

Ethylene Vinyl Alcohol (EVOH) Fiber Compared to Cotton Underwear in the Treatment of Childhood Atopic Dermatitis: A Double-Blind Randomized Study

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The aim of this study was to evaluate the effect of underwear made of ethylene vinyl alcohol (EVOH) fiber in children with atopic dermatitis (AD). Twenty-one AD children (11 EVOH group and 10 control group) were studied for 4 weeks. Their AD severity based on the Scoring Atopic Dermatitis (SCORAD) score and physiological functions were assessed. The objective SCORAD significantly decreased in both groups. However, the SCORAD score ($P<0.01$) and urinary cortisol levels ($P<0.05$) were decreased only in EVOH group. It was concluded that EVOH fiber underwear might be useful for children with atopic dermatitis.

Keywords: Atopic dermatitis, Children, Ethylene vinyl alcohol (EVOH), Fiber.

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The prevalence of atopic dermatitis (AD) is increasing worldwide(1,2). The fibers used to make underwear are in direct contact with skin and can cause itching and irritation in AD patients(3-5). Furthermore, previous studies have demonstrated the effect of underwear on physiological functions(6).

Cotton fiber is routinely recommended for AD patients(7). However, Ethylene Vinyl Alcohol (EVOH) fibre has certain advantages over cotton in terms of biocompatibility(8). Compared to cotton, EVOH underwear may stimulate the skin less and result in better effect on physiological functions. However, the effect of EVOH underwear in AD children is unknown. Therefore, a randomized controlled trial was conducted to examine the effects of EVOH fiber on the severity of AD and on various physiological parameters.

METHODS

This randomized, controlled trial was conducted between February to March 2005, which is the winter season in Japan. Children between 3-9 years of age, diagnosed as having atopic dermatitis based on the Hanifin and Rajka criteria(9) were eligible for the study. These children were randomly assigned to EVOH or cotton group.

The researcher provided a computer-generated list of random numbers. A person who was not involved in the analysis of the data or the assessment of the outcome packed the underwear with a code number according to the randomization list, which was kept concealed at the university until the end of the study.

The EVOH-fiber and cotton underwear were packaged and numbered identically and were

identified only by a study number, thus keeping the assignment hidden from both the subject and the investigator. Furthermore, the investigator responsible for the clinical evaluation did not know to which group each child belonged because the children were already undressed before the examination. Throughout the study, the same investigator did the clinical evaluations.

The EVOH fiber was produced by Kuraray (Osaka, Japan). The surface of each EVOH fiber consists of alternately arranged hydrophilic and hydrophobic nanoscale segments(8). The exterior of the underwear (60% of the material) was made of cotton; only the interior of the underwear (40% of the material) was made of EVOH. Both garments were short-sleeved, with the stitches turned inside-out at the neck, cuffs, and sides to avoid irritation caused by the seams.

The severity of atopic dermatitis was evaluated at baseline, after 2 weeks, and after 4 weeks. To ensure that the investigator who evaluated the outcomes was blinded to the type of underwear that the children were wearing, the children were undressed before the examination. The outcome was measured using the Scoring Atopic Dermatitis (SCORAD) score, which evaluates the extent and intensity of the lesions, as well as pruritus and sleep loss(10). In addition, the objective SCORAD components (extent and intensity) were determined for the area covered by the underwear. Furthermore, to evaluate the patients' physiological functions, urinary growth hormone (GH) and urinary cortisol levels were measured.

At least 10 subjects were required for each group to have 80% power of detecting a difference of 13 mean SCORAD score using a two-sided 5% level of significance, assuming a standard deviation of 10(11). Statistically significant differences between the groups were determined using Student's *t*-test (two-sided); significance within groups was determined using paired *t*-tests. SPSS ver 10.0 was used for statistical analysis. All statistical hypothesis tests were two-sided with a significance level of 5%.

The Institutional Review Board of the University of Kyoto approved the study, and the parents of each

patient gave their written informed consent.

RESULTS

Two participants from each group lacked both baseline data and at least one post-baseline visit; therefore, data from 21 participants were available for analysis. Furthermore, GH levels were insufficient in 2 children in the EVOH group and in 1 child in the control group. In addition, in the control group, 1 GH level and 1 cortisol level were missing.

No significant baseline differences were observed between the EVOH and the control groups (**Table I**). None of the children were treated with topical corticosteroids during the study. The SCORAD score for AD severity was decreased in the EVOH underwear group ($P=0.001$), while, in the control group, the SCORAD score for AD severity improved slightly from baseline, but the difference was not statistically significant ($P=0.12$). Urinary cortisol concentrations decreased significantly in the EVOH fiber underwear group, but remained constant in the control group (**Table II**).

One patient in the EVOH group reported increasing pruritus due to changed treatment prior to study entry. One patient in the control group reported increased pruritus of the legs, which were not covered by the underwear. The other patient in the control group reported increased pruritus before sleeping but less sleep loss. Most adverse events were considered unrelated to the underwear, and none were sufficient to cause withdrawal from the study.

TABLE I BASELINE DATA FOR PARTICIPANTS

Characteristics	EVOH group (n=11)	Control group (n=10)	Z score mean
Age (y), mean (range)	5.5 (3-8)	5.5 (3-9)	
Males, n(%)	6 (54.5)	4 (40)	
Height (cm), mean \pm SD	111.0 \pm 13.5	109.2 \pm 15.0	0.78
Weight (kg), mean \pm SD	19.6 \pm 4.9	19.3 \pm 5.6	0.89

EVOH: ethylene vinyl alcohol.

DISCUSSION

The present study found that the objective SCORAD improved statistically significantly in both groups during the course of the study. However, the SCORAD score that included not only the objective SCORAD components but also sleep loss and pruritus improved statistically significantly from baseline only in the EVOH group.

These results suggest that EVOH underwear is effective in preventing sleep loss and pruritus in AD children. The EVOH fibre is a biocompatible material(8), and this characteristic may reduce stressful stimuli applied to the skin. In a similar investigation involving adult AD patients, Kawachi, *et al.*(12) reported that 48 of 63 subjects wearing EVOH fiber underwear noted reduced itchiness. The reason why the SCORAD score improved in the control group (cotton) as well as in the EVOH group may be that both groups were given new underwear; thus, the new underwear may have caused less stimulation than the underwear used before study entry, because the amount of stressful stimuli in underwear increases with washing.

The effects of EVOH fabric on physiological function of the endocrine (GH excretion) and immune (cortisol excretion) systems were also studied. Previous research involving healthy volunteers has shown that the softness of underwear

affects the autonomic nervous system(6). It was also postulated that these effects may affect the endocrine and immune systems, since these three systems interact to maintain homeostasis. The skin is tightly embedded into complex neural and neuroendocrine regulatory networks that link it to systemic stress responses(13,14). Therefore, the finding that EVOH underwear significantly reduced urinary cortisol levels reflects the biocompatibility of this fiber (*i.e.*, softness), which reduces the amount of stressful stimuli applied to the skin.

The present study had several limitations. First, the sample size was small, which can limit the statistical power in detecting significant differences. Second, the degree of fibre degradation caused by wearing or washing during prolonged use is unknown. The process of degradation depends on the types of fibres that are present and the degree of degradation, which affects the degree of friction. Therefore, the effects of each type of fibre during prolonged use are unknown. Finally, the undershirts were short-sleeved; thus, not all AD areas were necessarily covered by the underwear. It is possible that differences between the underwear type may have been greater if the underwear had covered the entire AD-affected area. Owing to these limitations, this study should be considered as an initial, exploratory study. Further research involving a greater number of subjects that focuses on physiological functions is required.

TABLE II COMPARISON OF OUTCOME VARIABLES BETWEEN EVOH AND REGULAR UNDERWEAR GROUPS

Variables		<i>n</i>	Baseline mean (SD)	Follow up mean (SD)	<i>P</i> value	Mean difference [†]
SCORAD	EVOH	11	22.1 (19.1)	10.7 (12.1)	0.001*	11.4
	Regular	10	21.4 (17.0)	15.1 (14.3)	0.119	6.3
Objective SCORAD (Covered area)	EVOH	11	13.8 (12.5)	2.1 (4.1)	0.005*	11.7
	Regular	10	11.8 (10.1)	4.5 (6.5)	0.002*	7.3
Growth Hormone (pg/mg Cr) [‡]	EVOH	9	37.8 (16.0)	31.1 (14.6)	0.279	-6.6
	Regular	8	33.6 (17.2)	36.4 (7.9)	0.599	2.9
Cortisol (mg/g Cr) [‡]	EVOH	10	0.11 (0.04)	0.05 (0.02)	0.005*	0.05
	Regular	10	0.08 (0.03)	0.06 (0.03)	0.100	0.02

EVOH: ethylene vinyl alcohol; SCORAD: Scoring atopic dermatitis score. * $P < 0.05$ for the within-group comparisons using paired *t*-tests. [†]Mean difference calculated as (baseline - follow up) for growth hormone versus (follow up - baseline) for all other parameters. [‡] Urinary growth hormone and cortisol concentrations were normalized against creatinine concentration.

WHAT THIS STUDY ADDS?

- Wearing underwear made of EVOH fabric is safe for prolonged use in children with atopic dermatitis.

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