Randomized, Double-Blind, Split-Side, Comparison Study of Moisturizer Containing Licochalcone A and 1% Hydrocortisone in the Treatment of Childhood Atopic Dermatitis

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Background: *Atopic dermatitis (AD) is a common chronic inflammatory skin lesion in children. Topical corticosteroid is the mainstay of treatment.*
Objective: *To compare the efficacy of moisturizer containing licochalcone A (Lic A) and 1% hydrocortisone for the treatment of mild to moderate childhood AD.*
Material and Method: *This was a multicenter, randomized, prospective, split-side, double-blind study in 55 children between the age of three months and 14 years. Patients with AD were treated twice daily, simultaneously with either Lic A or 1% hydrocortisone on opposite sides of the lesion. The SCORAD and transepidermal water loss (TEWL) were performed at the baseline, 2-week, and 4-week visits. Lic A was used on both sides of the body for another four weeks to see the effects and TEWL.*
Results: *In a randomized period, both products were equally effective in the treatment. SCORAD decreased significantly from baseline for both treatments throughout the first four weeks ($p<0.001$). There was no statistically significant difference in SCORAD between both treatments ($p = 0.321$ and $p = 0.146$ at week 2 and 4, respectively). Lic A had statistically significant decrease in TEWL ($p = 0.027$ and $p = 0.03$ at weeks 2 and 4, respectively). One patient had infection on skin lesions of both sides of the body. Forty-three patients continued to the period of using Lic A on both sides of the body. SCORAD and TEWL were comparable to the end of the randomized period and significantly lower from baseline ($p<0.001$). Skin lesions flared up in three patients (7.5%).*
Conclusion: *Lic A had a similar result in terms of SCORAD compared to 1% hydrocortisone for the treatment of mild and moderate AD. TEWL was significantly lower than baseline on the side that used Lic A. Continuing use of Lic A for four weeks can maintain clinical and barrier improvement.*

Keywords: *Atopic dermatitis, Licochalcone A, Transepidermal water loss*

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Atopic dermatitis (AD) is a common chronic inflammatory skin disease in children. It is a multi-factorial genetically based of disturbance of epidermal barrier function and immune dysregulation[1,2]. AD patients had dry skin, defect in barrier function and allowed irritant, allergen and microbes to penetrate the skin to stimulate the immune system[3-5]. Skin barrier dysfunction in AD patients may be from several factors such as ceramide deficiency, filaggrin mutations, decrease involucrin, or over expression of the chymotryptic enzyme[6,7]. Most guidelines recommend the use of moisturizer regularly in atopic dermatitis to improve barrier function[8,9]. Topical corticosteroids are the mainstay of treatment during the flare-up period[8,9]. Topical calcinerin inhibitor can be used in moderate to severe atopic dermatitis to control inflammation.

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Proactive therapy with topical calcineurin inhibitor or topical corticosteroids, two to three times per week, on a previously frequent flare-up area during remission helps to reduce the number of flares[10,11]. Concern and fear of the side effects of anti-inflammatory agent, parents and patients tend to use medication very late[11,12].

For more than a decade, the authors know that moisturizer containing ceramide improves the barrier function. It can also decrease transepidermal water loss (TEWL) and the severity of AD (SCORing Atopic Dermatitis, SCORAD) value[13]. Concomitant usage of emollient and topical corticosteroid improves treatment results in childhood atopic dermatitis[14]. Licochalcone A (Lic A) is an extract from *Glycyrrhieza inflate* that has anti-inflammatory property[14-16]. There is evidence of its efficacy and safety in clinical use of atopic dermatitis[17] and infantile seborrheic dermatitis[18]. Other non-steroidal barrier cream that has glycerrhetinic acid as an anti-inflammatory effect in MAS063DP is effective for mild to moderate childhood atopic dermatitis. The aim of the present study was to compare the efficacy of moisturizer containing Lic A in ceramide-based lotion and 1% hydrocortisone lotion for the treatment of mild to moderate childhood AD[19].

Material and Method

Patients

The authors conducted a multicenter, randomized, prospective split-side, double-blind study at Department of Pediatrics of four tertiary care centers: King Chulalongkorn Memorial Hospital, Queen Sirikit National Institute of Child Health, Ramathibodi Hospital and Siriraj Hospital, Mahidol University, between March 2010 and December 2011.

Sample size was calculated by using PS (Power and Sample Size Calculation) program.

By setting the size of difference = 15% with 95% confidence and 80% power, a sample size of 53 subjects was required.

Diagnosis of atopic dermatitis was based on Hanifin and Rajka (1998)[20] and using SCORAD index to assess severity of the patients[21]. Fifty-five children with a clinical diagnosis AD were recruited for the present study. Inclusion criteria were AD patients with an age of three months to 14 years old with mild to moderate severity (SCORAD <40) and had active flare. Patients with skin infection, using topical corticosteroid and/or topical calcineurin inhibitor within two weeks were excluded from the present study. Approval for the study was obtained from the Ethic Committee of the Faculty of Medicine, Chulalongkorn University, Queen Sirikit National Institute of Child Health, Ramathibodi Hospital, and Siriraj Hospital, Mahidol University, Bangkok, Thailand. Written informed consent for participation in the present study was given by parents of all children.

Test product

Moisturizer containing 0.025% Lic A in ceramide and linoleic lotion (Eucerin® Soothing lotion, Biersdorf AG, Germany) was repacked in bottles, which were identical to 1% hydrocortisone lotion bottles, by the Department of Pharmaceutics, King Chulalongkorn Memorial Hospital.

Both lotions were similar in appearance.

Randomization

Patients with a clinical diagnosis of AD were given either 1% hydrocortisone lotion or moisturizer containing Lic A lotion to apply on the opposite sides of the lesion simultaneously, twice daily. The assignment of applying the test substance was performed by block randomization by the principal investigator to all four sites before the present study was started. These code numbers were assigned sequentially so that the patients were enrolled in each site. During the present study, investigators and patients were blinded regarding the use of either moisturizer containing Lic A lotion or 1% hydrocortisone lotion, which were supplied in similar containers.

Measuring

SCORAD index was used to assess the severity of the disease by measuring area of eczema, intensity scores, and subjective symptom. Transepidermal water loss (TEWL) was determined with the same Cutometer MPA580 of Courage & Khazaka. Three measurements per area were made and a mean of measurements was expressed in g/h/m^2. The SCORAD and TEWL were performed at the baseline, week 2 and 4.

After completing the randomized period, moisturizer containing Lic A was used for both sides of the body for another four weeks. SCORAD index and TEWL were assessed at 8-week visit.

Adverse events

Patients were instructed to report any local adverse events including infection at the site of

application and systemic adverse events to the investigators during study period. Patients who did not have improvement were withdrawn from the studies and treated with either topical corticosteroid, topical and/or systemic antibiotics provided by the investigator.

Statistical analysis

The characteristics were presented using mean (SD), proportion, and percentage if the data is continuous and categorical, respectively. Moisturizer containing Lic A lotion or 1% hydrocortisone lotion effects was compared with the use of Mc'Nemar Chi-square test. A p-value of less than 0.05 was considered statistical significance. All reported p-values are two-sided and data analyses were performed with the use of Stata statistical software, version 11.0 (STATA 11.0 USA).

Results

Randomized period

Fifty-five children (male = 27, female = 28), with a median age of 37.5 (11, 106) months were included in this study. Fifty-two patients completed four weeks of the randomized period, one patient had skin infection on both sides of the body, and five patients were lost to follow-up due to a logistic problem. Table 1 shows the details of evaluation comparing of moisturizer containing Lic A and hydrocortisone in randomized period and period of using moisturizer containing Lic A on both sides.

In the randomized period, both products were equally effective in the treatment. There was no statistical significant difference of SCORAD index between moisturizer containing Lic A and hydrocortisone during randomized period (p = 0.321 and p = 0.146 at week 2 and 4, respectively). For analysis of each for sign and symptom score, edema, excoriation, lichenification and pruritus score were not significantly different but moisturizer containing Lic A was better than hydrocortisone in erythema at week 2 and oozing at week 4 (p = 0.0389 and p = 0.0325, respectively).

Compared to baseline, SCORAD index for both treatments decreased significantly (p<0.001). Fig 1 shows p-value of data of evaluation between week 2, 4, and 8 compared to before treatment. Fig. 2 shows that moisturizer containing Lic A had statistically significant decrease in TEWL (p = 0.027 and p = 0.03 at week 2 and 4, respectively). Fig. 3 shows before and after treatments.

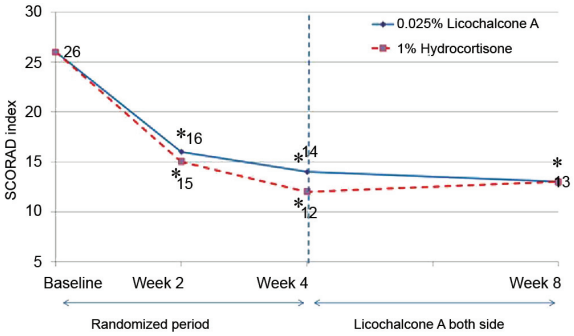

Fig. 1 SCORAD index reduction after 4 weeks of treatment in randomized period and continue with licochalconeA on both sides.
* p<0.01 compare to baseline

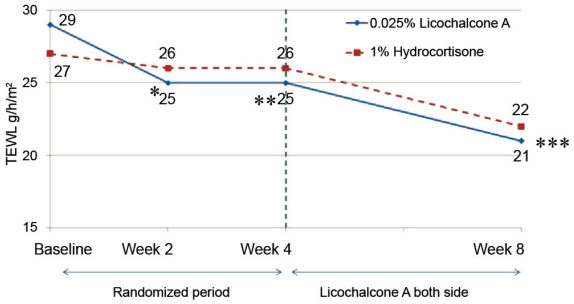

Fig. 2 Transepidermal water loss (TEWL) before, after 4 weeks of treatment in randomized period and continue with licochalcone A on both sides.
* p = 0.027 compare to baseline
** p = 0.030 compare to baseline
*** p = 0.016 compare to baseline

Using moisturizer containing Lic A on both sides

Forty-three patients continued to the period of using moisturizer containing Lic A on both sides of the body. Forty patients completed this period of the study. Table 1, Fig. 1 and 2 show that SCORAD and TEWL at the end of the study were comparable to the end of the randomized period and significantly lower from baseline (p<0.001). Skin lesions flared up in three patients (7.5%) and topical corticosteroid (0.02% triamcinolone cream) was prescribed.

There was no report of adverse events during the present study.

Discussion

Emollient has been recommended as basic treatment of atopic dermatitis because dry skin is one of the main symptoms of atopic dermatitis[8,9]. Emollients should be used regularly, even when the skin is clear. Many emollients that have been used in

Table 1. The details of evaluation comparing of moisturizer containing Lic A and hydrocortisone in randomized period and period of using moisturizer containing Lic A on both sides

Variables	Week 0			2nd week			4th week			8th week
	Licochalcone	Hydrocortisone	p-value	Licochalcone	Hydrocortisone	p-value	Licochalcone	Hydrocortisone	p-value	Licochalcone
Erythema			0.5930			0.0389			0.1379	
Absent	7 (12.73)	5 (9.09)		28 (53.85)	24 (46.15)		28 (57.14)	24 (48.98)		22 (55.00)
Mild	30 (54.55)	33 (60.00)		20 (38.46)	20 (38.46)		16 (32.65)	17 (34.69)		13 (32.50)
Moderate	18 (32.73)	16 (29.09)		4 (7.69)	7 (13.46)		5 (10.20)	8 (16.33)		5 (12.50)
Severe	-	-		-	1 (1.92)		-	-		-
Mean (SD)	1.2 (0.6)	1.2 (0.6)		0.5 (0.6)	0.7 (0.8)		0.5 (0.7)	0.7 (0.7)		0.6 (0.7)
Edema/papulation			1.0000			0.2059			0.7685	
Absent	10 (18.18)	11 (20.00)		27 (51.92)	23 (44.23)		29 (59.18)	28 (57.14)		24 (60.00)
Mild	30 (54.55)	28 (50.91)		19 (36.54)	24 (46.15)		17 (34.69)	18 (36.73)		14 (35.00)
Moderate	15 (27.27)	16 (29.09)		6 (11.54)	4 (7.69)		3 (6.12)	3 (6.12)		2 (5.00)
Severe	-	-		-	1 (1.92)		-	-		-
Mean (SD)	1.1 (0.7)	1.1 (0.7)		0.6 (0.7)	0.7 (0.7)		0.5 (0.6)	0.5 (0.6)		0.5 (0.6)
Oozing/crusting			0.7055			0.3173			0.0325	
Absent	29 (52.73)	29 (52.73)		35 (67.31)	40 (76.92)		34 (69.39)	28 (57.14)		30 (75.00)
Mild	19 (34.55)	20 (36.36)		16 (30.77)	9 (17.31)		14 (28.57)	18 (36.73)		7 (17.50)
Moderate	7 (12.73)	6 (10.91)		1 (1.92)	3 (5.77)		1 (2.04)	3 (6.12)		3 (7.50)
Severe	-	-		-	-		-	-		-
Mean (SD)	0.6 (0.7)	0.6 (0.7)		0.3 (0.5)	0.3 (0.6)		0.3 (0.5)	0.5 (0.6)		0.3 (0.6)
Excoriation			0.9750			0.4054			0.1336	
Absent	26 (47.27)	25 (45.45)		34 (65.38)	32 (61.54)		35 (71.43)	32 (65.31)		31 (77.50)
Mild	22 (40.00)	25 (45.45)		15 (28.85)	16 (30.77)		12 (24.49)	12 (24.49)		7 (17.50)
Moderate	7 (12.73)	5 (9.09)		3 (5.77)	4 (7.69)		2 (4.08)	5 (10.2)		2 (5.00)
Severe	55 (100.00)	-		-	-		-	-		-
Mean (SD)	0.7 (0.7)	0.6 (0.6)		0.4 (0.5)	0.5 (0.6)		0.3 (0.6)	0.4 (0.7)		0.3 (0.6)
Lichenification			0.3173			0.7055			0.4795	
Absent	30 (54.55)	29 (52.73)		34 (65.38)	35 (67.31)		36 (73.47)	34 (69.39)		29 (72.50)
Mild	22 (40.00)	23 (41.82)		17 (32.69)	16 (30.77)		12 (24.49)	14 (28.57)		10 (25.00)
Moderate	3 (5.45)	3 (5.45)		1 (1.92)	1 (1.92)		1 (2.04)	1 (2.04)		1 (2.50)
Severe	-	-		-	-		-	-		-
Mean (SD)	0.5 (0.6)	0.5 (0.6)		0.4 (0.5)	0.3 (0.5)		0.3 (0.5)	0.3 (0.5)		0.3 (0.6)
Dryness			0.3173			0.5637			0.1336	
Absent	1 (1.82)	2 (3.64)		10 (19.23)	11 (21.15)		18 (36.73)	13 (26.53)		12 (30.00)
Mild	23 (41.82)	24 (43.64)		34 (65.38)	30 (57.69)		26 (53.06)	30 (61.22)		23 (57.50)
Moderate	30 (54.55)	28 (50.91)		8 (15.38)	11 (21.15)		5 (10.2)	6 (12.24)		5 (12.50)
Severe	-	1 (1.82)		-	-		-	-		-
Mean (SD)	1.6 (0.6)	1.5 (0.6)		1 (0.6)	1 (0.7)		0.7 (0.6)	0.9 (0.6)		0.8 (0.6)

All comparing data using Mc'Nemar Chi-square test

Table 1. (cont.)

Variables	Week 0			2nd week			4th week			8th week
	Licochalcone	Hydrocortisone	p-value	Licochalcone	Hydrocortisone	p-value	Licochalcone	Hydrocortisone	p-value	Licochalcone
Pruritus/itching			0.3147			0.0661			0.6357	
Median (Q1, Q3)	5 (2, 7)	5 (2, 7)		2.5 (0, 5)	2.5 (0, 5)		1 (0, 4.5)	1 (0, 4)		0.5 (0, 5)
Skin tolerability						0.1243			0.0371	
Very poor	-	-		-	1 (1.92)		-	-		-
Poor	-	-		3 (5.77)	2 (3.85)		3 (6.12)	3 (6.12)		8 (19.51)
Satisfied/moderate	-	-		15 (28.85)	19 (36.54)		9 (18.37)	20 (40.82)		5 (12.20)
Good	-	-		29 (55.77)	27 (51.92)		32 (65.31)	23 (46.94)		17 (41.46)
Very good	-	-		5 (9.62)	3 (5.77)		5 (10.20)	3 (6.12)		11 (26.83)
SCORAD index			0.876			0.321			0.146	
Mean (SD)	26 (8.8)	26 (9.8)		15 (9.6)	16 (10.7)		12 (11.4)	14 (11.8)		13 (12.2)
Median (Q1, Q3)	26 (3.5, 44.4)	24 (3.5, 46.9)		13 (0, 34)	13 (2.2, 52.3)		7 (0, 44.3)	11 (0, 44.3)		12 (0, 49.2)
TEWL			0.167			0.789			0.212	
Mean (SD)	29 (12.1)	27 (14.0)		25 (11.5)	26 (13.9)		25 (11.3)	26 (13.0)		21 (9.2)
Median (Q1, Q3)	27 (7.4, 65.4)	24 (9.6, 78.3)		22 (9.2, 63.7)	22 (6.9, 59.2)		21 (8.9, 67.4)	22 (7.1, 66.8)		20 (9, 50.8)

All comparing data using Mc'Nemar Chi-square test

the treatment of atopic dermatitis[22,23]. Oil-in-water emollient and emollient containing ceramide have been proved to be effective in patients with atopic dermatitis[23].

In this multicenter, randomized, prospective split-side, double-blind study, moisturizer containing Lic A was equally effective to hydrocortisone lotion in treatment of childhood atopic dermatitis in terms of SCORAD. The same finding was reported in a comparative efficacy to 1% hydrocortisone in the treatment of childhood atopic dermatitis in a randomized, controlled, investigator-blinded study[17] which SCORAD and all signs and symptoms showed no statistical difference. In the present study, erythema at the second week on moisturizer containing Lic A side were significantly better than 1% hydrocortisone, but by the fourth week the difference was no longer significant. Oozing/crusting in the fourth week on moisturizer containing Lic A side was significantly better than hydrocortisone. Lic A has anti-inflammatory effect published both in vitro[1-16] and in vivo[17,18,24]. It can inhibit proliferation of T cells and production of pro- and anti-inflammatory cytokines in vitro[15,16] and has been reported to reduce erythema both in shave UV-induced, and facial redness both in rosacea and not attributed to rosacea[24].

In evaluation of improvement of skin barrier function, changes in TEWL have been used to reflect skin barrier function[25]. In the present study,

Fig. 3 a) before treatment, b) after 4 weeks of treatment in randomized period and c) continue with licochalcone A on both sides for 4 weeks.
Lic A = licochalcone A; HC = hydrocortisone

TEWL on the side that apply moisturizer containing Lic A has ceramide, which is significantly better than baseline throughout the study. Ceramide is a major component of intercellular lipid. Moisturizer containing ceramide improves barrier function measured by decreased TEWL[13]. Even though TEWL at baseline on the side that moisturizer containing Lic A was applied is slightly higher than the side that hydrocortisone was applied, but it was not significantly different. Having continued the use of moisturizer containing Lic A for 4 weeks on both sides, TEWL was still lower than baseline. This is very important because children with AD have skin barrier dysfunction that allows irritant, allergen, and microbes to penetrate the skin to stimulate the immune system. It will help decrease skin lesions flare up. In the present study 7% (3 from 43 patients) flared up during the use of moisturizer containing Lic A. The authors did not have any solid evidence regarding how often these patients had flare up before the present study. It would be interesting to further study in this issue.

In conclusion, moisturizer containing Lic A had the same result in term of SCORAD compared to 1% hydrocortisone for the treatment of mild and moderate AD. It also helps to decrease erythema and oozing. TEWL was significantly lower than baseline on the side that use moisturizer containing Lic A which reflect that skin barrier was improved after treatment with moisturizer containing Lic A. Continuing the use of moisturizer containing Lic A for four weeks can maintain clinical and barrier improvement. Children with mild to moderate AD can choose moisturizer containing Lic A instead of topical corticosteroid to avoid unwanted side effect and improve both clinical outcome and skin barrier function.

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Potential conflicts of interest

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การศึกษาร่วมหลายสถาบันเปรียบเทียบผลการรักษาผื่นภูมิแพ้ผิวหนังเด็กแบบสุ่มระหว่างสารให้ความชุ่มชื้นที่มีลิโคแคลโคน เอ (Licochalcone A) แบ่งครึ่งลำตัวและอีกข้างหนึ่งทาไฮโดรคอร์ติโซน (hydrocortisone)

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วัตถุประสงค์: เพื่อเปรียบเทียบผลการรักษาเด็กที่เป็นผื่นภูมิแพ้ผิวหนังที่มีระดับความรุนแรงของโรคน้อยถึงปานกลางด้วยสารให้ความชุ่มชื้นที่มีลิโคแชลโคน เอ (Licochalcone A, Lic A) และ hydrocortisone

วัสดุและวิธีการ: ทำการศึกษาในหลายสถาบันแบบไปข้างหน้า ในผู้ป่วยโรคผื่นภูมิแพ้ที่มีอายุระหว่าง 3 เดือนถึง 14 ปี จำนวน 55 ราย โดยในระยะแรกเป็นการสุ่มแบ่งพื้นที่การรักษาเป็นซ้าย-ขวาของลำตัวและหน้า ข้างหนึ่งทาสารให้ความชุ่มชื้นที่มี Lic A และอีกข้างหนึ่งทา hydrocortisone วันละ 2 ครั้ง โดยวัดความรุนแรงของโรคด้วย SCORAD และค่าการผ่านของน้ำออกจากผิวหนัง (TEWL) เพื่อดูหน้าที่ในการป้องกันของผิวหนังก่อนการรักษา, 2 สัปดาห์ และ 4 สัปดาห์ หลังการรักษา ในระยะต่อมาให้ผู้ป่วยทาสารให้ความชุ่มชื้นที่สาร Lic A ต่ออีก 4 สัปดาห์ ทั้งสองข้างของร่างกายเพื่อดูผลการรักษา

ผลการศึกษา: ผลการรักษาในระยะแรกพบว่าสารให้ความชุ่มชื้นที่มี Lic A และ hydrocortisone ให้ผลการรักษาได้ดี โดยมีค่า SCORAD ลดลงอย่างมีนัยสำคัญทางสถิติ ($p<0.001$) เปรียบเทียบกับก่อนรักษา การเปรียบเทียบผลการรักษาระหว่างข้างที่ทาสารให้ความชุ่มชื้นที่มี Lic A และ hydrocortisone พบว่าค่า SCORAD ไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติที่สัปดาห์ที่ 2 และ 4 ตามลำดับ ($p = 0.321$ และ $p = 0.146$) ส่วนค่า TEWL ลดลงในข้างที่ทาสารให้ความชุ่มชื้นที่มี Lic A มากกว่า hydrocortisone ในสัปดาห์ที่ 2 และ 4 ตามลำดับ ($p = 0.027$ และ $p = 0.03$) มีผู้ป่วย 1 ราย มีการติดเชื้อที่ผิวหนังบริเวณที่มีรอยโรคทั้งสองข้างของร่างกาย ในระยะต่อมาอีก 4 สัปดาห์ มีผู้ป่วยจำนวน 43 ราย ที่ทาสารให้ความชุ่มชื้นที่มี Lic A ทั้งสองข้างของร่างกายพบว่า SCORAD และ TEWL ไม่แตกต่างจากสัปดาห์ที่ 4 แต่ต่างจากก่อนรักษาอย่างมีนัยสำคัญทางสถิติ ($p<0.001$) มีผู้ป่วยจำนวน 3 ราย (ร้อยละ 7.5) ที่มีอาการกำเริบของโรค

สรุป: สารให้ความชุ่มชื้นที่มี Lic A ให้ผลไม่แตกต่างจาก hydrocortisone ในการรักษาผู้ป่วยที่เป็นผื่นภูมิแพ้ผิวหนังที่มีระดับความรุนแรงน้อยถึงปานกลาง แต่ค่า TEWL ซึ่งบ่งถึงหน้าที่ในการป้องกันของผิวหนังลดลงอย่างชัดเจนในข้างที่ใช้สารให้ความชุ่มชื้นที่มี Lic A และการทาสารให้ความชุ่มชื้นที่มี Lic A ต่ออีก 4 สัปดาห์ ทำให้อาการทางคลินิกและความสามารถในการป้องกันของผิวหนังดีขึ้น