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# A fact-finding study on treatment with ointment provided by parents of children with atopic dermatitis

Atsushi Sugiura<sup>1</sup>, Yutaka Matsumoto<sup>1</sup>, Tomoko Akase<sup>2</sup>, Tomomi Sato<sup>3</sup>, Yuko Yamakawa<sup>4</sup>, Sanami Takahashi<sup>5</sup> and Michiko Aihara<sup>6</sup>

- 1) Faculty of Nursing, School of Medicine, Tokai University,
- 2) Department of Biological Science and Nursing, Graduate School of Medicine Yokohama City University,
  - 3) Department of Pediatric Nursing, Graduate School of Medicine Yokohama City University,
    - 4)Yamakawa Dermatology Clinic,
    - 5) Higiriyama Dermatology Clinic,
  - 6) Department of Environmental Immuno-Dermatology, Graduate School of Medicine Yokohama City University

#### Summary

The treatment for atopic dermatitis consists primarily of application of topical steroids. In this study, we investigated the type of instructions on ointment use given to the parents of children with atopic dermatitis. We also measured the actual quantity of ointment applied and examined the relationship between the quantity of ointment applied and the method and content of such instructions, and the parents' anxieties about topical steroids.

We asked them to apply a topical steroid to an area of the skin about the size of a single palm (0.5 FTU = 0.25 g), and found that the amount of ointment they used was 0.04 g - 0.25 g, and the average amount used was 0.12 g (SD = 0.07). Parents who had received instruction orally and with demonstrations were shown to have used an amount of ointment that was closer to the amount prescribed in terms of a Fingertip Unit (FTU), or a guide to the appropriate amount of topical steroid to be applied to a body site, with one unit, or 0.5 g, describing the amount of ointment squeezed out from the distal interphalangeal (DIP) joint to the tip of an adult index finger. When asked if they were anxious about adverse reactions, five answered, "Yes," and eight said "Somewhat anxious," together accounting for over 80% of the participants. This research was novel in that we assessed the instructions for topical steroids by measuring the actual quantity of ointment applied by parents.

**Keywords:** Atopic dermatitis, Treatment with ointment, Children, Parents, Topical steroids, Steroid phobia, Medication adherence

Corresponding Author: Atsushi Sugimura 143 Shimokasuya, Isehara, Kanagawa, 259-1193

Tel/Fax: +81-463-90-2018

E-mail: sugimura.atsushi.r@tokai.ac.jp

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#### I. Introduction

Atopic dermatitis (AD) is a disease whose main lesion type consists of itchy eczema that repeatedly goes through an aggravation-remission cycle. It often develops during childhood. Pruritus, which is the primary symptom of AD, often causes sleep disorders(1), and a correlation is known to exist between the severity of symptoms and the quality of life (QOL) of children with AD (2). Parents of children with AD have reported that it is a challenge to manage their child's itchiness and sleep, as well as to provide skin care (3), with a correlation also seen between patients' severity of symptoms and parents' QOL (4). Moreover, some children have manifested serious complications such as hypoproteinemia and hypoalbuminemia, electrolyte imbalances, developmental disorders, and retardation (5). Working to improve the symptoms of children with AD therefore plays an important role in promoting the child's sound growth and development and allowing them to lead a normal and healthy family life.

The clinical practice guidelines for atopic dermatitis (6) set forth the following as the three pillars of basic treatment: searching for the causes and aggravating factors and dealing with them, skin care, and drug therapy. Regarding drug therapy, performing symptomatic treatment is the basic rule because AD is a multifactorial disease that includes genetic predispositions and no pharmacotherapies exist that can completely cure the disease itself. However, the efficacy of topical steroids used in drug therapy has been substantiated. Even so, it has been revealed that parents of children with AD are reluctant to use such ointments because of their anxieties about adverse reactions (7). Moreover, with regard to the quantity of ointment applied, the fact that the amount of ointment that

caregivers actually use is smaller than the amount equivalent to a Fingertip Unit (FTU; 0.5 g) has been cited as a problem (8). Since parents' awareness/recognition of a disease has also been shown to be related to the self-care or self-management behavior of children with chronic diseases (9), the provision of instruction to the parents, first and foremost, is of key importance to increasing their child's drug adherence.

In this study, therefore, we measured the amount of ointment that the mothers actually used and, based on the relationship between the content of instructions on the use of topical steroids that the mothers had received, the instruction methods, and their anxieties about drugs, we investigated how to optimize the instructions given on the use of topical steroids.

#### II. Study method

#### 1. Study participants

Sixteen parents of children with AD who received outpatient treatment at a dermatology clinic were recruited for the study. We did not specify the age of the children with AD and we selected parents who had applied topical steroids to their children in the past.

#### 2. Procedure

We asked medical institutions that agreed to participate in our study to refer eligible parents to us. The researchers then explained the objectives of the study to the participants and obtained their written informed consent. Our study consisted of having the parents demonstrate how to apply the ointment, measuring the amount applied, and subsequently having them complete a questionnaire regarding the content of the instructions they had thus far received, as well as any anxieties they might be experiencing.

## 1) Measurement of the amount of ointment applied

We covered the researchers' forearms with a polyvinylidene chloride wrap. Using a black magic marker, we drew a circle on the wrap, as a dotted line, about the size of a palm (0.5 FTU = 0.25 g). The parents were told to assume the inside of the area drawn with the marker to be the site of inflammation. After putting on a pair of nitrile gloves, they were asked to apply Antebate® Ointment 0.05% (Torii Pharmaceutical Co., Ltd., Tokyo, Japan). To determine the amount of ointment applied, we measured the difference in the weight of the ointment tube before and after use.

#### 2) Questionnaire content (a) Overview of the parents and the children with AD

To acquire information on the background of each parent/caregiver, we collected information on their age, attributes, occupation, educational history, and their history of having received instruction on ointment use; with regard to the background of the children with AD, we collected information on their age, period of onset, and chronic diseases other than AD. If there was more than one AD patient in the same family, we obtained information on the older child.

(b) Content of the most recent instructions received on the use of topical steroids

Participants who had previously received instructions on the use of topical steroids were asked about the details regarding the most recent instructions that they had received. The questions consisted of the period of the most recent instructions, the instructor's occupation, method of instruction, content of instructions, understanding of the instructions given, and agreement/ satisfaction with the instructions. The participants provided answers regarding

their understanding of, and agreement/ satisfaction with, the instructions given using a 4-point Likert scale ranging from "1: Understood" to "4: Could not understand at all." Further, with regard to the content of the most recent instructions on how to apply ointment, we assessed any reason(s) for not being able to implement the instruction given. (c) Anxieties about adverse reactions to topical steroids

The participants provided answers regarding any anxieties about topical steroids, using a 4-point Likert scale ranging from "1: I have anxieties" to "4: I have no anxieties." Parents who answered "1: I have anxieties" or "2: I have slight anxieties" were then asked to answer with either "Yes" or "No" if they were reducing the application frequency or amount of ointment because of their anxieties about possible adverse reactions to topical steroids.

#### 3. Method of analysis

We tabulated the background of the parents and children with AD, the method and content of the most recent instructions received on the use of topical steroids, anxieties about possible adverse reactions to topical steroids, and the amount of ointment applied. The method of instruction on the use of ointment and the quantity of ointment applied were analyzed using the Kruskal-Wallis test to the three instruction groups (orally only, orally+brochures, and orally+demonstrations). Mann-Whitney U test was performed to analyze the relationship between the quantity of ointment applied and anxieties to topical steroids. We further performed Spearman's rank correlation coefficient, Mann-Whitney U tests, and X2 tests concerning the period since receiving instruction and the amount of ointment, having received instruction but being unable to implement it, and anxiety

about side effects, as well as ointment instruction method and having received instruction but being unable to implement it. SPSS v. 25 (IBM, Tokyo) and the Mann-Whitney U test table were used for statistical analysis, with p < .05 considered to be statistically significant.

#### 4. Ethical considerations

We explained the objectives of the study to the participants, both orally and in writing. The parents were told that their participation in the study was completely voluntary, that they would not suffer any disadvantages by refusing to participate, and the protection of their personal information and the publication of study results at academic meetings were fully explained. Parents who agreed to participate were asked to sign the consent form, with the consent of the parent being regarded as consent for both the parent and child. The questionnaires were completed anonymously. This study was carried out after obtaining a Certificate of Approval from the Yokohama City University Ethics Committee (Approval Nos. 171096 and 181020).

#### III. Results

The study was conducted from August to November 2015 at three medical institutions (one general hospital and two clinics). Our participants were sixteen parents who had provided their consent. Each of the three medical institutions saw approximately 200 AD patients (including adult patients) each month. They provided instructions regarding the ointment at the first appointment and observed the patient's symptoms before explaining orally, with a pamphlet, or by demonstration.

### 1. Overview of the parents and children with AD

Table 1 shows an overview of the parents and children with AD, as well as the measurement results of the quantity of ointment applied. All the parents were mothers, aged between 29 and 54 years, with their average age being 39.6 years (SD = 6.4). Nine held jobs (56.3%). Their academic history showed that eleven parents were university graduates (68.8%). The children with AD were aged between 0 and 17 years, with their average age being 6.4 years (SD = 4.1). One was aged 0, four were aged 1 - 5, ten

**Table 1.** An overview of the subjects and children with AD, and the quantity of ointment applied

		n = 16
Subjects' ages (years)		$39.6 \pm 6.4^{**}$
	$20\mathrm{s}$	1
	30s	7
	40s and older	8
Subjects' attributes	Mother	16
Subjects' employment status	Employed	9
	Not employed	7
Educational history	High school	4
	Vocational college	1
	University	11
Patients' ages (years)		$6.4 \pm 4.1^{*}$
Patients' age of onset (years)		$1.3\pm1.3$ *
Experience of having received instruction on	Yes	15
how to apply ointment	No	1_
Quantity of ointment applied (g)		$0.12 \pm 0.07^{*}$

AD, atopic dermatitis

 $mean \pm SD$ 

were aged 6 - 12, and one was older than 13. The age of onset of AD was between 0 and 4 years, with the average age being 1.3 years (SD = 1.3). Fifteen of the parents (93.8%) had taken classes that taught the use of topical steroids.

#### 2. Quantity of ointment applied

The parents were asked to apply a topical steroid to an area of the skin the size of a palm. The results showed that the quantity of ointment applied was between 0.04 and 0.25 g, and the average quantity applied was 0.12 g (SD = 0.07 g).

# 3. Content of the most recent instruction on the use of topical steroids

Table 2 shows the content of the most recent instruction received on the use of topical steroids. Eight parents (53.3%) had receive instruction within the last year. The average period was 1.2 years (SD = 1.9) ago. There was very little correlation between the period since instruction and the quantity of ointment

applied and a significant difference was not found (r = 0.018, p = 0.950).

Of the medical professionals who provided instruction to the parents, 13 (86.7%) were physicians, followed by pharmacists (6 individuals; 40.0%), and nurses (3; 20.0%). With regard to the method of instruction, most instruction was given orally only (eight parents; 53.3%), followed by instruction given orally and with demonstrations (four parents; 26.7%), and instruction given orally and with brochures (three parents; 20.0%).

Frequency of application was a topic mentioned the most often (cited by 12 parents; 80.0%), followed by sites of application (10 parents; 66.7%), quantity of application (7 parents; 46.7%), and duration of application (5 parents; 33.4%). When asked if they understood the content of the instruction, 12 parents (80.0%) answered "Understood," and 3 (20.0%) answered "Understood to some extent," indicating that all fifteen

**Table 2.** Content of instruction on how to apply ointment using topical steroids

Table 2. Content of histraction on how to a	pply official desirg topical steroids	n = 15
Period since the latest instruction		$1.2 \pm 1.9^{*}$
on how to apply ointment (years)		
Occupation of instructors	Physician	13
(multiple response)	Pharmacist	6
	Nurse	2
Method of instruction	Orally only	2 8
	Orally and brochures	3
	Orally and demonstrations	4
Content of instruction	Frequency of application	12
(multiple response)	Sites of application	10
•	Quantity of application	7
	Duration of application	5
	Order of application with moisturizers	3
	Strength of topical steroid	6
	Adverse reactions to topical steroids	1
Understanding of the content	Understood; Understood to some extent	15
instructed	Did not understand very much; Did not	0
	understand at all	
Agreement/satisfaction with the	Yes, I thought I could; I thought I could to some	15
instruction given (Did you think	extent	
that you'd do exactly as told?"	I did not think I could very much; I did not think	0
W. CD	I could at all	

parents answered that they "understood to some extent" or better. When asked about their agreement/satisfaction with the instruction given or, in other words, whether or not they thought that they were able to do exactly as they had been told, 14 participants (93.3%) answered "Yes, I thought so" and one (6.7%) answered "I thought so, to some extent," indicating that all fifteen parents answered that they "thought so, to some extent" or higher.

4. Items the parents were unable to implement despite having received instruction on the use of ointment, and the reasons why

Table 3 shows the items the participants were unable to implement despite having received instruction on the use of ointment, and the reasons why. Seven out of 12 parents (58.3%) were unable to comply with the application frequency prescribed. The reasons included "I forgot," "It's a bother," "I have no time," and "I cannot apply ointment at nursery school." Three out of five parents, or 60.0%, could not comply with the duration of application prescribed. The parents' answers included "Because symptoms improved," and "Worried about adverse reactions." Other than these, the results showed

that three out of seven parents (42.9%) were unable to comply with the quantity of application prescribed, and two out of ten parents (20.0%) were unable to comply with the sites of application prescribed. We tested correlations between items the parents were unable to implement despite having received instruction on the use of ointment, instruction method, and period since instruction, but found no items with significant differences. Analysis of period since the latest instruction and unpracticable contents (Frequency of application p = 0.929, Duration of application p = 0.329, Quantity of application p = 0.907, Site of application p = 0.258). Analysis of method of instruction and unpracticable contents (Frequency of application p = 0.432, Duration of application p = 0.800, Quantity of application p = 0.629, Site of application p = 0.267).

#### 5. Anxieties about topical steroids

Figure 1 shows the parents' anxieties about topical steroids. A majority of the parents indicated some degree of anxiety about using topical steroids, with five (31.3%) saying that they were "anxious," eight (50.0%) saying that they were "somewhat anxious," one (6.3%) saying that she was "not very anxious," and two

**Table 3.** Things the subjects are unable to put into practice despite receiving instruction on how to apply ointment

	Applicable subjects	Share (%)	Reasons for inability to put into practice
Frequency of application 12 targets	7	58.3	I forgot; It's a bother; Have no time; My child fell asleep; My child resists; Cannot apply ointment at nursery school
Duration of application 5 targets	3	60.0	Symptoms improved; Worried about adverse reactions
Quantity of application 7 targets	3	42.9	Worried about adverse reactions; it's sticky
Site of application 10 targets	2	20.0	I have no time; Worried about adverse reactions

(12.5%) saying that they were "not anxious."

Of those who answered that they were "somewhat anxious" or "anxious," four (30.8%) answered that they were reducing the frequency of application, and five (38.5%) were reducing the quantity of application, citing anxieties about topical steroids as the reason.

Regarding what types of adverse reactions they were anxious about, three, or the largest number of parents (23.1%), answered that they were not sure. Others mentioned "darkening of the skin," "thickening of the skin," "thinning of the skin," and "relapse of symptoms."

6. Relationship between the quantity of ointment applied, and instruction methods/anxieties about the use of topical steroids

Differences in the quantity of ointment applied were examined according to the method of instruction

(three groups: orally only, orally + brochures, and orally + demonstrations). No significant differences were seen among the three groups in terms of the quantity of ointment applied (p = 0.058; Kruskal-Wallis test). Pair-wise differences between the groups were examined using the Mann-Whitney U test. The results showed that the difference between "orally only" and "orally + brochures" was p = 0.085; the difference between "orally only" and "orally + demonstration" was p = 0.048, and the difference between "orally + brochures" and "orally + demonstration" was p = 1.000. The findings revealed that the quantity of ointment applied was significantly closer to an amount equivalent to 0.5 FTU with the instruction method including demonstrations, rather than "orally only." Even with instruction using a brochure, the quantity of ointment applied tended to be closer to the volume

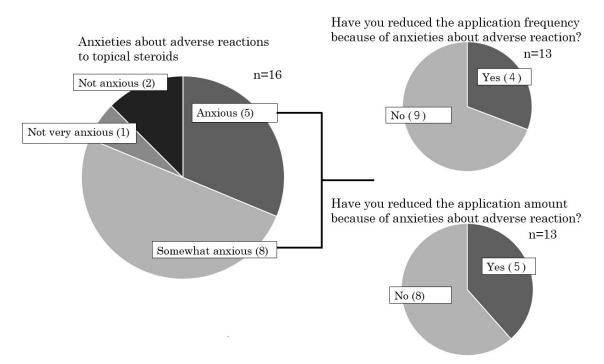


Figure 1. Anxieties about the adverse reactions to topical steroids, their influence on the treatment with ointment

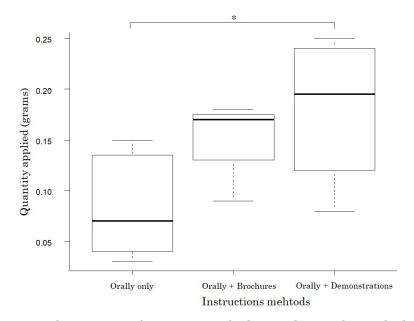
The charts above show the breakdown of the degree of anxieties. They also indicate the number of people who, among those who answered, "Am anxious" and "Am somewhat anxious," are reducing the application frequency and amount because of their anxieties.

equivalent to 0.5 FTU (Figure 2). There were no significant differences in the quantity of ointment applied vis-à-vis the parents' anxieties about topical steroids (Table 4).

#### IV. Discussion

In this study, we measured the amount of ointment applied by the parents, and found that the average quantity applied was smaller than an amount equivalent to 0.5 FTU. Insufficient quantity of topical steroids applied has been cited as one of the

reasons for delaying the improvement of AD symptoms (3). Our study showed that parents who had received instructions coupled with demonstrations were able to apply an amount of ointment that was close to the recommended 0.5 FTU. It is likely that providing instructions on the use of ointment not only orally, but also by using brochures and demonstrations, may promote better understanding on the part of the parents. The fact that instructions that incorporated a demonstration component, in particular, proved even more effective, was a finding



**Figure 2.** Differences in the quantity of ointment applied, according to the method of instruction Quantity of ointment applied by parents who had received instruction on how to apply ointment the most recently by "Orally only (n = 8)," "Orally + Brochures (n = 3)," and "Orally + Demonstrations (n = 4)." p < 0.05

**Table 4.** Relationship between anxieties about topical steroids, and the quantity of ointment applied

Anxious/ somewhat anxious about the adverse reactions to topical steroids  Reduced the quantity of topical steroids applied because of anxieties about $n$ mean $\pm$ SD $p$ $n$ mean $\pm$ SD $p$ $n$ $n$ mean $\pm$ SD $p$ $n$				Quantity of ointme	ent applied (g)
anxious about the adverse reactions to topical steroids  Those who did not apply $3$ Reduced the quantity of topical steroids applied because of anxieties about $0.12 \pm 0.07$ Subjects who applied $0.12 \pm 0.07$ N.s. $0.12 \pm 0.07$ $0.12 \pm 0.07$ $0.12 \pm 0.07$ $0.12 \pm 0.08$			n	$mean \pm SD$	p
reactions to topical steroids  Those who did not apply $3$ $0.11 \pm 0.06$ Reduced the quantity of topical steroids applied because of anxieties about $0.12 \pm 0.09$	anxious about the adverse reactions to topical	Subjects who applied	13	$0.12\pm0.07$	ns
topical steroids applied n.s.		Those who did not apply	3	$0.11\pm0.06$	11.5.
because of anxieties about n.s.	1	Subjects who applied	5	$0.12\pm0.09$	
them Those who did not apply $8   0.12 \pm 0.06$	because of anxieties about	Those who did not apply	8	$0.12\pm0.06$	n.s.

n.s.: not significant 8 Mann-Whitney U-test

similar to those noted in previous studies (7, 10). When providing instruction for the first time, therefore, it is deemed desirable to carry out demonstrationstyle instruction on the use of ointment, and educate the parents in a manner in which they can actually learn, firsthand, the quantity of ointment to apply (e.g. measuring the quantity applied, experience converting to an FTU quantity). However, it should be noted that this study did not assess the severity of the patients' AD. It is likely that healthcare providers instruct parents on the quantity of ointment to apply while monitoring the patients' symptoms and in relation to the severity of AD. We should, therefore, have assessed the degree of severity of the patients' symptoms as a factor in the quantity of ointment applied. According to the results of our study, however, the amount of ointment applied was small overall, with the minimum quantity being less than one-fifth the amount equivalent to 0.5 FTU. Thus, our findings suggest that if the symptoms do not improve as much as expected, the amount of ointment used should be assessed and, if the amount of ointment applied is found to be insufficient, provide instruction on the use of ointment again.

This study also examined two factors related to the quantity of ointment applied: anxiety about topical steroids on the part of the parents and the method of instruction on the use of ointment. With regard to anxieties about adverse reactions, no significant differences were seen between the "anxious" and "slightly anxious" group, and the "not very anxious" and "not anxious" group. One possible reason for this may have been that, because the parents in this study tended to use small amounts of ointment overall, and because the number of participants was small to begin with,

differences based on anxieties about adverse reactions to topical steroids were less likely to manifest. In this study, although anxieties about topical steroids did not affect the actual amount applied, we cannot state that anxieties about adverse reactions do not necessarily lead to aggravation of symptoms. Our findings showed that the adverse reactions feared by some parents were not very clear. We found that some parents held the erroneous view that the skin gets darker because of an adverse reaction to topical steroids, and deliberately reduced the frequency and amount of ointment applied due to their anxieties in this regard. It has been shown that mothers take the time to acquire self-care or selfmanagement behavior through repeated trial and error and by learning from their child's reactions (9). In providing instruction on the use of ointment, it is important to not only explain the method of application, but also to discuss with the parents the potential outcomes of discontinuing medication based on personal or unscientific views. It is also necessary to emphasize the need to not adjust the quantity of topical steroids used, and to provide information about adverse reactions.

Regarding treatment with ointment containing topical steroids, a majority of the parents had undergone instruction on the use of this medication, with over half having received the most recent instruction within the last year. One reason for this may be the Clinical Practice Guidelines for Atopic Dermatitis, which stresses the importance of patient and parent education (6), and the awareness, on the part of a growing number of hospitals and clinics, of the importance of providing instruction on the use of ointment. On the other hand, however, we learned that, although parents who had received instruction on the use of

ointment tried to comply exactly with what they had been taught, many in fact were unable to do so. Of particular note was that over half of the parents who had received instruction answered that they were unable to comply with the prescribed application frequency and duration, citing reasons such as "I forgot," "it's a bother," and "the symptoms improved." These reasons show that, even though the parents' motivation to provide treatment rose temporarily after receiving instruction on the use of ointment, they were unable to maintain adherence. Past studies have also emphasized the importance, when making nursing interventions in AD, of enhancing the caregivers' sense of selfefficacy, by having them realize that their children's symptoms are actually improving, and to continue with regular interventions (10, 11). It is therefore important to provide instruction on applying ointment using topical steroids not just once, but regularly, (i.e., at each hospital visit) by focusing on the key points. Moreover, as the child ages the primary provider of medical care, such as treatment with ointment, will gradually shift from the parents to the children themselves. This means that healthcare providers must take the child's developmental stage into consideration and offer instruction not only to the parents but also to the children themselves.

#### V. Conclusion

Our study of instructions given to parents on the use of topical steroids suggested the following:

- Almost all (93.8%) of the parents had undergone instruction on the use of topical steroids.
- Even though the parents received instruction on how to apply ointment and understood its content, there were things they were unable to implement. Notably,

over half of the parents were unable to comply with the required application frequency or treatment duration of topical steroids.

This study was novel in that we measured the actual quantity of ointment applied by parents in order to examine the relationship between the quantity of topical steroid applied and the method of instruction. This examination revealed the following:

- The average quantity of ointment that the parents had applied to an area of the skin equivalent to a palm was 0.12 g, less than half of the recommended quantity of one-half of a Fingertip Unit, or FTU (0.25 g).
- Regarding the relationship between the quantity of ointment applied and the method of providing instruction, the quantity of ointment used by parents who had received instruction "orally + demonstrations by medical professionals" was close to the recommended quantity of FTU (0.25 g).

# VI. Limitations of the study and future tasks and challenges

This study investigated sixteen parents, and examined the understanding of the mothers after receiving instruction on applying ointment as well as the status of care provided at home. Since all the participants were mothers of pediatric patients, however, there is a possibility that the results would have differed from those of this study had the care providers been individuals other than the mother. There are also cases where the quantity may differ from the appropriate, recommended amount, or 0.5 FTU, depending on the severity of the children with AD, such as when applying ointment over a wide area of the body, or when no improvements are seen due to the symptoms being severe. Because this study did not impose restrictions on the degree of severity, and since the number

of participants was not very large, there are limitations to generalizing our findings. Moving forward, therefore, there is a need to carry out additional studies and increase the number of participants to assess the effects of varying degrees of severity as well as the wide range of family situations.

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#### アトピー性皮膚炎をもつ患児の保護者の軟膏処置に関する実態調査

杉村篤士 1、松本裕 1、赤瀬智子 2、佐藤朝美 3、山川有子 4、高橋さなみ 5、相原道子 6

- 1) 東海大学医学部看護学科
- 2) 横浜市立大学大学院医学研究科看護生命科学分野
- 3) 横浜市立大学大学院医学研究科小児看護学分野
  - 4) 山川皮ふ科
  - 5) ひぎりやま皮ふ科
- 6) 横浜市立大学大学院医学研究科環境免疫病態皮膚科学

#### 要旨

アトピー性皮膚炎の治療では、ステロイド外用薬を使用した軟膏処置が主軸を成している。そこで、本研究はアトピー性皮膚炎をもつ児の保護者がステロイド外用薬についてどのような軟膏指導を受けているかを調査するとともに、実際の軟膏塗布量を計測し、軟膏指導の方法や内容及びステロイド外用薬への不安と、軟膏塗布量の関係を調査した。

手のひら1枚分の広さにステロイド外用薬を塗布してもらった結果、軟膏塗布量は0.04~0.25gで、平均塗布量と標準偏差は0.12±0.07gであった。軟膏塗布量は口頭+実演による指導を受けた保護者の方がFTU換算量に近かった。副作用の不安については、「ある」5名、「少しある」8名の回答が8割以上を占めた。本研究の新規性は保護者の実際の軟膏塗布量を測定しステロイド外用薬指導について検討した論文である。

**キーワード**:アトピー性皮膚炎、軟膏処置、小児、保護者、ステロイド外用薬、ステロイドフォビア、アドヒアランス