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Topical corticosteroid phobia in atopic dermatitis: international feasibility study of the TOPICOP score

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Abstract

Background: Adherence to topical corticosteroids (TCS) is essential for the effective treatment of atopic dermatitis but can be limited by concerns about their use. This study examined the feasibility of applying the validated TOPICOP score for assessing TCS phobia across different countries.

Methods: This was a prospective multicenter feasibility study conducted in 21 hospitals in 17 countries. Patients >3 months of age with atopic dermatitis or their parents or legal representatives completed a validated translation of the TOPICOP questionnaire in the country's native language. Respondents also completed questionnaires collecting opinions about the feasibility and acceptability of the TOPICOP questionnaire.

Results: 1564 participants in 15 countries were included in the analysis. 81% of respondents considered the questions clear or very clear and 79% reported that it took less than 5 min to complete. Each of the individual items in the TOPICOP questionnaire was considered to be not at all difficult to answer by 49% to 74% of participants. The mean global TOPICOP score was $44.7\% \pm 20.5$. Mean TOPICOP subscores were $37.0 \pm 22.8\%$ for knowledge and beliefs, $54.7 \pm 27.8\%$ for fears, and $50.1 \pm 29.1\%$ for behaviours. Global scores and subscores differed between countries, although the subscores did not always vary in parallel, suggesting different levels of TCS phobia and different drivers for each country.

Conclusions: The TOPICOP score can be feasibly applied across countries and may therefore be useful for obtaining qualitative and quantitative data from international studies and for adapting patient education and treatment.

Key words: atopic dermatitis; corticosteroid; adherence

Introduction

Atopic dermatitis (AD), also known as atopic eczema, is a common inflammatory skin condition (1). Topical corticosteroids (TCS) associated with emollients are first-line therapeutic agents for AD (2, 3). Adherence to treatments is low in chronic disease—only 50% of prescribed treatments are actually used by patients—and even lower for chronic skin disease (4, 5). Adherence to topical treatments is a key issue in AD, and the failure to treat AD successfully can often be directly linked to poor treatment adherence (6). The efficacy and safety of TCS, when used appropriately, has been well established (7). Unfortunately, parents and patients often have many beliefs and concerns about TCS, frequently referred to as TCS “phobia” or “corticophobia”, although this is not a true phobia but rather a collection of fears, beliefs, and behaviours associated with avoidance (8, 9).

TCS phobia is a frequent, complex, and widespread phenomenon. A 1998 survey in Nottingham, UK found rates of 70% in adult patients and 73% in parents of children with AD (8), and 2009 survey in France found that 81% of parents of children with AD had fears about TCS and 36% admitted poor adherence to treatment (9). Similarly, a 2013 survey in South Korea found TCS phobia in 67.5% of parents of children with AD (10). Possible causative factors for TCS phobia include patients’ personal experiences of previous side effects and misinformation from media or healthcare providers (9-14). Whether the contributing factors and rates differ between countries and cultures is unknown because TCS phobia has not been compared across different countries using the same tool.

The Topical Corticosteroid Phobia (TOPICOP) score is based on 12 items assessing the three different dimensions of TCS phobia (fears, beliefs, and reluctance to use topical steroids), each scored on a 4-point Likert scale (9). TOPICOP is currently the only score validated to explore TCS phobia. A previous study demonstrated that the TOPICOP score has very good

psychometric properties (15), but the questionnaire remains to be validated for international use. Here, we report the results of a large international study that evaluated the feasibility and comprehensibility of the TOPICOP score.

Methods

This was a prospective multicenter study conducted at 21 hospitals in 17 countries (Australia, Belgium, Brazil, Canada, Denmark, France, Germany, Hungary, Japan, Mexico, Poland, Sweden, Ukraine, United States and Taiwan) between May 2014 and August 2015. Members of the Opened Dermatology network (<http://opened-dermatology.com/>) were invited to participate as investigators. The objective of the study was to validate the feasibility and comprehensibility of the TOPICOP score across different countries. The study was approved by the Nantes University Hospital Ethics Committee (Nantes, France) and by the ethics review board for each institution.

Patients >3 months of age with AD or their parents or legal representatives at the included hospitals were invited to participate. To be included in the study, patients had to meet the United Kingdom Working Party definition of AD (16). During the recruitment period and before consulting with a physician, consecutive AD patients at each site, or for patients <7 years of age, their parents or legal representatives, completed the TOPICOP questionnaire (15). The TOPICOP questionnaire includes 12 items assessing concerns about TCS scored on a 4-point Likert scale. Depending on the question, the scale was from never to always (0=never, 1=sometimes, 2=often, 3=always) or from totally disagree to totally agree (0=totally disagree, 1=do not really agree, 2=almost agree, 3=totally agree). Patients or their legal guardians also completed a questionnaire asking the following: whether the respondent considered the form difficult to fill in (not at all difficult, not very difficult, a little difficult, very difficult); whether the questions were clear (not at all clear, not very clear, very clear,

extremely clear); how long it took to complete the questionnaire (less than 5 min, 5–10 min, more than 10 min); and for each of the 12 items in the TOPICOP questionnaire, whether it was difficult to answer the question (not at all difficult, not very difficult, a little difficult, very difficult). For each country, the questionnaire was translated by an official translator and validated by a clinical expert who was a native speaker of the language. The questionnaire was provided to and completed by participants using an electronic device (iPad®, Apple Computers, Cupertino, CA). Anonymous data were transferred via internet to the Clinical Research Center at Nantes University Hospital.

Statistical Analysis

Sites were included in the analysis if they had enrolled at least 40 participants. Missing data were not replaced. As described previously (15), the global TOPICOP score and domain subscores for each participant was calculated as 100% times the sum of all responses divided by the maximum possible sum for the included questions, resulting in a score of 0% to 100% TCS phobia.

Results

A total of 1796 participants at 21 sites in 17 countries were included and answered questionnaires (**Figure 1**). Participants from The Netherlands (n=19) and the UK (n=1) were not included in the analysis because fewer than 40 participants were recruited in each.

Another 212 participants were excluded from the analysis due to errors in data entry. Thus, the analysis included responses from 1564 participants at 19 sites in the following 15 countries: Japan (n=287), Canada (n=185), France (n=154), Belgium (n=153), Poland (n=123), Hungary (n=101), Ukraine (n=98), Sweden (n= 88), Denmark (n=86), Taiwan (n=61), Germany (n=50), Brazil (n=48), the US (n=46), Australia (n=44), and Mexico (n=40). Most participants (n=1252; 80.1%) were <18 years of age. For children < 8 years of

age (n=890), questionnaires were answered by the parents or legal guardians. For all cases (n=674), questionnaires were answered by the patient.

Intelligibility of the TOPICOP questionnaire

Overall, 81% of respondents considered the 12 items in the TOPICOP questionnaire to be clear or very clear (**Table 1**). Approximately the same proportion (79%) reported that it took less than 5 min to complete the questionnaire. Most of the remainder (19%) reported that it took 5 to 10 min to complete.

The individual items in the TOPICOP questionnaire were considered to be “not at all difficult” by 49–74% of participants (**Table 2**). Overall, most of the individual items were considered easy to answer. The most difficult to answer items were in the knowledge/belief dimension, where 9–23% found the items extremely or very difficult to answer. The three most difficult to answer items were “TCS pass into the bloodstream” (item 1), “TCS can lead to infections” (item 2), and “TCS can lead to asthma” (item 6). Items about behaviour appeared to be the easiest to answer, with 72–74% reporting the items not at all difficult to answer and only 9–10% very or extremely difficult to answer. For all 12 items combined, only 13% were considered very or extremely difficult.

TOPICOP scores and subscores

The mean global TOPICOP score was $44.7 \pm 20.5\%$. In the full population, the subscores were $37.0 \pm 22.8\%$ for the knowledge and beliefs domain, $54.7 \pm 27.8\%$ for the fears domain, and $50.1 \pm 29.1\%$ for the behaviour domain.

Mean global TOPICOP scores varied by country and were highest for Poland, Ukraine, and Taiwan and lowest for Germany, Denmark, and Brazil (**Figure 2**). As with the global TOPICOP scores, the different subscores for each country varied, although not necessarily in parallel with each other or with the global scores. For example, although Japan and Mexico

had similar global TOPICOP scores and similar fears subscores, their behaviour and knowledge & beliefs subscores differed substantially.

Discussion

TOPICOP is currently the only score validated to explore TCS phobia in AD. A study in a French population demonstrated that the TOPICOP questionnaire and score has very good psychometric properties, meaning that it reliably measures concerns and beliefs about TCS (15). The current analysis, which included 1564 respondents in 15 countries, showed that the TOPICOP questionnaire was considered by most to be easy to answer and to require less than 5 min to complete.

Overall, most of the individual items were considered easy to answer. The most difficult to answer were “TCS pass into the bloodstream”, “TCS can lead to infections”, and “TCS can lead to asthma” (item 6), which is not surprising because, for some of these items, even medical professionals have not reached a consensus due to conflicting evidence (2).

TOPICOP scores were highest, and therefore TCS phobia most pronounced, in Taiwan, Poland, and Ukraine, whereas scores were lowest and TCS phobia least pronounced in Japan, Brazil, and Denmark. Based on the overall TOPICOP score, the average level of corticophobia for all included countries was 44%. However, the overall score differed substantially between countries (from 35% to 58%). Corticophobia is a complex phenomenon and can be affected by doctors’ attitudes and messaging as well as multiple other factors that can differ in each country. Factors that can affect corticophobia in each country include the time taken by the doctor to counsel patients, the health system, the educational programs in place, nurse involvement, patients’ socio-professional situations, the system for dispensing medicine, and cultural attitudes (17). Even within a single country, clinical settings and some of these factors can differ. Furthermore, different or discordant dimensions can lead to

identical overall scores. In cases where countries have similar global scores, such as Japan and Mexico, reasons can differ: for these two countries, behaviour dimensions of TCS phobia were more dominant in Japan, whereas the knowledge & beliefs dimensions were more dominant in Mexico.

In addition to the original French version (15), a Japanese translation of TOPICOP was recently described (18). Here, we showed that the TOPICOP questionnaire and score were easily applied to another 15 countries. The results confirmed that, globally, reticence to using TCS is common.

The study was not designed and did not include a statistical analysis that would allow the main drivers of TCS phobia to be determined, nor did it include adjustments for potential confounders including differences in respondent demographics. This has been examined many studies around the world (6, 8, 10, 11, 13-15, 19, 20), although this was the first to assess TCS phobia using the same methodology across many countries. TOPICOP should therefore be useful for obtaining quantitative and qualitative data about TCS phobia from international studies and for creating personalized education and treatment.

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Conflicts of interest statement

The authors declare no conflicts of interest related to this study.

Author contributions

All authors contributed to the design and conduct of the study, collection and analysis of data, reviewing and revising the manuscript, and approving the final submitted version of the manuscript.

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Figure legends

Figure 1. Flow of patients included in the study

Figure 2. TOPICOP scores and subscores by country

Participants completed the 12 items in the TOPICOP questionnaire (see Table 2) on a 4-point Likert scale. Depending on the item, the scale was from never to always (0=never, 1=sometimes, 2=often, 3=always) or from totally disagree to totally agree (0=totally disagree, 1=do not really agree, 2=almost agree, 3=totally agree). TOPICOP scores and subscores ranged from 0% (no concern/fear) to 100% (maximum concern/fear). The dashed box highlights the findings from Japan and Mexico, which had similar global TOPICOP scores and fears subscores but, as highlighted by the numbers in bold, substantially different behaviour and knowledge & beliefs subscores.

Figure 3. TOPICOP questionnaire

Shown is the English language version of the TOPICOP questionnaire. Foreign language translations are available at <http://www.edudermatologie.com>.

Table 1. Clarity and time to complete the TOPICOP questionnaire

Topic	n	%
Overall clarity of the questionnaire	N=1556	
Extremely clear	686	44.1
Very clear	590	37.3
Somewhat unclear	267	17.2
Not at all clear	23	1.5
Time to complete the questionnaire	N=1557	
<5 min	1236	79.4
5–10 min	289	18.6
>10 min	32	2.1

Participants were asked to rate the overall clarity of the 12 items included in the TOPICOP questionnaire and the time to complete it. Missing responses were excluded.

Table 2. Difficulty answering each question

Dimension	No.	Item	N	n (%)			
				Extremely difficult	Quite difficult	A little difficult	Not at all difficult
Knowledge & beliefs	1	TCS pass into the bloodstream	1555	118 (7.6)	246 (15.8)	425 (27.3)	766 (49.3)
	2	TCS lead to infections	1542	81 (5.3)	201 (13.0)	401 (26.0)	859 (55.7)
	3	TCS make you fat	1541	60 (3.9)	150 (9.7)	304 (19.7)	1027 (66.6)
	4	TCS damage your skin	1540	52 (3.4)	133 (8.6)	364 (23.6)	991 (64.4)
	5	TCS will affect your future health negatively	1409	63 (4.5)	64 (4.5)	425 (30.2)	857 (60.8)
	6	Using TCS can lead to asthma	1539	76 (4.9)	204 (13.3)	339 (22.0)	920 (59.8)
Fears	7	I'm afraid of putting TCS cream on certain zones like eyelids	1538	49 (3.2)	131 (8.5)	304 (19.8)	1054 (68.5)
	8	I don't know of any side effects but I'm still afraid of TCS	1539	70 (4.5)	134 (8.7)	332 (21.6)	1003 (65.2)
	9	I'm afraid of applying too much TCS cream	1536	31 (2.0)	113 (7.4)	268 (17.4)	1124 (73.2)
Behaviour	10	I wait as long as I can before treating with TCS	1537	49 (3.2)	105 (6.8)	280 (18.2)	1103 (71.8)
	11	I stop the TCS treatment as soon as I can	1537	49 (3.2)	105 (6.8)	280 (18.2)	1103 (71.8)
	12	I need reassurance about TCS	1516	48 (3.2)	96 (6.3)	252 (16.6)	1120 (73.9)

Participants were asked to rate the difficulty of each of the 12 items in the TOPICOP questionnaire as extremely difficult, quite difficult, a little difficult, or not at all difficult.

Missing responses were excluded.

Responded to questionnaires

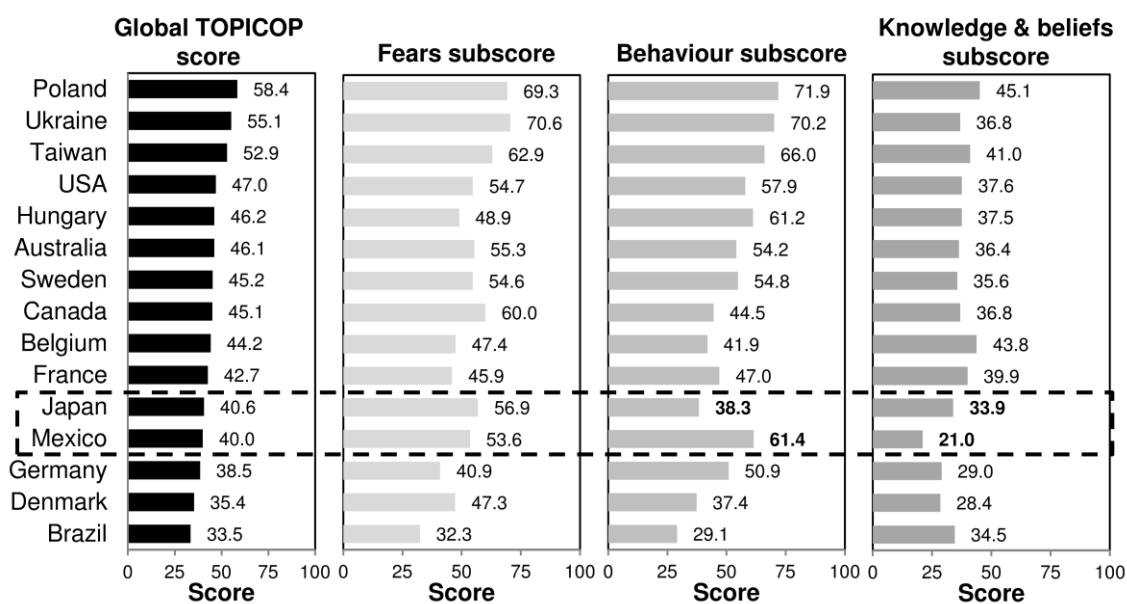
N=1796
21 sites in 17 countries

Data entry errors
N=212

<40 respondents per country
UK N=1
Netherlands N=19

Included in analysis

N=1564
19 sites in 15 countries



TOPICOP

Your doctor has prescribed or is prescribing topical corticosteroids for you or your child, to be applied to the affected skin. Through this questionnaire we would like to know your feelings about this type of treatment.

For each question, mark the answer that best fits your opinion.

Mark **one** box per line

Topical corticosteroids can be absorbed into the bloodstream.

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

Topical corticosteroids can lead to infections.

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

Topical corticosteroids can make you fat

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

Topical corticosteroids damage your skin.

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

Topical corticosteroids will affect your future health negatively

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

Using topical corticosteroids can lead to asthma.

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

I am afraid of putting topical corticosteroids on certain skin areas such as eyelids.

☐ Absolutely not ☐ Not really ☐ A little ☐ Absolutely ☐ I do not understand the

I do not know of any side effects, but I am still afraid of using topical corticosteroids

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

I am afraid of applying too much topical corticosteroids.

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement

I wait as long as I can before treating myself or my child with topical corticosteroids.

☐ never ☐ sometimes ☐ often ☐ always ☐ I do not understand

I stop topical corticosteroid treatment as soon as I can.

☐ never ☐ sometimes ☐ often ☐ always ☐ I do not understand

I need reassurance about topical corticosteroids.

☐ Not at all ☐ Not really ☐ To some extent ☐ Absolutely ☐ I do not understand the statement