

Predictors of Topical Corticosteroid Adherence Among Caregivers of Children with Atopic Eczema

Elaine Li Fong Liew¹, Noraida Mohamed Shah¹, Wei Wen Chong¹, Latha R Selvarajah²,
Umami Syahida Sulaiman¹, Nirmala Ponnuthurai³

¹Centre of Quality Management of Medicine, Faculty of Pharmacy, Universiti Kebangsaan Malaysia, Jalan Raja Muda Campus, Jalan Raja Muda Abdul Aziz, Kuala Lumpur, Kuala Lumpur, 50300, Malaysia; ²Dermatology Department, Hospital Sultan Ismail, Jalan Persiaran Mutiara Emas Utama, Taman Mount Austin, Johor Bahru, 81100, Malaysia; ³Pediatric Dermatology Unit, Pediatric Department, Hospital Tunku Azizah, Jalan Raja Muda Abdul Aziz, Kuala Lumpur, Kuala Lumpur, 50300, Malaysia

Correspondence: Noraida Mohamed Shah, Centre of Quality Management of Medicine, Faculty of Pharmacy, Universiti Kebangsaan Malaysia, Jalan Raja Muda Campus, Jalan Raja Muda Abdul Aziz, Kuala Lumpur, Kuala Lumpur, 50300, Malaysia, Tel +60392898038, Email noraida_mshah@ukm.edu.my

Purpose: Poor adherence to topical treatment regimens is linked to treatment failure and results in using systemic agents with more toxic effects. Studies on the factors that affect caregivers' adherence, especially in using topical corticosteroid (TCS) are still lacking. This study aims to determine the adherence score to TCS among caregivers of children with atopic eczema (AE) and the predictors of their adherence.

Patient and Methods: Caregivers of children with AE who used TCS in the past three months at the dermatology clinic of two major hospitals were recruited to complete a self-reported survey on the child's eczema severity, degree of TCS phobia using TOPICOP© and caregivers' adherence to TCS using a 12-item medication adherence scale. Multiple linear regression was utilised to determine the predictors of caregivers' adherence.

Results: Responses were received from 121 caregivers, with mean age of 35.9 years (SD ± 5.43) and 73.6% (n = 89) were females. The mean global TOPICOP© score was 25.4% (SD ± 14.5) and the mean adherence score was 48.5 (SD ± 6.6; maximum score = 60). Severe eczema (B = 4.330, CI 1.907 to 6.754, p < 0.001) and those who do not know the name of their child's medication (B = 6.922, CI 2.126 to 11.718, p < 0.05) were positive predictors of TCS adherence. TCS phobia was a negative predictor of TCS adherence (B = -0.300, CI -0.449 to -0.510, p < 0.001).

Conclusion: Caregivers of children with AE showed good adherence score towards TCS use. Addressing TCS phobia may improve TCS adherence among caregivers of children with AE.

Keywords: atopic eczema, caregivers, topical corticosteroid adherence, topical corticosteroid phobia, predictors

Introduction

The chronicity of atopic eczema (AE) causes a wide range of complications such as skin infections,^{1,2} ophthalmic comorbidities^{3,4} and increased burden on the mental health and the quality of life of patients.^{5,6} The negative impact on the caregivers' quality of life was more severe or comparable to prevalent paediatric chronic diseases, such as congenital heart disease and psychiatric disease.⁷

The mainstay of AE treatment is to apply emollients at any stage of eczema and the use of topical corticosteroids (TCS) during flares.^{8,9} AE patients who are on topical medications have the lowest mean adherence score in a study on adherence among five dermatological diseases.¹⁰ Poor adherence to topical treatment regimens is linked to failure in treating the eczema^{11,12} and result in using systemic agents with more toxic effects.¹³ As children are still under the care of their parents, medication adherence depends on the knowledge, motivation and ability to follow through the instructions given by the child's health care professional.^{14,15} However, studies on the factors affecting caregivers'

adherence, especially in using TCS are still needed. Thus, our study aims to determine adherence score to TCS among caregivers of children with AE and the predictors of their adherence to TCS.

Materials and Methods

This cross-sectional study was conducted between December 2022 and June 2023 at the outpatient clinics of Hospital Tunku Azizah, a national pediatric dermatology referral center and Hospital Sultan Ismail, a tertiary hospital in Malaysia. Caregivers of children with AE presented at the clinic for their child's appointment were screened for eligibility and invited to enrol in the study. Data were collected using self-reported questionnaires either in English or Malay Language.

Inclusion criteria were caregivers of children less than 12 years old with confirmed diagnosis of AE (according to the UK Working Party's Diagnostic Criteria for Atopic Dermatitis¹⁶) by a pediatrician and prescribed with TCS for the past 3 months. These were sourced from electronic medical records. Those with incomplete medical records; caregivers who did not understand either English or Malay Language; and those whose children with other major skin or systemic diseases were excluded. The sample size required was 120 subjects, following the sample size recommendation by Sackett et al (1991) to investigate a total of 10 factors or predictors of adherence to TCS.

There were five sections to the questionnaire. Subjects completed the questionnaire within 25 minutes. Section one and two obtained socio-demographic data of the child and caregiver (age, gender, education level and household income). Section three was on the clinical data of the child including AE severity. Patient-Oriented Eczema Measure (POEM) questionnaire was used to measure the AE severity from the perspective of the caregivers by asking about the frequency of seven symptoms during the past seven days on a four-point Likert scale: (0) No Days; (1) 1–2 Days; (2) 3–4 Days; (3) 5–6 Days; (4) Every Day with a maximum score of 28. Higher scores indicate a higher disease severity. The interpretation of the score is as follow: 0–2 Clear or almost clear; 3–7 Mild eczema; 8–16 Moderate eczema; 17–24 Severe eczema; 25–28 Very severe eczema.¹⁷ In section four, caregivers filled up the Topical Corticosteroid Phobia (TOPICOP©) questionnaire, which measures the worries and beliefs about TCS. TOPICOP© comprises of 12 items divided into three dimensions which are “knowledge and belief”, “fear” and “behaviour”. Caregivers responded using a four-point Likert scale (score range 0–3: 0 = never, 1 = sometimes, 2 = often and 3 = always; or 0 = totally disagree, 1 = do not really agree, 2 = almost agree and 3 = totally agree) to a maximum of 36 with higher scores reflecting more severe phobia. The maximum score for TOPICOP© is 36 where higher scores reflect more phobia. Global TOPICOP© score and domain sub-scores were calculated as a percentage of the sum of all answered questions, which results in a score between 0% and 100%.¹⁸ The final section used the 12-item Medication Adherence Scale (MAS) to assess caregivers' adherence toward TCS on their children, which was also the outcome measured. This scale consisted of 12 items and had four categories, which include measurement of treatment, collaboration with healthcare providers, willingness to access and use information about treatment, and acceptance to take treatment and how taking treatment fits patients' lifestyles. The scale has a maximum score of 60, with higher scores indicating greater adherence.¹⁹ Words in this scale have been changed to suit administration of topical medications, for example take “my medication” was altered to “apply the medication”. Permission to use all questionnaires, including where changes were made was obtained from the original authors prior to its use. For the translation of TOPICOP© and the 12-item MAS into the Malay version, a standard “forward-backward” method was used. The Malay version of the questionnaire was pretested among 12 caregivers of children with AE to check for language clarity and to verify its feasibility prior to study initiation. Results of the pretest were not included in the final analysis. There were no major issues from the pretesting of the Malay questionnaire.

Statistical Analysis

Continuous variables were expressed as mean and standard deviation (SD) and median and interquartile (IQR) range. Descriptive statistics were used to provide an overview of the subjects recruited in this study. Socio-demographic data for the subjects were expressed as proportions (for dichotomous variables) or mean with standard deviation (for continuous variables), where appropriate. The relationship between medication adherence and the caregivers' socio-demographic data (age, gender, education level, household income), disease severity and TCS phobia scores was first evaluated by linear regression analysis. Thereafter, variables which were found to have a statistically significant relationship with medication adherence were then evaluated again using multiple linear regression analysis. A p-value of <0.05 was set as

statistical significance. The data analysis was performed using the IBM® Statistical Package for Social Sciences (SPSS) Desktop version 26 for Windows.

Ethical Consideration

This study was approved by the Medical Research and Ethics Committee, Ministry of Health, Malaysia (NMRR-22-00960-ITH (IIR)) and the Research Ethics Committee, Universiti Kebangsaan Malaysia (UKM PPI/111/8/JEP-2022-499). All procedures were conducted in compliance with the ethical standards established in the 1964 Declaration of Helsinki and its subsequent amendments. Patient information sheet was used to explain the study to potential participants. Those who agreed to participate signed the informed consent prior to study commencement.

Results

A total of 156 caregivers were approached and 121 of them agreed to participate and filled up the questionnaire (response rate of 77.6%). The mean age of the participants was 35.96 ± 5.43 years. Majority of them were females ($n = 89$, 73.6%) and Malays ($n = 107$, 88.4%). The most prescribed TCS was betamethasone valerate cream in varying strengths from 0.0125% up to 0.1% ($n = 88$, 72.7%). Seven caregivers (5.8%) did not know the name of the medication their child was on. A total of 39 subjects reported their child of having moderate eczema (32.2%) (Table 1). The mean global TOPICOP® score was $25.4 \pm 14.5\%$. The mean scores were $20.2 \pm 14.6\%$, $34.7 \pm 20.1\%$ and $26.3 \pm 22.9\%$ for knowledge and beliefs, fear and behaviour domains, respectively (Table 2). The mean MAS score was 48.54 ± 6.59 and Table 3 shows the score for each category in the MAS scale, with the category “collaboration with healthcare providers” having a score of 13.

Table 1 Subject Characteristics and Clinical Data ($n=121$)

Characteristics	Total ($n=121$)
Age of child, mean (SD), years	4.94 (3.28)
Male child, n (%)	65 (53.7)
Age of caregiver, mean (SD), years	35.96 (5.43)
Female caregiver, n (%)	89 (73.6)
Caregiver's Ethnicity, n (%)	
Malay	107 (88.4)
Chinese	7 (5.8)
Indian	5 (4.1)
Others	2 (1.7)
Caregiver's highest education level, n (%)	
Primary school	1 (0.8)
Secondary school	27 (22.3)
Pre-university/college	32 (26.4)
University	61 (50.4)
Caregiver's household income per month, n (%)	
Below RM3,000	23 (19)
RM3,000 – RM5,000	50 (41.3)
RM5,000 – RM10,000	40 (33.1)
Above RM10,000	8 (6)
Length of duration on TCS, mean (SD), years	3.27 (2.71)

(Continued)

Table 1 (Continued).

Characteristics	Total (n=121)
Using additional treatments besides prescribed TCS, n (%)	
Yes	27 (22.3)
No	94 (77.7)
Types of TCS prescribed by physician, n (%)	
Hydrocortisone 1%	74 (61.2)
Clobetasone butyrate 0.05%	16 (13.2)
Betamethasone valerate (0.0125%, 0.025%, 0.05%, 0.1%)	88 (72.7)
Mometasone furoate 0.1%	19 (15.7)
Clobetasol propionate 0.05%	4 (3.3)
Does not know the name of the medication	7 (5.8)
Having other comorbidities (asthma, allergic rhinitis), n (%)	
Yes	21 (17.4)
No	100 (82.6)
Disease severity (based on POEM scores), n (%)	
Clear or almost clear	14 (11.6)
Mild eczema	34 (28.1)
Moderate eczema	39 (32.2)
Severe eczema	28 (23.1)
Very severe eczema	6 (5.0)

Abbreviations: POEM, Patient-Oriented Eczema Measure; TCS, Topical corticosteroids; RM, Ringgit Malaysia; SD, Standard deviation; RM, Ringgit Malaysia.

Table 2 Domains of TCS Phobia Based on TOPICOP® Scale

Dimension	Domain Subscore (n=121) Mean \pm SD (%)
Knowledge and belief	20.2 \pm 14.6%
Fears	34.7 \pm 20.1%
Behaviour	26.3 \pm 22.9%
Global TOPICOP® score	25.4 \pm 14.5%

Abbreviations: TOPICOP®, Topical Corticosteroid Phobia questionnaire; SD, Standard deviation.

Table 3 The MAS Score According to Each Category

Category	Category Subscore
Medication compliance	12.21 (2.51) ^a
Collaboration with healthcare providers	13.00 (2.19) ^b
Willingness to access and use information about medication	11.36 (2.86) ^a
Acceptance to take medication and how taking medication fits patient's lifestyle	11.96 (2.09) ^a

Notes: ^aMean (SD) with maximum score of 15; ^bMedian (IQR) with maximum score of 15.

Abbreviations: MAS, 12-item Medication Adherence Scale.

Predictors of TCS Adherence

Both univariate and multivariate analyses of the results revealed that severe AE was a positive predictor of higher MAS score ($B = 4.177$, $CI\ 1.416\ to\ 6.938$, $p < 0.001$ and $B = 4.330$, $CI\ 1.907\ to\ 6.754$, $p < 0.001$, respectively). TCS phobia was a negative predictor of MAS scores in both univariate and multivariate analyses ($B = -0.339$, $CI\ -0.502\ to\ -0.176$, $p < 0.001$ and $B = -0.300$, $CI\ -0.449\ to\ -0.51$, $p < 0.001$, respectively). Caregivers that did not know the name of their child's TCS were a positive predictor of higher MAS scores when analysed using with univariate ($B = 9.784$, $CI\ 4.927\ to\ 14.642$, $p = 0.000$) and multivariate analyses ($B = 6.922$, $CI\ 2.126\ to\ 11.718$, $p < 0.05$). Other variables did not show any significant relationship with MAS scores (Table 4).

Table 4 Univariate and Multivariate Regression Analyses on Variables of Medication Adherence

Variables	Pearson Correlation	Crude Regression Coefficient			Adj. Regression Coefficient		
	r	B	95% CI	p-value	B	95% CI	p-value
Disease severity (POEM)		1.348	(0.245, 2.452)	<0.05			
Clear or almost clear		-1.539	(-5.304, 2.225)	0.42			
Mild eczema		-1.397	(-4.071, 1.278)	0.303			
Moderate eczema		-1.984	(-5.497, 1.529)	0.263			
Severe eczema	0.265	4.177	(1.416, 6.938)	<0.05	4.330	(1.907, 6.754)	<0.001
Very severe eczema		2.1	(-3.449, 7.649)	0.455			
TCS Phobia (TOPICOP®)	-0.353	-0.339	(-0.502, -0.176)	<0.001	-0.300	(-0.449, -0.51)	<0.001
Child's Age		-0.039	(-0.409, 0.331)	0.834			
Child's Gender		1.222	(-1.189, 3.634)	0.318			
Child's Ethnicity							
Caregiver's age (years)		0.127	(-0.995, 0.349)	0.261			
Caregiver's Gender		0.685	(-2.049, 3.420)	0.621			
Caregiver's Ethnicity		0.133	(-1.951, 2.217)	0.9			
Caregiver's Religion		1.012	(-1.631, 3.654)	0.45			
Caregiver's highest education level		0.19	(-1.263, 1.643)	0.796			
Primary		10.583	(-2.615, 23.781)	0.115			
Secondary		-0.554	(-3.452, 2.345)	0.706			
College		-1.025	(-3.457, 1.706)	0.459			
University		0.835	(-1.576, 3.245)	0.494			
Caregiver's household income per month (Ringgit Malaysia, RM)		0.714	(-0.713, 2.140)	0.324			
Less than 3000		0.29	(-2.787, 3.367)	0.852			
3000-5000		-1.2	(-3.642, 1.242)	0.333			
5000-10,000		-0.268	(-2.834, 2.299)	0.837			
More than 10,000		4.948	(0.172, 9.724)	<0.05	4.114	(-0.17, 8.245)	0.051
Number of children below 12 years old at home		-0.281	(-1.496, 0.935)	0.648			
Duration of disease (years)		-0.212	(-0.776, 0.351)	0.458			
Type of TCS used							
Hydrocortisone 1%		-2.112	(-4.559, 0.336)	0.09			
Clobetasone butyrate 0.05%		-2.012	(-5.558, 1.534)	0.263			
Betamethasone valerate (0.0125%, 0.025%, 0.05%, 0.1%)		-3.527	(-6.161, -0.892)	<0.05	-1.284	(-3.789, 1.221)	0.312
Mometasone furoate 0.1%		0.348	(-2.970, 3.666)	0.836			
Clobetasol propionate 0.05%		0.521	(-6.232, 7.274)	0.879			
I do not know the name of the medication my child is on		9.784	(4.927, 14.642)	<0.001	6.922	(2.126, 11.718)	<0.05
Duration using TCS (years)		0.145	(-0.389, 0.68)	0.591			
Using other treatments for atopic eczema		0.649	(-2.249, 3.547)	0.658			
Having comorbidities		0.034	(-3.154, 3.222)	0.983			

Notes: Bold values are statistically significant at $p < 0.05$.

Abbreviations: POEM, Patient-Oriented Eczema Measure; TOPICOP®, Topical Corticosteroid Phobia questionnaire; TCS, Topical corticosteroids; RM, Ringgit Malaysia.

Discussion

To our knowledge, this is the first study to determine adherence towards TCS and its associated factors among caregivers of children with AE in Malaysia. Following findings from this study, caregivers with high and low adherence scores were interviewed to explore potential facilitators and barriers towards TCS adherence (unpublished ongoing study). Finally, recommendations pertaining to counselling for caregivers of children with AE, suitable for our local population, will be made based on findings from these studies.

In the present study, overall adherence score was relatively high. However, this was expected as subjectively measured adherence rates including self-reported questionnaires and patient diaries are generally higher than those objectively measured like the Medication Event Monitoring Systems (MEMS). In a study assessing adherence to topical medication using the Morisky Medication Adherence Scale in 209 patients with atopic dermatitis, overall adherence was 65%²⁰ and was 32% to 50% when measured with MEMS.^{13,21} In our study, adherence was measured using the 12-item medication adherence score, which was a self-reporting questionnaire created by Ueno et al to assess medication adherence in chronic diseases including AE. Overall MAS score in this study was similar to a study in Japan, which was 49.2 ± 10.2 ,²² but lower than another in Saudi Arabia, which was 42.6 ± 7.8 .¹⁰ Both studies utilised the same questionnaire as in the present study. The high adherence rate of our subjects could possibly be due to good relationship between the caregivers and their child's physicians, as shown in the relatively high score in the category "collaboration with healthcare providers". Studies have reported that providing patients with a good supportive and caring environment,²³ fostering good relationship and increased trust with their physicians²⁴ were able to improve adherence among patients. Kamei et al showed MAS scores were higher among AE patients who were satisfied with the communication with health care providers (physician, nurses, and pharmacists), the information given to them from these providers, and the explanation of its content (disease overview, prognosis of disease, importance of treatment, and treatment options).²²

Three predictors of TCS adherence were identified in this study. Caregivers whose children had severe eczema and those who do not know the name of the child's medication were positive predictors of TCS adherence, whereas caregivers with low TOPICOP© score was a positive predictor of TCS adherence.

Severity of disease has been found to be associated with adherence in other studies.²⁵ Intentional non-adherence in chronic diseases have been suggested to be caused by patients' perceptions of personal need for treatment and concerns about potential adverse effects from the treatment.^{25,26} In children with severe eczema, intentional non-adherence may occur when caregivers believe that TCS is required by visually looking at their child's skin condition, and stop using TCS when the eczema has improved. Parental health beliefs were identified as one of the reasons of nonadherence to treatment in AE.²⁷ According to the health belief model, one's involvement in health-related behaviours is explained by one's perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, and cues to action.²⁸ This would mean that parents would use TCS if they perceived the risks of AE are high (in severe AE) and using TCS would benefit their child. Similarly, parental perceived severity towards chronic diseases such as asthma, chronic kidney disease, congenital heart disease is positively correlated to their child's medication adherence.²⁹ A positive association between medication adherence and disease severity was also reported in children with irritable bowel syndrome aged between 13 and 18 years old and their parents.³⁰ Thus, parental perceived severity of their child's AE encourages their adherence to TCS.

In this study, caregivers whose children have severe eczema but not very severe eczema was significantly associated with higher TCS adherence. Due to the small number of subjects, it was possible that there was insufficient statistical power to detect a significant association with TCS adherence in the very severe eczema category compared to those in other categories of eczema severity. Further studies with larger sample size are warranted to elucidate this finding.

Health literacy (HL) is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.³¹ Lower levels of HL is strongly associated with poor medication adherence³² and poor HL among parents has a clear link with the outcomes for children with chronic disease.³³ Although there are not many studies on AE, poor parental HL has been associated with poor adherence among children with epilepsy, asthma and diabetes.³⁴ Caregivers who do not know the name of the TCS which

their child has been prescribed is an example of poor HL. In a study among adults with hypertension, patients with lower HL were less able to name any of their antihypertensive medications.³⁵ Interestingly, in this study, those who do not know the name of their child's TCS was a predictor of higher adherence to TCS. The reason for this non-concordance is unknown and warrants more studies to understand the cause of this finding among caregivers of children with AE in our local population.

Caregivers with higher TCS phobia had significantly lower adherence towards TCS use in their child with AE, unless their child had severe eczema. The mean global TOPICOP© score in our study was 25.4%, which is relatively low TCS phobia compared to other published studies. Studies in Singapore, Japan and Thailand reported mean global TOPICOP© score of 44.4%,³⁶ 40.3%³⁷ and 37.0%,³⁸ respectively. Adherence findings from this study was similarly observed in another local study among caregivers and patients with AE and psoriasis, which showed a statistically significant inverse relationship between adherence and TOPICOP© scores.³⁹ In two studies from Japan and Korea that compared non-adherence in the TCS phobia group and non-phobia group, the rate of nonadherence was higher in the phobia group.^{40,41} TCS phobia is not only associated with poor adherence, but also results in persistent AE with higher severity.⁴² Other studies also reported that patients with higher TOPICOP© scores had lower adherence rate.^{43,44} These findings highlighted the importance of tackling steroid phobia in parents of children with AE in order to improve adherence.

Caregivers' gender, age, ethnicity, household income and education level were not significantly associated with adherence to TCS. There was also no association between TCS adherence and child's age, gender, duration of disease, duration of TCS used, type of TCS and presence of other comorbidities. These results were in line with a similar study conducted in Singapore.⁴⁵ However, sociodemographic factors such as being educated, employed and having support at home showed higher adherence rates in other studies.^{46,47}

This study provides valuable insights on adherence to TCS and its predictors. However, there are a few limitations in this study. This study was carried out at two centers only. Thus, findings in this study may not be generalisable to the broader population. Furthermore, other factors which may influence adherence to TCS, such as illness perception, medication beliefs, patient-physician relationship, caregivers' personal experience with AE, current or prior use of TCS, whether eczema education was given, and complexity of treatment regimen were not investigated in this study. The convenience sampling method used may also potentially created sampling bias. Next, reporting bias may also exist as it relied on self-administered questionnaires by the caregivers, which may have resulted in high adherence score. Additionally, the findings of this study should be interpreted with caution. The small number of caregivers who did not know the name of their child's TCS, despite being identified as a significant predictor of TCS adherence, may weaken the credibility of its significance in multiple linear regression. Finally, the Malay version of the questionnaire was not validated prior to its use due to operational limitations including logistical and financial constraints. Nonetheless, this study provides useful information on the predictors to TCS adherence among the caregivers of children with AE in Malaysia. In future, reasons for TCS phobia should be explored and addressed. Appropriate interventions should then be planned to improve adherence accordingly.

Conclusion

The overall adherence score to TCS among caregivers of children with AE was high. Severe eczema and those who do not know the name of their child's medication were positive predictors of TCS adherence, while TCS phobia was a negative predictor of TCS adherence. Factors that affect medication adherence may be unique to different populations and for the present study, addressing caregivers' fear of TCS phobia may improve TCS adherence. Understanding the predictors of TCS adherence will assist in the development of appropriate interventions to tackle non-adherence and ultimately improve clinical outcomes.

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Disclosure

The authors report no conflicts of interest in this work.

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