for proliferation. Secondly, the AEM 5772/5 antimicrobial finish has demonstrated *in vitro* the ability to decrease *Candida* contamination of the fabric. It does not migrate from the fabric to the skin, and so it does not alter local microbiota such as *Lactobacillus* spp. Finally, Dermasilk[®] decreases external sources of vulvar irritation, thanks to its smooth fibres, and does not exacerbate the immuno-mediated inflammatory processes already present in many women with recurrent VVC, in line with the theory of vaginal allergic immune response against *Candida*.

We appreciate that our study has limitations. The sample consists of women affected by long-term RVVC with a high number of active episodes every year and an incomplete remission after antimycotic treatment. This fact makes it difficult to undertake a comparison with other data in the literature. We are unable to specifically separate the improvement due to the use of fluconazole from that due to the use of specific underwear, but as both sets of patients followed the same fluconazole regime, it is logical to link any variation in outcome with the choice of briefs.

In conclusion, we believe that advice on appropriate underwear could benefit patients suffering from RVVC. This study shows that Dermasilk[®] briefs are safe and comfortable underwear for women suffering from RVVC and appear to provide greater benefit than cotton. They

can contribute to the control of vulvovaginal symptoms by diminishing external sources of irritation, managing local humidity and helping restore skin barrier function. Our data suggest that Dermasilk® briefs could be a useful and safe adjunctive to antimycotic treatment, free of side effects, in patients with persistent and recurrent vulvovaginitis.

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

A. PATRIZI, F. GIACOMINI, C. GURIOLI, I. NERI



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E D I Z I O N I M I N E R V A M E D I C A

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

A. PATRIZI, F. GIACOMINI, C. GURIOLI, I. NERI

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 Dermalilk®, 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 Dermalilk® briefs in association to conventional treatments.

Results. Dermalilk® 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. Dermalilk® 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

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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 *Haemophilus 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

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 Dermalilk[®], 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, Dermalilk[®] has antibacterial properties thanks to an exclusive water-resistant treatment with AEM 5772/5 (3-trimethylsilylpropyl-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 Dermalilk[®] 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) *Haemophilus 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	<i>Candida albicans</i>
2	7	Itching	Present	Negative	Negative	<i>Haemophilus influenzae</i>
3	5	Soreness	absent			<i>Streptococcus pyogenes group A</i> Mixed bacterial growth
4	6	Itching	Present	Egg white	Negative	<i>Staphylococcus aureus</i>
5	6	Itching	Present	Negative	Negative	<i>Streptococcus pyogenes group A</i> and <i>Staphylococcus aureus</i>
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 Dermsilk® 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 Dermsilk® 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 Dermsilk® 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 Dermsilk® 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 *Haemophilus 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*, *Haemophilus 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 specifici, 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.

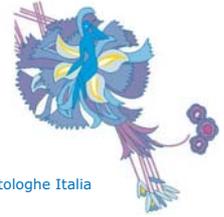
Parole chiave: Vulvite - Età pediatrica - Seta.

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TERAPIA ALTERNATIVA DI PATOLOGIE VULVARI RECIDIVANTI

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A cura di:
Donne Dermatologhe Italia

INTRODUZIONE

Numerosi processi patologici di natura infettiva, infiammatoria e neoplastica possono colpire la regione genitale e perineale femminile, che risultano spesso una unità indissociabile. Sono infatti strutture colpite frequentemente da infezioni batteriche e micotiche, talvolta ricorrenti soprattutto in pazienti con fattori predisponenti (es. diabete). Inoltre essendo coinvolte nella funzione sessuale, sono esposte a malattie a trasmissione sessuale. Nelle patologie di natura infiammatoria rientrano sia dermatosi che hanno la regione vulvare come organo privilegiato (es. lichen sclerosus) sia dermatosi che possono coinvolgere altre aree cutanee (es. psoriasi, dermatite seborroica, dermatite allergica e irritativa da contatto, lichen planus). Non va dimenticato che spesso la regione vulvare è sede di processi di somatizzazione (vulvodinia). La sintomatologia soggettiva di queste patologie è rappresentata dal prurito e bruciore, che per la persistenza e recidivanza anche dopo la sospensione della terapia influiscono notevolmente sulla qualità della vita delle donne, generando disagio psico-sociale e notevole senso di frustrazione.

MATERIALI E METODI

Nel periodo Gennaio-Aprile 2006 alcune Dermatologhe, appartenenti all'Associazione Donne Dermatologhe Italia, hanno selezionato un gruppo di pazienti affette da patologie vulvari ricorrenti di varia natura al fine di valutare l'effetto adiuvante e/o terapeutico dell'utilizzo di slip in seta, privi di sericina, tipo DermaSilk® con AEM 5772/5 (www.alpretec.com).

Il protocollo dello studio prevedeva:

- Visita dermatologica iniziale con raccolta di breve e mirata anamnesi ed esame obiettivo della regione genitale e perineale (tamponi cutanei ad inizio e fine trattamento, se indicato);
- Utilizzo esclusivo per 10 giorni di slip in seta consegnati insieme alle istruzioni di lavaggio;
- Compilazione quotidiana da parte della paziente di un diario di autovalutazione sull'evoluzione dei sintomi e sulla gradevolezza dello slip;
- Divieto di utilizzo di alcun tipo di medicamento topico;
- Ripetizione della valutazione dermatologica il 3° e 10° giorno di utilizzo degli slip in seta.

DISCUSSIONE

Visti i buoni risultati ottenuti utilizzando gli indumenti in seta in pazienti con dermatite atopica, si è effettuata una valutazione sui vantaggi dell'utilizzo di slip in seta DermaSilk® in pazienti con patologie vulvari recidivanti di varia origine e non trattate contemporaneamente con nessuna terapia topica specifica. A tale scopo sono state selezionate 32 pazienti tra i 16 e i 79 anni (età media 45 anni) che presentavano differenti quadri morbosi genito-perineali, in molti casi persistenti e già trattati con medicinali topici di vario tipo con benefici temporanei (tabella 1).

La valutazione clinica, effettuata dalle Dermatologhe alle scadenze fissate dal protocollo, presenta nel complesso un significativo miglioramento dei segni sia obiettivi che soggettivi (tabella 2).

In particolare il principale disturbo delle patologie vulvari rappresentato dal prurito, testimoniato dalla presenza delle lesioni da grattamento, si è notevolmente ridotto. Tale andamento viene confermato anche dai dati ricavati dalle schede di autovalutazione delle pazienti (tabella 3). La risposta delle varie patologie trattate è sostanzialmente equivalente. Si nota infatti una progressiva riduzione del punteggio attribuito ai segni e ai sintomi con un andamento parallelo soprattutto per quanto riguarda prurito vulvare sine materia, candidosi recidivanti, dermatiti irritative e lichen sclerosus (tabella 4). La possibilità di provare un trattamento alternativo per problemi spesso recidivanti ha favorito la buona adesione a questo studio, che nel complesso, ha fornito risultati soddisfacenti che permettono di indicare l'utilizzo degli slip in seta DermaSilk® come possibile terapia adiuvante per patologie spesso croniche ed invalidanti.

Tabella 1

Patologie trattate

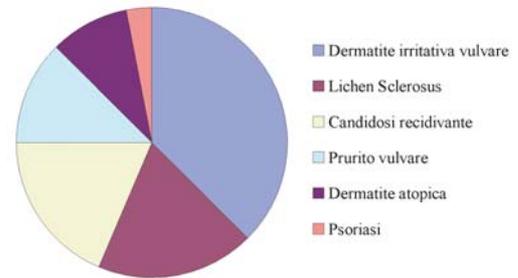


Tabella 2

Valutazione della Dermatologa

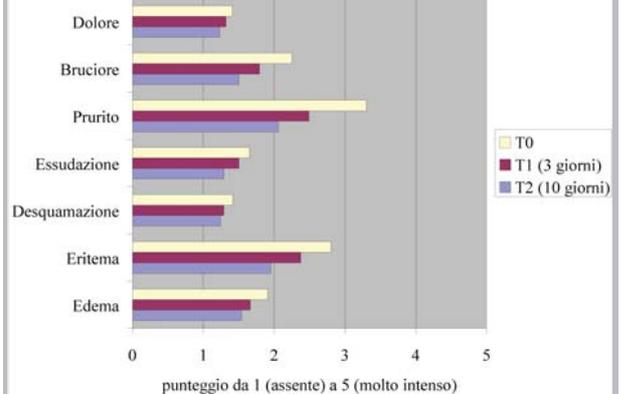


Tabella 3

Valutazione della paziente

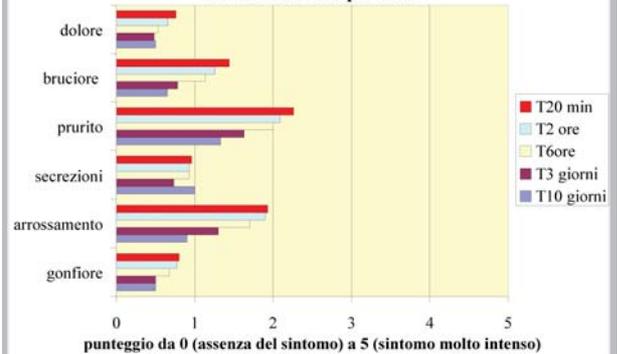
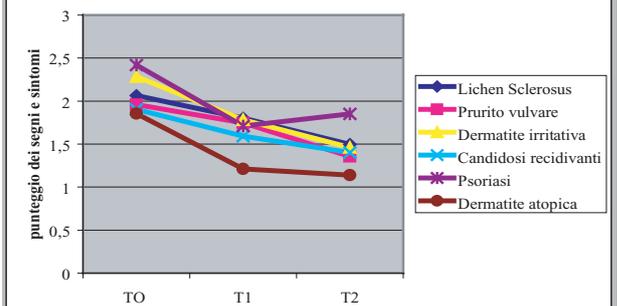


Tabella 4

Andamento delle patologie



Poster presentato per la prima volta all'81° Congresso Nazionale SIdEMaST, Torino, 31 maggio - 3 giugno 2006.

ALTERNATIVE THERAPY OF RECURRENT VULVAR PATHOLOGIES

We thank Doctors P. Betto, A. Barba (Verona), A. Belloni Fortina (Padua), M. Bertazzoni (Vicenza), A. Cantù (Milan), M. De Carli (Treviso), A. Di Landro (Bergamo), L. Germi (Vicenza), C. Rigoni (Milan), D. Schena (Verona), R. Strumia (Ferrara).

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INTRODUCTION

Numerous pathological processes of an infective, inflammatory and neoplastic nature can strike the female genital and perineal region, which are often inseparably linked.

These structures are frequently affected by bacterial and mycotic infections, at times recurrent, especially in patients with predisposing factors (e.g. diabetes). Moreover, as they are involved in the sexual function, they are exposed to sexually transmitted diseases.

The inflammatory pathologies include both dermatoses located prevalently in the vulvar region (e.g. lichen sclerosus) and dermatoses involving other areas of the skin (e.g. psoriasis, seborrhoeic dermatitis, allergic and irritative contact dermatitis, lichen planus). It must not be forgotten that the vulvar region often hosts somatization processes (vulvodynia).

The subjective symptoms of these pathologies consist in itching and burning which, due to their persistence and recurrence even after suspending therapy, have a considerable influence on the quality of life of the women affected, causing psycho-social uneasiness and a notable sense of frustration.

MATERIALS AND METHODS

In the period January-April 2006 a number of members of the Italian Association of Women Dermatologists selected a group of patients suffering from recurrent vulvar pathologies of various kinds in order to assess the adjuvant and/or therapeutic effect of using silk briefs, sericin free, of the type DermaSilk® with AEM 5772/5 (www.alpretec.com).

The study protocol contemplated:

- Initial dermatological examination collecting a brief and specific anamnesis and objective examination of the genital and perineal region (skin swabs at start and end of treatment, if indicated);
- Exclusive use for 10 days of silk briefs provided along with washing instructions;
- Daily compiling of a diary by the patient with her own assessment of the evolution of the symptoms and of the agreeableness of the briefs;
- The use of any kind of topical medication was forbidden;
- Repetition of the dermatological assessment on the 3rd and 10th day of using the silk briefs.

DISCUSSION

Considering the good results obtained using silk garments in patients with atopic dermatitis, an evaluation was made of the advantages of using DermaSilk® silk briefs in patients with recurrent vulvar pathologies of various origin and not treated at the same time with any kind of specific topical therapy. For this purpose 32 patients were selected, between 16 and 79 years of age (mean age 45 years) who presented different genito-perineal pathologies, in many cases persistent and already treated with various types of topical medications obtaining temporary benefits (table 1).

The clinical evaluation, carried out by the Dermatologists at the intervals established by the protocol, presents on the whole a significant improvement of both the objective and the subjective signs (table 2).

In particular, the main disturbance in vulvar pathologies, i.e. itching, demonstrated by the presence of scratching lesions, was notably reduced. This trend is also confirmed by the data obtained from the patients' self-assessment charts (table 3). The response of the various pathologies treated is substantially the same. A gradual reduction is noted in the score attributed to the signs and symptoms, with a parallel trend above all for vulvar pruritus sine materia, recurrent thrush, irritative dermatitis and lichen sclerosus (table 4). The possibility of trying an alternative treatment for often recurring problems encouraged good collaboration in this study, which on the whole provided satisfactory results that indicate the use of DermaSilk® silk briefs as a possible adjuvant therapy for frequently chronic and invalidating pathologies.