Effectiveness of silk fabric underwear as an adjuvant tool in the management of vulvar lichen simplex chronicus: results of a double-blind randomized controlled trial

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OBJECTIVE:
Avoiding potentially irritating contact is a key point in vulvar lichen simplex chronicus (VLSC) management. This study aims to assess the use of nonirritating silk fabric underwear (Dermasilk) as an adjuvant tool in the treatment of Vulvar Lichen Simplex Chronicus (VLSC).

METHODS:
Number of patients: twenty women.
Exclusion criteria: systemic or topical VLSC treatment in the 4 weeks before enrollment; active infectious diseases or other dermatoses or carcinoma of the vulva; clinical or histological features showing possible resemblance with other diseases, such as lichen planus, lichen sclerosus, or plasma cell vulvitis; and lack of agreement between clinical and histological features.

The study was organised in two phases:
Phase 1:
a 1-week open-label active treatment phase with topical 0.1% mometasone furoate (MMF) ointment, once daily on the affected surface.
The women were instructed to wear their own briefs and not the study briefs.

Phase 2:
Participants then entered a 4-week double-blind maintenance phase (MP) in which they were randomized to wear either 3 pairs of briefs made of silk fabric (DermaSilk) (10 women) or 3 pairs of white 100% cotton briefs (10 women). During MP, participants were allowed to use MMF once daily on an as-needed basis until symptoms healed. No other treatments were allowed.

The main efficacy endpoints were to assess and compare the two intervention groups on the following:
A) number of participants who needed to apply MMF throughout MP;
B) mean number of MMF applications;
C) mean symptom-free interval before MMF reapplication;
D) changes in the severity of symptoms and signs. Subjective evaluation of itching, burning and stinging was obtained using a Visual Analogue Scale (VAS). The objective assessment of signs (erythema, lichenification, hyperpigmentation, itching-related excoriations, purpuric lesions and scaling) was obtained using a four-point scale.

RESULTS:
During maintenance phase:

A) 4 women in DermaSilk briefs group applied mometasone furoate ointment vs 6 women in the cotton briefs group.

B) Mean number of MMF applications:
   1 (range 0-7) in DermaSilk group vs 3.8 (range 0-18) in the cotton briefs group. The use of DermaSilk briefs reduced the mean number of monthly corticosteroid applications in an almost significant way (p=0.074).

C) Vulvar Lichen Simplex Chronicus symptom-free interval was 22.5 days (range 20-25) in DermaSilk briefs group vs 7.2 days (range 1-11) in the Cotton briefs group. The between group difference was statistically significant (P = 0.0003) for the DermaSilk Group.
<table>
<thead>
<tr>
<th></th>
<th>DermaSilk briefs group (n=10)</th>
<th>Cotton briefs group (n=10)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants who reapplied mometasone furoate (MMF) ointment, n (%)</td>
<td>4 (40%)</td>
<td>6 (60%)</td>
<td>0.65</td>
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<tr>
<td>Number of MMF applications mean (range)</td>
<td>1 (0-7)</td>
<td>3.8 (0-18)</td>
<td>0.074</td>
</tr>
<tr>
<td>Symptom-free interval among relapsing participants, mean (range)</td>
<td>22.5 (20-25)</td>
<td>7.2 (1-11)</td>
<td>0.0003</td>
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</table>

Reapplications of corticosteroid in DermaSilk group during the maintenance phase

- 0 reapplications – 6 women
- 1 reapplications – 3 women
- 7 reapplications – 1 woman

Reapplications of corticosteroid in Cotton group during the maintenance phase

- 0 reapplications – 4 women
- 1 reapplication – 1 woman
- 2 reapplications – 2 women
- 4 reapplications – 1 woman
- 11 reapplications – 1 woman
- 18 reapplications – 1 woman
At the end of the 4 weeks:

D) symptom improvement determined after corticosteroid use (ATP) increased in the DermaSilk briefs group but worsened in the cotton briefs group; the worsening was statistically significant for the GSS (Global Subjective Score).

Mean GOS (Global Objective score) decreased in both DermaSilk Group and Cotton Group, but the improvement was significant only in DermaSilk Group (p =0.006 in DermaSilk Group vs p=0.081 in Cotton Group).
DISCUSSION:
“(…) daily use of silk fabric briefs has been shown to be effective in controlling the disease and in delaying VLSC exacerbation. (…) silk fabric briefs were shown to efficiently protect from symptom relapse. (…)”

“(…) the mean number of monthly applications of corticosteroid was found to be lower among women wearing silk fabric briefs, with a difference close to statistical significance (1 vs 3.8). (…)”

“(…) time before needing corticosteroid reuse[ was much significantly longer in silk fabric briefs participants in comparison (…)”

“(…) silk fabric underwear may be considered a corticosteroid-sparing tool, providing relief of symptoms more effectively than normal cotton underwear. (…)”

CONCLUSIONS:
“The results of the present study provide evidence that silk fabric underwear may be a useful tool for VLSC management by diminishing external sources of irritation and by synergizing with the anti-inflammatory action of topical corticosteroids. Symptom relief is expected to reduce the use of corticosteroids while improving women’s quality of life”.