INDEXED BY
INDEX MEDICUS
(MEDLINE)
SCIENCE CITATION INDEX
EXPANDED (ISI)

GIORNALE ITALIANO DI

DERMATOLOGIA E VENEREOLOGIA

OFFICIAL JOURNAL OF THE SOCIETÀ ITALIANA DI DERMATOLOGIA MEDICA, CHIRURGICA, ESTETICA E DELLE MALATTIE SESSUALMENTE TRASMESSE (SIDeMaST)

PUBBLICAZIONE PERIODICA BIMESTRALE - POSTE ITALIANE S.P.A. - SPED. IN A. P. D.L. 353/2003 (CONV. IN L. 27/02/2004 N° 46) ART. 1, COMMA 1, DCB/CN - ISSN 0026-4741 TAXE PERÇUE

DERMASILK IN LONG-TERM CONTROL OF INFANTILE ATOPIC DERMATITIS: A DOUBLE BLIND RANDOMIZED CONTROLLED TRIAL

C. FONTANINI, I. BERTI, L. MONASTA, G. LONGO

VOLUME 148 - No. 3 - PAGES 293-297 - JUNE 2013

EDIZIONI MINERVA MEDICA

G ITAL DERMATOL VENEREOL 2013;148:293-7

DermaSilk in long-term control of infantile atopic dermatitis: a double blind randomized controlled trial

C. FONTANINI [1], I. BERTI [2], L. MONASTA [2], G. LONGO [2]

[1]University of Trieste, Trieste, Italy
[2]Institute for Maternal and Child Health IRCCS "Burlo Garofolo", Trieste, Italy

***Aim*. Atopic dermatitis is a chronic inflammatory disease characterized by severe itching, skin dryness, blistering and remittent-relapse course. The critical feature is a skin barrier dysfunction that leads to epidermal inflammation and to bacterial superinfection. The aim of our study is to assess the usefulness of DermaSilk in reducing dermatitis relapses, in infants affected by atopic dermatitis, previously treated with topical corticosteroid and, if needed, with antibiotics.**

***Methods*. This is a double blind randomized study involving 22 infants, aged 4 to 18 months, affected by atopic dermatitis. Disease severity has been evaluated by the SCORAD Index. To achieve a complete remission, acute phases were managed following international guidelines. Subsequently, infants were randomized to either wear a set of DermaSilk body and tights (group A), or wear clothes in pure cotton (group B) for 24 months with the exception of the warmer months (from mid-May to mid-September).**

***Results*. The use of topical steroid per month was significantly lower in the DermaSilk group compared to the cotton group (P=0.006). The subjective evaluation reflecting itching reduction was also statistically significant (P=0.014).**

***Conclusion*. This study shows that DermaSilk products can reduce relapses in infants with eczema during the maintenance phase and play a pivotal role in itching control, improving the quality of life of children and their family.**

KEY WORDS: Eczema - Recurrence - Administration, topical.

Atopic dermatitis (AD) is a chronic inflammatory disease of the skin characterized by severe itching, dryness, blistering and frequent relapses. It affects 10% to 20% of children and its prevalence is increasing.[1, 2] AD has a considerable impact on quality of life for the patients and their families. The determining factor, responsible for the disease, is a skin barrier dysfunction (genetically predisposed) [3] which leads to skin inflammation and facilitates bacterial superinfection, in particular by *Staphylococcus aureus*.[1]

Eczema treatment is based on anti-inflammatory therapy, in addition to emollients for skin barrier reconstruction, skin hydration, identification and elimination of triggering factors including irritants, allergens and infectious agents.[4, 5] Fabrics have been included among the physical irritants.[5]

DermaSilk is proposed as a non-irritating tissue due to its sericin-free composition, with antibacterial properties given by an exclusive water resistant treatment with AEM 5772/5 (3-trimethylsilypropyldimethyloctadecyl ammonium chloride), a non-migrating permanent antimicrobial agent also called AEGIS, that reduces bacteria survival and growth.[6]

It could be a beneficial device in the treatment of atopic dermatitis, through itching reduction and bacterial inhibition.[6]

DermaSilk has been demonstrated to be significantly more effective than cotton in the management of AD.[7, 9-11]

Several studies have been conducted to prove its efficacy in the acute phase, compared to placebo;[6, 7, 9, 10] few papers report its efficacy compared to topical

Corresponding author: Dr. I. Berti, MD, Institute for Maternal and Child Health, IRCCS "Burlo Garofolo", Via dell'Istria 65/1, 34137 Trieste, Italy. E-mail: berti@burlo.trieste.it

steroids.[8] Only two studies are randomized controlled trials [9, 11] and both aimed to prove DermaSilk effectiveness during AD flares.[12]

We strongly believe that eczema relapses need to be treated with steroids and eventually with antimicrobial agents, but we have imagined a possible role of DermaSilk in reducing relapse recurrence, once eczema has been controlled with the currently accepted therapy. The aim of our study is to evaluate, in infants affected by AD, the DermaSilk effectiveness measured as topical corticosteroids consume (1 tube 30 g) compared to cotton bodies and panties.

Materials and methods

This is a double blind randomized trial involving infants younger than 18 months, affected by atopic dermatitis, recruited at the dermatologic or allergic clinic of the Institute for Maternal and Child Health – IRCCS "Burlo Garofolo" – Trieste, Italy, between March 2009 and December 2010. The study was approved by the committee on research ethics at the institution in which the research was conducted and any informed consent from human subjects was obtained as required.

The children were allocated into 2 groups, A (DermaSilk) and B (cotton), with the intent to minimize differences related to eczema severity. Neither the investigators nor the parents knew whether the child was wearing cotton or DermaSilk clothes. We asked the children to wear the clothes provided by ALPRETEC free of charge, every day for 24 months, except during the summer and very hot days in other seasons (from mid-May to mid-September). The clothes were body long sleeves and panties covering the trunk, the arms and the legs entirely. Increasing sizes of DermaSilk or cotton bodies and panties were supplied to the children according to child growth. We explained to the parents our interest in comparing different kinds of fabrics, but no further details about the tissues were discussed with them, so that they would not be influenced in their judgment. Patients were asked to use only these clothes, day and night, for the whole duration of the study, except for the medical controls in our clinic, in order to avoid the identification of the allocation by the investigator.

In addition, to minimize differences between children due to environmental factors, families were also given anti-mite mattresses and pillow covers for the beds and pillows of the child and parents.

Parents were asked to fill daily an open diary recording the use of topical corticosteroid, the quantity and the body area in which the cream was applied.

All children were treated as needed with mometasone furoate, a corticosteroid medium power, widely used in the topical treatment of eczema.

Every child entering the study was evaluated with the SCORAD index, which takes into account extent of disease, intensity (edema, erythema, papules, secretion, crusts…) and subjective symptoms (itching and sleep loss).[13] SCORAD total index ranges from 0 to 103. The severity of atopic dermatitis according to the SCORAD is graded as follows: Mild < 25 points, Moderate 25-50 points, and Severe >50 points.[13] The intent of using the SCORAD index was to divide the children equally by gravity in the two groups at the beginning of the study.

Data were analyzed according to the intention to treat principle.

Results

Twenty two infants affected by atopic dermatitis, aged 4 to 18 months, were recruited during routine visits. Two children were lost at follow up and 20 infants completed the study. At the end of the study we collected all patients' records and we acknowledged that children in group A were wearing DermaSilk cloths while group B wore cotton bodies and panties. All children followed the assigned treatment except one: the parents of a five month old girl assigned to the DearmaSilk group, after five months of wearing it, stopped using it because the girl had grown, the size did not fit anymore, and parents did not ask for other clothes as expected by the protocol. For the entire period, the girl used five tubes of topical corticosteroid. As for the intention to treat principle, this girl was kept in the DermaSilk group.

The data were processed by the Epidemiology and Biostatistics Unit of our Institute.

Given the small number of data and the difficulty in verifying the assumptions of normality and homoscedasticity, we used exact (Fisher) and non-parametric tests (Mann-Whitney, Kolmogorov Smirnov, Somer's D) for the statistical analysis.

All the results are listed in Table I. The study groups did not differ for age, sex, extension of ec-

TABLE I.—*Description of the sample and differences between children wearing DermaSilk and children wearing cotton bodies and panties.*

	Type of treatment				Test**	
	Cotton* (Group B)		Silk* (Group A)			
Sex						
M	8	73%	6	67%	Fisher	P=1.000
F	3	27%	3	33%		
Age in months at enrollment	6	(4-9)	7	(5-13)	M-W	P=0.305
					D	P=0.303
Features of the Atopic Dermatitis at baseline						
Extension	12	(9-12)	11	(7-17)	K-S	P=0.504
					D	P=0.974
Strength	25	(10-28)	32	(10-50)	K-S	P=0.347
					D	P=0.671
Symptoms	10	(7-12)	8	(5-15)	K-S	P=0.783
					D	P=0.892
SCORAD	47	(25-50)	50	(25-86)	K-S	P=0.688
					D	P=0.605
SCORAD rating						
Mild	1	9%	1	11%	χ^2	P=0.705
Moderate	8	73%	5	56%	Fisher	P=0.796
Severe	2	18%	3	33%		
Outcome measures						
Months of actual use of the jumpsuit	17	(15-18)	17	(17-18)	M-W	P=0.255
					D	P=0.246
Nr. tubes of topical corticosteroid used	3.0	(1.0-6.0)	1.2	(0.7-1.5)	M-W	P=0.051
					D	**P=0.023**
Nr. tubes/month of topical corticosteroid used	0.17	(0.09-0.33)	0.07	(0.05-0.09)	**M-W**	**P=0.006**
					D	**P=0.000**
Outcome (expressed as itching reduction)						
Unsatisfied	6	55%	0	0%	**Fisher**	**P=0.014**
Satisfied	5	45%	9	100%		

*In the Cotton and Silk columns, data are expressed as frequencies and percentages, or medians and interquartile ranges.
**Fisher: two-tailed Fisher exact test; M-W: non-parametric Mann-Whitney test for equality of populations for continuous data; K-S: non-parametric Kolmogorov-Smirnov test for the equality of continuous, one-dimensional probability distributions; D: non-parametric Somer's D coefficient measures the strength of association between two ordered scale variables; χ^2: Chi-square test.

zema, and SCORAD index at baseline. There was a male prevalence in both groups (73% group A and 67% group B).

The number of steroid tubes used per month during the study period was significantly lower in group A (DermaSilk) if compared to group B (cotton) (P=0.006). Moreover the patient/parents satisfaction was higher in the DermaSilk group (P=0.014), especially in regard to itching decrease, main symptom responsible for child discomfort.

Discussion

Atopic dermatitis is a very common chronic inflammatory disease starting in early age for the majority of children.[1, 14] Its prevalence has doubled in industrialized countries during the past three decades, with 15% to 30% of children affected.[15] Management of AD, when the skin does not present acute flare, is based on hydrating topical treatment and avoidance of specific and unspecific provocation factors.[16] Anti-inflammatory treatment is used for exacerbation and among them topical corticosteroids remain the first choice.[17-19] Systemic anti-inflammatory treatment should be kept to a minimum, but may be necessary in rare refractory cases and might be needed when eczema is very severe and skin involvement very extensive.[20] Microbial colonization and superinfection (*e.g.* with *Staphylococcus aureus*, *Malassezia furfur*) can have a role in disease exacerbation and can justify the use of antimicrobials in addition to the anti-inflammatory treatment.[21]

We have tested the effectiveness of DermaSilk

in reducing eczema flares among children younger than 18 months with eczema, treated following recommendations of international guidelines.[16, 20, 21] Other studies have already proved DermaSilk utility in eczema management [6-11] either compared to placebo or to topical steroid. We believe that dermatitis needs to be treated with steroids locally when active and no other device can substitute this approach with the same results. Our intent, however, was to assess if DermaSilk could be of any help in prevention of eczema recurrence and our results support this hypothesis.

We observed a consistently lower use of topical corticosteroid among children in group A (DermaSilk) compared to group B (cotton) (P=0.006). The subjective evaluation expressed by families (100% DermaSilk group A, group B 45% cotton; P=0.014) was also statistically significant.

Conclusions

In conclusion, this study found a possible role of DermaSilk in reducing relapses of AD. In particular, the use of DermaSilk leaded to a reduction of subjective symptoms such as itching, the most important factor responsible for the deterioration of the quality of life of both patients and their families, giving greater benefits than cotton, and without any side effect.

Riassunto

DermaSilk nel controllo a lungo termine della dermatite atopica infantile: uno studio randomizzato controllato in doppio cieco

Obiettivi. La dermatite atopica è una malattia infiammatoria cronica della cute ad andamento intermittente, caratterizzata da prurito, secchezza cutanea, vescicolazione. L'elemento patogenetico fondamentale è una disfunzione della barriera cutanea che porta a infiammazione epidermica e sovrainfezione batterica. Lo scopo del nostro studio è stato quello di valutare l'utilità del tessuto DermaSilk nel ridurre le recidive in bambini con dermatite in remissione, precedentemente trattati con corticosteroidi topici e, se necessario, con antibiotici.

Metodi. Questo è un studio in doppio cieco randomizzato condotto su 22 bambini, dai 4 ai 18 mesi, affetti da dermatite atopica. La gravità della malattia è stata valutata mediante l'indice SCORAD. Per ottenere una remissione completa, le fasi acute sono state gestite seguendo le linee guida internazionali. Successivamente i bambini sono stati randomizzati in due gruppi ed hanno indossato un body e una calzamaglia di DermaSilk (gruppo A), o abiti equivalenti in puro cotone (gruppo B) per 24 mesi, con l'eccezione dei mesi estivi (da metà maggio a metà settembre).

Risultati. L'utilizzo mensile di steroidi topici è risultata significativamente più bassa nel gruppo DermaSilk rispetto al gruppo cotone (P=0,006), così come la valutazione soggettiva di efficacia, che rifletteva prevalentemente la riduzione prurito (P=0,014).

Conclusioni. Questo studio dimostra che gli abiti DermaSilk possono ridurre le recidive in bambini con eczema durante la fase di mantenimento e svolgere un ruolo centrale nel controllo del prurito, migliorando la qualità della vita dei bambini e dei loro familiari.

PAROLE CHIAVE: Eczema - Ricorrenza - Somministrazione topica.

References

1. Bieber T. Atopic Dermatitis. N Engl J Med 2008;358:1483-94.
2. Brown S, Reynolds NJ. Atopic and non-atopic eczema. BMJ 2006;332: 584-8.
3. Irvine AD, McLean WH, Leung DY. Filaggrin mutations associated with skin and allergic diseases. N Engl J Med 2011;365:1315-27.
4. Tan BB, Weald D, Strickland I, Friedmann PS. Double-blind controlled trial of effect of housedust-mite allergens avoidance on atopic dermatitis. Lancet 1996;347:15-8.
5. Hanifin JM, Cooper KD, Ho VC, Kang S, Krafchik BR, Margolis DJ *et al.* Guidelines of care for atopic dermatitis. J Am Acad Dermatol 2004;50:391-404.
6. Stinco G, Piccirillo F, Valent F. A randomized double-blind study to investigate the clinical efficacy of adding a non-migrating antimicrobial to a special silk fabric in the treatment of atopic dermatitis. Dermatology 2008;217:191-5.
7. Patrizi A, Giacomini F, Gurioli C, Neri I. Clinical effectiveness of a special silk textile in the treatment of recurrent pediatric inflammatory vulvitis: an open label pilot study. G Ital Dermatol Venereol 2011;146:317-20.
8. Senti G, Steinmann LS, Fischer B, Kurmann R, Storni T, Johansen P *et al.* Antimicrobial Silk Clothing in the Treatment of Atopic Dermatitis Proves Comparable to Topical Corticosteroid Treatment. Dermatology 2006;213:228-33.
9. Koller DY, Halmerbauer G, Böck A, Engstler G. Action of a Silk fabric treated with AEGIS in children with Atopic Dermatitis: a 3-month trial. Ped Allergy Immunol 2007;18:335-8.
10. Ricci G, Patrizi A, Bendandi B, Menna G, Varotti E, Masi M. Clinical effectiveness of a silk fabric in the treatment of atopic dermatitis. Br J Dermatol 2004;150:127-31.
11. Ricci G, Patrizi A, Mandrioli P, Specchia F, Medri M, Menna G *et al.* Evaluation of the antibacterial activity of a special silk textile in the treatment of atopic dermatitis. Dermatology 2006;213:224-7.
12. Vlachou C, Thomas KS, Williams HC. A case report and critical appraisal of the literature on the use of DermaSilk in children with atopic dermatitis. Clin Exp Dermatol 2009;34:e901-3.
13. Kunz B, Oranje AP, Labrèze L, Stalder JF, Ring J, Taïeb A. Clinical validation and guidelines for the SCORAD index: consensus report of the European Task Force on Atopic Dermatitis. Dermatology 1997;195:10-9.
14. Leung DY, Bieber T. Atopic dermatitis. Lancet 2003;361:151-60.
15. Williams H, Flohr C. How epidemiology has challenged 3 pre-

vailing concepts about atopic dermatitis. J Allergy Clin Immunol 2006;118:209-13.
16. National Institute for Health and Clinical Excellence. Atopic eczema in children: management of atopic eczema in children from birth up to the age of 12 years. London: NICE, 2007.
17. Flohr C, Williams HC. Evidence based management of atopic eczema. Arch Dis Child Educ Pract Ed 2004;84:35-9.
18. Hanifin J, Gupta AK, Rajagopalan R. Intermittent dosing of fluticasone proprionate cream for reducing the risk of relapse in atopic dermatitis patients, Br J Dermatol 2002;147: 528-37.
19. Berth-Jones J, Damstra RJ, Golsch S, Livden JK, Van Hooteghem O, Allegra F *et al.* Twice weekly fluticasone propionate added to emollient maintenance treatment to reduce risk of relapse in atopic dermatitis: randomized, double blind, parallel group study. BMJ 2003;326:1367-73.
20. Akdis CA, Akdis M, Bieber T, Bindslev-Jensen C, Boguniewicz M, Eigenmann P *et al.* Diagnosis and treatment of atopic dermatitis in children and adults: European Academy of Allergology and Clinical Immunology/American Academy of Allergy, Asthma and Immunology/PRACTALL Consensus Report. Allergy 2006;61:969-87.
21. Darsow U, Lübbe J, Taïeb A, Seidenari S, Wollenberg A, Calza AM *et al.* Position paper on diagnosis and treatment of atopic dermatitis for the European Task Force on Atopic Dermatitis. J Eur Acad Dermatol Venereol 2005;19:286-95.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Received on March 6, 2013.
Accepted for publication on April 5, 2013.