Clinical effectiveness of a special silk textile in the treatment of recurrent pediatric inflammatory vulvitis

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STUDY OBJECTIVE
Evaluation of the safety and efficacy of the use of DermaSilk® briefs, made of pure silk fibroin with a permanent antimicrobial treatment, in the recurrent pediatric inflammatory vulvitis (PIV).

MATERIALS AND METHODS
- **Prospective cohort study of 12 pre-pubertal girls**, aged between 2 and 10 years (mean age 5.75 y.), affected by recurrent PIV.
- **Inclusion criteria**: pre-pubertal age and 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).
- **Exclusion criteria**: diagnosis of lichen sclero-atrophicus, immunosuppression, diabetes or insulin-resistance.
- **At the baseline visit**: patients complained of a history of at least three relapses of PIV during the last three months; at physical examination they showed vulvitis characterized by erythema, edema and sometimes fissurations associated with burning and itching.

Patients were divided into two groups:

**Group 1 – non specific irritative PIV**

- **8 patients** out of 12 with negative microbiological examination
- **Treatment**: aqueous cream or emulsifying ointment + DemaSilk briefs
Group 2 – infective PIV

4 patients out of 12, 3 of which with bacterial infections (1 positive for *Streptococcus pyogenes* group A, 1 for *Streptococcus pyogenes* group A and *Staphylococcus aureus*, 1 for *Haemophylus influenzae*) and 1 with *Candida Albicans*

Treatment:
In cases of bacterial infections:
- topical mupirocine ointment, twice a day for 10-14 days + DermaSilk briefs
In case of Candida infection:
- topical econazole cream, twice a day for two weeks + DermaSilk briefs
The most inflamed cases were also treated with topical application of mild-potency steroids for 5-7 days.

RESULTS

- After 1 month (second examination): all the patients reported a significant improvement of symptoms (both burning and itching) and physical examination revealed a decrease in erythema and inflammation.

- After 3 months (third examination): 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 60 to 3 (P<0.001).

- 7 months after the beginning of the study, all parents were contacted by phone and asked to answer a questionnaire to obtain more details about possible relapses and the use of DermaSilk® 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 (DermaSilk®) instead of their own briefs made of other fabrics.

CONCLUSIONS

It is important to note that all the 8 patients of Group 1, affected by non-specific irritative PIV, improved, both in symptoms and in objective signs, only thanks to the use of DermaSilk® briefs together with a standard aqueous cream/ emulsifying ointment.

“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 (…). 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”.

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