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DERMASILK® BRIEFS IN RECURRENT VULVOVAGINAL CANDIDOSIS. AN ALTERNATIVE OPTION IN LONG-LASTING DISEASE

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Dermasilk® briefs in recurrent vulvovaginal candidosis. An alternative option in long-lasting disease

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Aim. Recurrent vulvovaginal candidosis (RVVC) can be a long-lasting disease; some patients refuse one of the most used treatment based on the assumption of oral fluconazole and resort to self-medication, risking poor control of symptoms and the development of local side effects. The aim of the study is to compare underwear made of Dermasilk®, a pure fibroin fabric bonded with a permanent antimicrobial protection, with cotton placebo briefs to see whether it would be a useful tool in the management of RVVC in patients not receiving oral or topical antimycotic treatment.

Methods. A double-blind, randomized study was carried out on 30 women who had a long-term history of RVVC with mild to moderate symptoms. The patients were randomly divided into two groups and instructed to use either white cotton placebo briefs (CT group) or Dermasilk® briefs (DS group) for 6 months.

Results. All vulvovaginal symptoms and signs showed a statistically significant improvement in the DS group compared with the CT group (P<0.001) at the follow-up visits after 3 and 6 months. The number of flares of vulvovaginal symptoms was significantly lower in the DS group compared to the CT group (24 episodes versus 68 episodes during the 6-month study, P<0.001).

Conclusion. In the absence of both topical and oral antimycotics, Dermasilk® briefs appear to be a useful tool, in reducing the signs and symptoms and the episodes of vulvovaginal discomfort in patients suffering from RVVC.

KEY WORDS: Candidiasis, vulvovaginal - Therapeutics - Textile.

Vulvovaginal candidosis (VVC) is one of the most frequent genital disturbances and many women will experience recurrent episodes during part of their lifetime, more often in their childbearing years. Recurrent VVC (RVVC), usually defined as four or more recurrences per year including at least one confirmed by microbiological culture, severely affects the quality of life of these women, both in terms of their daily activities and in their emotional and sexual behavior.[1] Moreover, RVVC has been identified as an important trigger for chronic inflammation due to the development of a hypersensitivity response to Candida species with consequent local hyperinnervation. In rare cases, probably when other predisposing factors are associated, this mechanism may promote the development of chronic pain, or vulvodynia.[2, 3]

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The first choice treatment of RVVC is oral fluconazole, administered in various doses and regimens.[4] Despite the low incidence of side effects and contraindications, some women prefer not to take oral drugs for extended periods or they may have already used systemic antimycotic drugs without achieving the expected benefits. As a result, many of these patients resort to self-medication with topical cream and vaginal pessaries, following advertising exposure or recommendations from acquaintances. This can result in poor therapeutic outcomes and in the development of local side effects, such as irritant or allergic contact dermatitis [5] and secondary superinfections.[6] In addition, cases of fluconazole resistance probably due to long-term usage have been reported in the literature.[7, 8]

In order to offer an alternative option also to patients with RVVC disinclined to take systemic antimycotic drugs, we designed a clinical trial comparing the exclusive use of white cotton briefs with the exclusive use of briefs made of Dermasilk®, a pure silk fibroin fabric impregnated with a permanent antimicrobial protection agent (AEM 5772/5), which has been shown to be useful as an adjuvant tool during the treatment of RVVC with oral fluconazole.[9]

Materials and methods

We recruited women, older than 18 years but not yet in menopause, who were attending our Centre for Sexually Transmitted Diseases and had a history of long term RVVC. All patients had declined treatment with oral antimycotic drugs, some because they had already received them in the past and some because they feared the side effects. A characteristic of this group of patients was the frequent occurrence of vulvovaginal symptoms (often monthly), but a mild or moderate severity of the symptoms. Many of these women, driven to attend our Centre to find a solution for their discomfort, resorted to self-medication with different kinds of topical antiseptics and anesthetics when the symptoms flared. Some patients reported a worsening of symptoms induced by the use of some topical therapies, probably due to an irritant contact dermatitis.

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 two weeks.

At the time of recruitment, eligible patients presented with an episode of vulvovaginal discomfort, attested by a vaginitis severity score > 3, and a culture from vaginal discharge positive for Candida species. The severity score is derived from the presence of symptoms (itching, burning and dyspareunia) and signs (erythema, oedema, leukorrhea and excoriations/fissures). The severity of each sign and symptom was scored on a scale from 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 participating in the study received a sealed anonymous envelope containing either three pairs of white Dermasilk® briefs or 3 pairs of white cotton placebo briefs. The study was double-blinded and each envelope containing briefs was identified by a progressive number. The matching between the envelope number and its content was determined by the producer of briefs using a simple randomization system and it was only revealed to the medical staff at the end of the study. Patients were asked to exclusively wear these briefs, day and night, for the 6 months duration of the study. They were instructed to wash the briefs by hand with a mild shampoo of their choice, using water at 30 or 40 °C. Furthermore, the

patients were asked not to apply topical creams or vaginal pessaries and to wash the area after defaecation and not more than twice a day, with a mild cleanser which was free of perfume and preserving agents.

During the follow-up visits, after 3 and 6 months, cultural examination for Candida species and scoring of symptoms and signs were repeated. A severity score > 3 with positive culture was considered a recurrence. At every follow-up visit, patients were also interviewed about symptoms and the presence of vaginal discharge during the 3 months between the current and the previous visit. Each significant flare of clinical symptoms remembered by the patients was registered and added to the recurrences confirmed by a positive culture.

The primary aim of the study was to evaluate whether the use of Dermasilk® briefs alone was able to improve vulvovaginal symptoms and signs in RVVC; the secondary aim was to assess the effect on the number of exacerbation of symptoms.

The study was approved by the Ethics Committee of the Sant'Orsola-Malpighi Hospital, Bologna.

Statistical analysis

Statistical analysis was performed with R statistical software for Windows. The comparison between the group of patients wearing Dermasilk® and the group wearing white cotton briefs was based on non-parametric statistical tests. The Mann-Whitney test (otherwise known as Wilcoxon rank-sum test) was used to highlight differences between the groups. The Wilcoxon signed-rank test was used to perform a pair-wise comparison of the paired records across the different time periods of each group of patients.

Results

Thirty women aged between 20 and 50 years (median age 31.7) were recruited. Yeast cultures revealed *C. albicans* in all patients at the time of recruitment; the same species of Candida was isolated also in swabs positive for yeast during the follow-up visits. The subjects were randomly divided into two groups: 15 women wore Dermasilk® briefs (DS group) and 15 white cotton placebo briefs (CT group). All patients completed the study. The median age was 32.9 years in DS group and 30.6 in the CT group; prevalence of symptoms and signs did not show any statistically significant difference between the two groups, even though itching and erythema were described as slightly more severe in the DS group. Also the number of flares of symptoms during the 6 months preceding the study was similar between the DS and CT groups. All patients reported between 3 and 6 episodes of vulvar discomfort, the mode value being 3; each patient tested positive for vaginal Candida during at least one of these episodes.

At the follow-up visits after 3 and 6 months, all symptoms and signs showed a statistically significant improvement in the DS group in comparison with the CT group ($P<0.001$), the only exception being with excoriations/fissures which were seen so rarely in both groups at the time of recruitment as to make statistical comparison impractical. In particular, the majority of patients in the DS group were free from symptoms (itching, burning sensation, dyspareunia) after 3 months and at the end of the study, and showed only mild clinical signs of erythema and leukorrhea. The clinical signs and symptoms improved also in the CT group throughout the study, but the majority of patients still complained of mild symptoms and exhibited mild or moderate clinical signs at the 2 follow-up visits (Tables I, II, Figures 1, 2). The number of referred flares of symptoms during the study was significantly lower in the DS group compared to the CT group (24 episodes versus 68 episodes, $P<0.001$) (Table III, Figure 3).

Regarding the improvement of the variables in each group between one control visit and the next, patients in the DS group reported a statistically significant improvement of all symptoms and signs (itching, burning

TABLE I.—*Presence of each vulvovaginal symptom and its severity score in the patients of CT and DS group at recruitment and after 3 and 6 months; U of Mann-Whitney test indicates a statistically significant difference between the presence and severity of each symptom at every visit in the CT and DS group with P<0.0001.*

Symptoms of CT group									
Severity score	Itching			Burning sensation			Dyspareunia		
	T0	T3	T6	T0	T3	T6	T0	T3	T6
0			1	2	3	7	4	6	7
1	12	14	12	13	12	8	11	9	8
2	3	1	2						
3									
Symptoms of DS group									
Severity score	Itching			Burning sensation			Dyspareunia		
	T0	T3	T6	T0	T3	T6	T0	T3	T6
0		12	13	1	13	15	1	13	15
1	7	3	2	11	2		12	2	
2	8			3			2		
3									
U of Mann-Whitney test	75.0	201.0 ***	204.5 ***	85.5	187.5 ***	172.5 ***	79.0	165.0 ***	172.5 ***
Mann-Whitney test ***P<0.001; **P<0.05; *P<0.01									

TABLE II.—*Presence of each vulvovaginal sign and its severity score in the patients of CT and DS group at the recruitment and after 3 and 6 months; U of Mann-Whitney test indicates a statistically significant difference between the presence and severity of each sign at every visit in CT and DS group with P<0.001.*

Clinical signs of CT group												
Severity score	Erythema			Oedema			Excoriations/fissures			Leukorrhea		
	T0	T3	T6	T0	T3	T6	T0	T3	T6	T0	T3	T6
0				3	5	6	13	13	15			
1	9	11	15	11	10	9	2	2		4	8	10
2	6	4		1						11	7	5
3												
Clinical signs of DS group												
Severity score	Erythema			Oedema			Excoriations/fissures			Leukorrhea		
	T0	T3	T6	T0	T3	T6	T0	T3	T6	T0	T3	T6
0		7	10	2	15	15	13	15	15		8	9
1	5	8	5	12			2			4	7	6
2	10			1						11		
3												
U of Mann-Whitney test	82.5	181.0 ***	187.5 ***	105.5	197.5 ***	180.0 ***	112.5	127.5 *	112.5	112.5	197.0 ***	195.0 ***
Mann-Whitney test ***P<0.001; **P<0.05; *P<0.01												

sensation, dyspareunia, erythema, oedema, leukorrhea, P<0.001) evaluated during the first 3 months of the study. No further significant improvement was observed between T3 and T6 because the majority of symptoms had already disappeared at time T3. By contrast, patients of the CT group showed no statistically significant improvement between T0 and T3, a statistically significant improvement being recorded between T3 and T6 only for burning sensation and erythema (P<0.05) and between T0 and T6 only for erythema and leukorrhea (P<0.001) (Wilcoxon signed-rank test, data not shown).

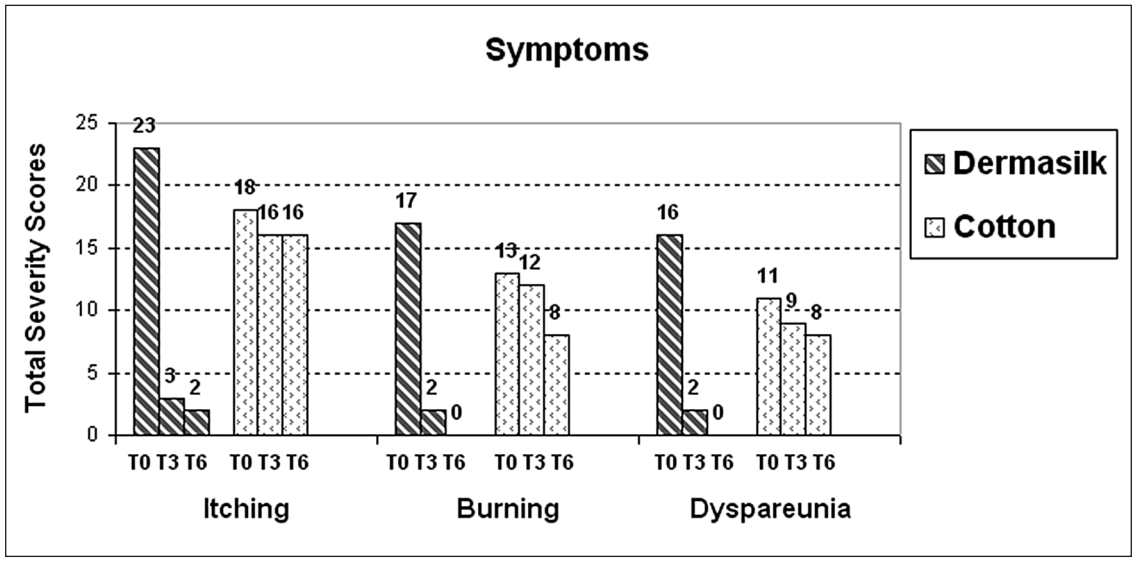

Figure 1.—Total severity score (the sum of severity scores regarding a specific symptom for all patients in the group considered) for each symptom registered at time 0, 3 and 6 for the DS and CT group.

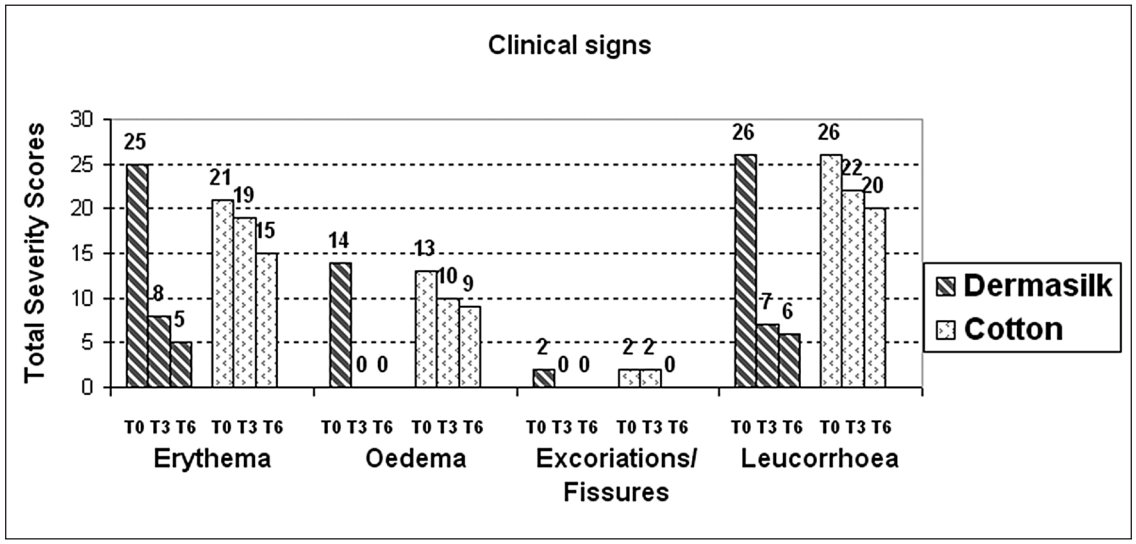

Figure 2.—Total severity score (the sum of severity scores regarding a specific clinical sign for all patients in the group considered) for each clinical sign registered at time 0, 3 and 6 for the DS and CT group.

The number of flares, including real recurrences and merely clinical flares, reported during the 6 months preceding the study and during the 6-month study demonstrated significant differences between the two groups. A statistically significant reduction of relapses of vulvar symptoms was registered only in the DS group, in which 9 of 15 (60%) patients reported only one or no episodes during the 6-month study, while the total incidence of vulvar discomfort even increased slightly in the CT group (Table III).

No patients asked for additional supplies of garments, indicating that they remained serviceable for the duration of the study.

TABLE III.—*Number of flares of vulvar discomfort in the 6 months before the study and during the study, for CT and DS group. U of Mann-Whitney test shows a statistically significant difference between the number of flares in CT and DS group during the 6-month study, but not before. S of Wilcoxon signed-rank test shows that during the 6-month study the number of flares diminished in a significant way only in the DS group.*

	CT group		*S* of Wilcoxon signed-rank test
N° flares	T0 (flares in the previous 6 months)	T0-T6 (flares during the 6-month study)	
0			
1			
2			
3	7	2	
4	4	8	
5	3		
6	1	5	
Total n° of flares	58	68	15 P=0.978
	DS group		*S* of Wilcoxon signed-rank test
N° flares	T0 (flares in the previous 6 months)	T0-T6 (flares during the 6-month study)	
0		2	
1		7	
2		3	
3	6	1	
4	5	2	
5	3		
6	1		
Total n° of flares	59	24	120 P<0.001
U of Mann-Whitney test	107.0 P=0.604	205.0 P<0.001	

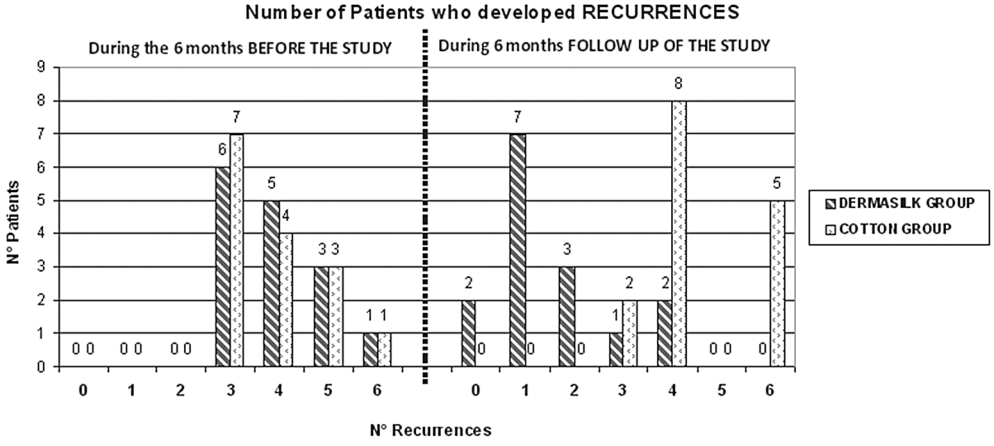

Figure 3.—On the left: the number of flares of vulvovaginal symptoms during the 6 months preceding the study is similar between the two groups. On the right: a significant reduction in the number of flares was registered in the DS group, while the total number of relapses during the study even increased slightly in the CT group.

Discussion

RVVC affects around 5-8% of women of childbearing age, worsening their quality of life and couple relationships. Women suffering from RVVC usually have a long history of medical consultations and treatment, sometimes successful, sometimes less

so. In recent times, a reduced susceptibility of *C. albicans* to fluconazole has been noted, probably linked to the widespread use of fluconazole as long-term treatment for RVVC.[7, 8]

It may happen that patients lose confidence and give up medical treatment, resorting to self-medication. Random and repeated use of topical creams rarely leads to a good control of symptoms and increases the risk of side effects such as irritant or allergic contact dermatitis. Some papers report that women who constantly treat chronic vulvar itching with topical treatments, present a high rate of relevant positive patch test reactions to some ingredients, such as preservatives, fragrance and antiseptics.[12, 13]

Susceptibility to RVVC is due to several factors. First of all, the expression of polymorphism of mannose-binding lectine gene may increase the receptivity of the vaginal epithelium to yeast, making some patients more prone to develop candidosis.[14] Recently, the development of new technologies has led to the discovery of genetic mutations that seem to predispose to Candida infection, such as the deficiency of dectine-1, a receptor that recognizes the β-glucans present on the yeast cell wall, or an impaired Th17 response.[15] Moreover, considering the intrinsic properties of the microorganism, *C. albicans* seems able to cause contact allergy especially at low concentrations. It is thought that C. albicans at low concentration can stimulate the toll-like receptor 2 with consequent upregulation of IL10 and CD4+CD25+ T-cells, resulting in suppression of the immune response to Candida species.[2]

RVVC may also be promoted by the presence of Candida "reservoirs". Recently, Beikert *et al*. demonstrated that the external vulva, in particular the interlabial sulci, may be a site of persistence of the yeast. This specific area is characterized by high humidity that, when combined with minimal external irritation, can easily lead to maceration and disruption of the stratum corneum, weakening the epithelial integrity and its natural antimicrobial activity. Moreover it appears that leucocytes do not penetrate the keratinized epithelium as well as they do in the vaginal mucosa, so cell-mediated immunity is also less efficacious in the interlabial sulci.[16, 17] The prolonged persistence of low levels of Candida on the vulval skin could maintain the contact allergy mentioned above and worsen the clinical symptoms; the authors underline the importance of caring also the vulvar skin in women with RVVC.

Based on this knowledge, we hypothesized that the best therapeutic behavior, for patients affected by RVVC that either refused or are resistant to treatment with oral antimycotic, could be the removal of potential external irritants found in topical medication and aggressive cleaning, combined with the maintenance of a suitable humidity in the vulvar environment, in order to restore the integrity of the epithelium and its barrier function.

Consequently, we designed a clinical trial consisting of the exclusive use of briefs made of Dermasilk® compared with the exclusive use of white cotton briefs, as placebo, in patients free from treatments. During this study, patients wearing Dermasilk® briefs combined with abstinence from self-medication and excessive cleaning obtained a dramatic improvement in vulvar symptoms and a good reduction of clinical signs and number of flares. By contrast, patients wearing cotton briefs showed only a minimal improvement in some of their symptoms probably due to the discontinuation in the use of irritant creams plus a reduction in the frequency of washing with aggressive soaps, but their clinical signs remained unchanged and the number of episodes of vulvar discomfort they experienced slightly increased.

Dermasilk® is a pure silk knitting fibroin fabric bonded with a permanent antimicrobial protection agent (AEM 5772/5). This medical grade silk is able to retain up to 30% of its own weight in moisture without feeling damp, and to eliminate excess moisture and thus maintain the proper body temperature, acting as a second skin and preventing the development of a moist environment where proliferation of yeast would be encouraged. The AEM 5772/5 antimicrobial finish has demonstrated the ability in vitro to decrease Candida contamina-

tion of the fabric.[18] The antimicrobial finish is closely anchored to the fabric, so it does not migrate from the fabric to the skin and does not alter local bacterial flora such as Lactobacillus *spp*; thanks to this feature, its effectiveness is maintained over time. Moreover, fibroin is a smooth and hypoallergenic protein fiber that does not exacerbate the immunomediated inflammatory processes already present in many women with RVVC, in line with the theory that vaginal contact dermatitis is elicited by Candida, thus preventing it from further affecting the barrier function of the vulvar skin.

The specific features of this fiber have led to the inclusion of Dermasilk® fabric in the European guidelines for the management of atopic dermatitis.[19] Dermasilk® briefs have already been demonstrated to be a useful and safe adjunctive to antimycotic treatment in patients with persistent and recurrent VVC [9] and to topical steroid treatment in patients affected by vulvar lichen sclerosus;[20] Dermasilk® has also proven useful in the management of recurrent pediatric inflammatory vulvitis.[21] In all these chronic vulvar diseases, as in atopic dermatitis, a functional and structural alteration of the vulvar mucosa probably predisposes to a greater susceptibility to inflammation by microorganisms and environmental antigens.

We recognize that the study has some limitations. The sample consisted of a small number of patients due to the requirement to avoid all local therapy; during the recruitment we explained in detail the reasons why local therapies were to be avoided and our patients confirmed that they accepted this.

We did not perform a patch test with the topical creams used before the study, so we cannot determine whether part of the improvement is due to elimination of contact dermatitis sources.

In addition, our study would surely have provided more information if the patients had been subjected to clinical examination and vaginal swab during each flare of subjective symptoms, but in this way the follow-up would have become too expensive and burdensome both for us and for the recruited patients. Although we could not prove that each flare of symptoms corresponded to a proliferation of vaginal Candida, data about subjective symptoms and clinical signs show a positive effect of Dermasilk® briefs on our patients, with a significant decrease in the frequency of vulvovaginal discomfort.

Conclusions

The study we have presented, performed on patients affected by RVVC with mild symptoms and signs in the absence of pharmacological treatments, demonstrated the importance of eliminating the factors which induce local irritation and the use of appropriate underwear in the management of this disease.

Dermasilk® has been shown to be a safe and comfortable underwear which is more suitable than white cotton to control vulvovaginal symptoms and signs of RVVC and to decrease the flares of symptoms when used routinely in the absence of antimycotic medication of any type. These results are due to the pure silk fibroin bonded with a specific permanent antimicrobial/antifungal protection, which decreases external sources of irritation, manages excessive moisture with a consequent decrease in Candida proliferation, and helps the restoration of the skin barrier function.

Our data suggest that Dermasilk® briefs can be considered as an alternative option in patients affected by RVVC who are disinclined to take systemic drugs and are not satisfied with the long-term results obtained with topical antimycotic therapy. Further studies about this special fabric and its applications in recurrent vulvovaginal diseases, considering larger samples of patients, may be useful.

Riassunto

Utilizzo di tessuto Dermasilk® nella candidiasi vulvo-vaginale recidivante. Un'opzione terapeutica in una patologia di lunga durata

Obiettivo. La vulvovaginite recidivante da Candida (VVRC) può essere un disturbo di lunga durata; alcune pazienti rifiutano uno dei trattamenti

più utilizzati a base di fluconazolo per os e ricorrono all'automedicazione, rischiando un controllo incompleto dei sintomi e lo sviluppo di effetti collaterali locali. Lo scopo dello studio è comparare l'utilizzo di slip di tessuto Dermasilk®, fibroina di seta nobilitata con una protezione antimicrobica permanente, con slip di cotone bianco, per valutare se tale slip può essere di aiuto nella cura delle VVRC in pazienti che non utilizzano antimicotici topici o sistemici.

Metodi. Il presente studio è in doppio cieco, randomizzato e considera 30 donne che hanno una storia di vulvovaginite recidivante da Candida con sintomatologia lieve/moderata. Le pazienti sono state divise in due gruppi e istruite a utilizzare per 6 mesi gli slip loro forniti, di cotone bianco (gruppo CT) o di tessuto Dermasilk® (gruppo DS).

Risultati. Tutti i sintomi e segni clinici vulvovaginali sono migliorati nel gruppo DS rispetto al gruppo CT (P<0,001) alle visite di controllo a 3 e 6 mesi. Il numero di riaccensioni della sintomatologia è più basso nel gruppo DS rispetto al gruppo CT (24 contro 68 riaccensioni dei sintomi durante i 6 mesi di studio, P<0,001).

Conclusioni. In assenza di antimicotici, sia topici sia orali, gli slip in tessuto Dermasilk® sembrano essere uno strumento utile, nel ridurre i segni clinici, i sintomi e gli episodi di riaccensione della sintomatologia vulvovaginale nelle pazienti che soffrono di VVRC.

PAROLE CHIAVE: Candidiasi vulvovaginale - Trattamento - Tessuto.

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