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

D’Antuono A., Bellavista S., Gaspari V., Filippini A., Patrizi A.
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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 antymycotic treatment.

MATERIALS and METHOD
- Double-blind randomized study DermaSilk Briefs vs white cotton placebo briefs.
- Duration of the study: 6 months.
- Patients involved: 30 women (mean age 31,7 years) who had a long-term history of RVVC with mild to moderate symptoms, all patients had declined treatment with oral antymycotic drugs, some because they had already received them in the past and some because they feared the side effects.
- The patients were randomly divided into two groups and instructed to use either white cotton placebo briefs (CT group) or DermaSilk® briefs (DS group)*. Patients were asked to exclusively wear these briefs, day and night, for the 6 months duration of the study.
- 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.
- 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 antymycotic agents during the previous two weeks.
- In the six months before the beginning of the study all patients reported between 3 and 6 episodes of vulvar discomfort.
- 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.

* 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.

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

RESULTS

- 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 (fig. 1-2).
- The number of referred flares of symptoms during the study was significantly lower in the DS Group, where the 60% of the patients reported only one or no episodes during the 6-month study, (24 episodes in DS Group versus 68 episodes in the Cotton Group, P<0.001).
- No patients asked for additional supplies of garments, indicating that they remained serviceable for the duration of the study.

![Symptoms](image1)

**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.

![Clinical signs](image2)

**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.

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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. 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. (...) We hypothesized that the best therapeutic behavior, for patients affected by RVVC that either refused or are resistant to treatment with oral antifungal, 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 contamination of the fabric. 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 therapy 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. Dermasilk® briefs have already been demonstrated to be a useful and safe adjunctive to antifungal treatment in patients with persistent and recurrent VVC and to topical steroid treatment in patients affected by vulvar lichen sclerosus; Dermasilk® has also proven useful in the management of recurrent pediatric inflammatory vulvitis. 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. (…)”

CONCLUSIONS

“In the absence of both topical and oral antifungals, 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”.

“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 antifungal therapy”.

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