Dermasilk Briefs in Vulvar Lichen Sclerosus: An Adjuvant Tool

Antonietta D'Antuono, MD,[1] Sara Bellavista, MD,[1] Francesca Negosanti, MD,[1] Stefania Zauli, MD,[1] Elena Baldi, MD,[2] and Annalisa Patrizi, MD[1]

[1]*Department of Internal Medicine, Geriatry and Nephrology, Section of Dermatology, San'Orsola-Malpighi Hospital, University of Bologna; and* [2]*Department of Medicine and Public Health, University of Bologna, Bologna, Italy*

■ **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, 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 nonresponding 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%

Correspondence to: Sara Bellavista, MD, Section of Dermatology, University of Bologna, Via Massarenti 1, 40139 Bologna, Italy. E-mail: sara.bellavista4@unibo.it

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

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)	$p < .0001$	17 (40.48)
Dyspareunia	36 (85.71)		25 (59.52)
Itching	27 (64.29)	$p < .0001$	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)	$p < .0001$	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	$p < .0001$	21
Dryness	21	21	21		21	18		21
Soreness	21	21	19		20	0	$p < .0001$	17
Dyspareunia	20	16	20		16	9		16
Itching	13	14	4	$p < .05$	12	0		4
Urinary problems	13	11	12		11	8		11
Constipation	1	0	1		0	0		0
Clinical signs								
Erythema	21	21	20		20	9	$p < .05$	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

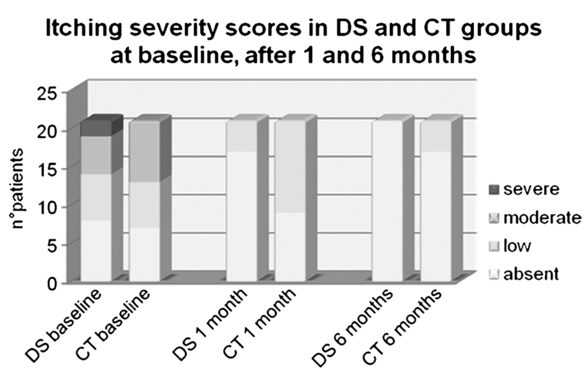

Figure 1. Itching severity scores (according to an increasing severity score from 0 to 3, in which 0 means absent and 3 means severe) in the 2 groups at baseline, after 1 month, and after 6 months.

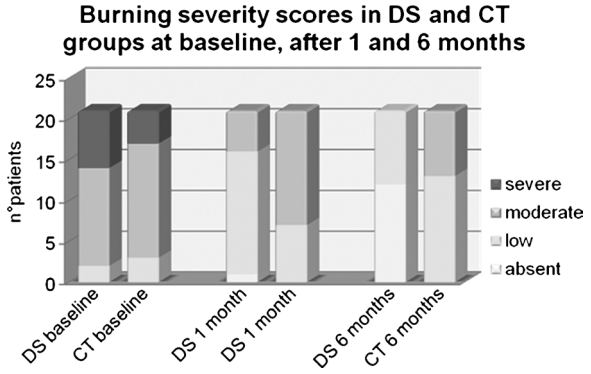

Figure 2. Burning severity scores (according to an increasing severity score from 0 to 3, in which 0 means absent and 3 means severe) in the 2 groups at baseline, after 1 month, and after 6 months.

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 antimicotics. 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

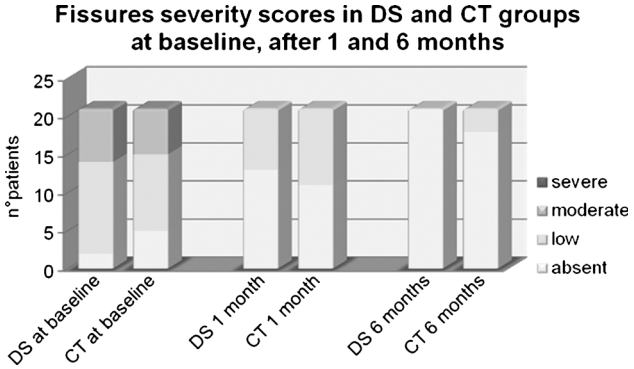

Figure 3. Fissures severity scores (according to an increasing severity score from 0 to 3, in which 0 means absent and 3 means severe) in the 2 groups at baseline, after 1 month, and after 6 months.

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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