Prevalence of Sodium Lauryl Sulfate Allergy and Association of Patch Testing of Sodium Lauryl Sulfate Allergy and Self-Reported Recurrent Aphthous Stomatitis in Thai Healthy Volunteers

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Abstract

The objectives of this study were to determine the prevalence of sodium lauryl sulfate (SLS) allergy in Thai healthy volunteers and investigate the association between SLS allergy and self-reported recurrent aphthous stomatitis (RAS) history. This study collected data from 71 Thai healthy participants at the Faculty of Dentistry, Prince of Songkla University. Eligible participants received 0.5% SLS and distilled water (negative control) patch testing on the forearm for 48 hours. Twenty-four hours after removal of the patch testing, participants were recalled for a test interpretation. In addition, participants were also requested to respond to the baseline characteristics and related history of RAS, including the presence of RAS and the number, size, duration, frequency, location, prodromal symptoms, family history, and stress related to RAS. Descriptive statistics described baseline characteristics, characteristics of RAS, SLS allergy interpretation, and prevalence of SLS allergy among Thai healthy subjects. Fisher's exact test was used to determine the association between SLS allergy and RAS history. The results showed that the prevalence of SLS allergy was 81.82% in Thai healthy subjects. The subjects with a history of RAS were mainly female, usually presenting one RAS ulcer with ≤ 5 mm size of ulcer located on non-keratinized mucosa, of less than one week in duration, occurring over three times per year, presenting prodromal symptoms, and being related to family history. All subjects with a history of RAS were 100% positive for SLS allergy; in contrast, subjects without a history of RAS were 67.74% positive for SLS. A significant association was found between SLS allergy and self-reported RAS history (p=0.003). However, no significant association between the scoring level of SLS allergic reactions and self-reported RAS history was found. In conclusion, SLS allergy is associated with self-reported RAS events. Therefore, SLS allergy should be considered as one factor in patients with a history of RAS.

Keywords: *Sodium lauryl sulfate/ Recurrent aphthous stomatitis/ Allergy/ Thai*

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Introduction

Recurrent aphthous stomatitis (RAS) is one of the most common oral diseases, characterized by recurrent, solitary, or multiple ovoid-shaped ulcers of yellowish color surrounded by a red halo. [1,2] A wide range of RAS prevalence depends on populations, which have been reported to be approximately 20-60% prevalent. [3] The etiology of RAS is still unclear. Several studies demonstrated that type IV hypersensitivity played a role in RAS by increasing the number of cytotoxic CD8 T-lymphocytes and cytokines. Furthermore, this type of hypersensitivity can also be demonstrated via skin patch testing. [4–6]

Many other factors are considered to be related to the disease, such as tobacco, hormonal changes, trauma, drug inducement, systemic diseases, stress, etc. Sodium lauryl sulfate (SLS) is one of the agents that has been investigated and proposed to be etiopathogenesis and affect the severity of RAS. [1] Previous studies showed that SLS affected oral mucosa, which led to susceptibility to RAS. [1] The

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prevalence of SLS allergy in general populations was about 41.8 %.[7] SLS can also be found in daily life, especially in toothpaste which contains 0.5-2.0% of SLS. Therefore, RAS patients with SLS allergy may have the chance of being exposed to SLS substances. Moreover, SLS-containing toothpaste prolonged the duration and affected the healing process of RAS patients.[2] Several studies investigated the effect of SLS-free toothpaste, revealing that it decreased the number of lesions, size, duration, pain level, and increased episodes of ulcerations in RAS patients.[8–10] On the other hand, there is evidence suggesting that some of the RAS parameters, as mentioned above, did not show a significant difference between SLS and non-SLS toothpaste.[9,11] Therefore, different findings in some previous studies have led to the role of SLS-related RAS occurrence.

Therefore, this study aimed to determine the prevalence of SLS allergy in Thai healthy volunteers and to investigate the association between SLS allergy and self-reported RAS history.

Materials and methods

Study design and Ethics approval

A clinical trial study aimed to determine the prevalence of SLS allergy in Thai healthy individuals. Moreover, we also determined the association of SLS allergy in participants with and without a history of recurrent aphthous stomatitis by using a questionnaire. This study was granted ethical approval by the Human Research Ethics Committee (HREC) of the Faculty of Dentistry, Prince of Songkla University (EC6311-037). All participants were informed of the information of this study and signed a consent form.

Sample size calculation and eligible criteria

A previous study showed the prevalence of RAS patients to be approximately around 46.7% of the population.[12] Sample size was calculated using the infinite population proportion formula (α = 0.1 and d = 0.1). The total number of participants was seventy-one, with a 5% drop-out rate. Thai healthy individuals were recruited for the study whose eligibility criteria included individuals between 18- 40 years old, without pregnancy, and without systemic diseases related to RAS such as Human immunodeficiency virus (HIV), Bechet's syndrome, Crohn's disease, and celiac disease. Then we excluded participants who could not read and understand Thai, had mental health illnesses or had a history of severe allergic reactions to SLS.

Data collection

Eligible participants were recruited at the Faculty of Dentistry, Prince of Songkla University by convenient sampling. Participants were requested to respond to a questionnaire about the baseline characteristics and history of related RAS, which included the RAS's number, size, duration, frequency, location of ulcers, prodromal symptoms, related family history, and stress related to RAS for their life-time of RAS events.

Afterwards, an SLS allergy test was performed on seventy-one Thai healthy subjects as per the previous study.[7] According to the test result's concordance of the back and the forearm[13], the forearm was chosen as a convenient site for patch placement. Then we applied 70% ethyl alcohol on the selected participant's forearm (2 inches from the cubital fossa) and two chambers of Fin Chamber® on Scanpore tape® (Epitest, Tuusula, Finland), which contained 20 µL of 0.5% SLS and 20 µL of distilled water for the negative control. After that, we also placed a water-resistance film (Tegaderm®) to prevent fall-off of the Fin Chamber®. Patch testing was maintained on the participant's forearm for 48 hours, then removed, and 24 hours[14] later, it was assessed to see if it was an SLS allergy. We used the scoring system to interpret allergic tests as in the previous study[7] (Table 1). One interpreter, chosen from all the investigators, was also blind to the substance used and the participant's group when interpreting the participants' skin reactions. Furthermore, the interpreter was standardized by an oral medicine specialist with a Kappa coefficient of 0.83.

Table 1 Scoring system for SLS-allergy interpretation. [7]

Score	Skin manifestation
0	No reaction
1+	Weak, spotty or diffuse erythema/scaling
2+	Weak, good visible erythema/scaling
3+	Moderate erythema
4+	Strong erythema and/or minute epidermal defect
5+	Very strong erythema with epidermal defect

Statistical analysis

Data were described as the baseline characteristics of all participants and the prevalence of SLS allergy in all Thai healthy subjects. In addition, the prevalence and association of SLS allergy in Thai healthy subjects with RAS and without RAS history were also determined by descriptive statistics and the Chi-square or Fisher's exact test, respectively (α=0.05). We also compared the number, size, duration, and frequency of RAS between SLS allergy and non-SLS allergy in subjects who reported a history of RAS by the Chi-square or Fisher's exact test (α=0.05).

Results

Of 71 Thai healthy subjects, 55 subjects came back to interpret the SLS allergy patching test. The dropout rate was 22.54%. The baseline characteristics of Thai healthy subjects were mainly female (61.82%). The mean age was 22.82±1.44 years old. There were no significant differences in age and sex between subjects with and without a history of RAS, as shown in Table 2.

Of the 55 Thai healthy subjects, the prevalence of SLS allergy among Thai healthy subjects was 81.82%. Moreover, 24 subjects reported a history of RAS (43.64%) via a self-reported questionnaire, and all of them were allergic to SLS (100%). Among the 31 subjects who did not report a history of RAS, 10 subjects (32.26%) were non-SLS allergic, and 21 subjects (67.74%) were SLS allergic. Considering the association between SLS allergy and self-reported RAS history, the results showed that subjects with SLS allergy were significantly associated with a history of RAS by Fisher's exact test (p=0.003). In addition, the group of subjects who were positive from patch testing showed no statistically significant difference in scoring or severity reaction between subjects with and without a history of RAS (Table 2).

Table 2 Baseline characteristics and SLS allergy among Thai healthy subjects

Variables	Thai Healthy Subjects		p-value
	With RAS history (N =24)	Without RAS history (N=31)	
1. Age (years, mean ± S.D.)	23.17 ± 1.13	22.63 ± 1.65	0.183*
2. Sex			1.00
Female	15 (62.50%)	19 (61.29%)	
Male	9 (37.50%)	12 (38.71%)	
3. SLS-allergy			**0.003****
No	0 (0.00%)	10 (32.26%)	
Yes	24 (100.00%)	21 (67.74%)	
4. SLS-allergy scoring			
0	0 (0.00%)	10 (32.26%)	
1+	17 (70.83%)	13 (41.94%)	0.329 +
2+	4 (16.67%)	7 (22.58%)	
3+	3 (12.50%)	1 (3.23%)	

* independent t-test, α = 0.05

**fisher's exact test, α = 0.05

+comparing between only subjects with and without a history of RAS who were positive on patch testing (1+ to 3+ score) via Fisher's exact test, α = 0.05

Due to the fact that there were no subjects with a history of RAS who showed an SLS-allergy score of 0, we cannot compare the association of the number, size, duration, frequency, and prodromal symptoms of RAS between RAS subjects who were positive and negative for patch testing. Descriptive data in subjects with a history of RAS are shown in Table 3. In subjects with a history of RAS, RAS was usually found to occur in one ulcer, ≤ 5 millimeters in size, persisting less than one week, and recurring more than three times per year. Most subjects with a history of RAS reported no stress related to RAS events and had a family history of RAS (Table 3).

Table 3 Self-reported history of RAS among subjects

Related history of RAS	Subjects with a history of RAS (N= 24) * n (%)
1. Numbers of ulcers	
1 ulcer	18 (75.00%)
≥ 2 ulcers	6 (25.00%)
2. Size of ulcers	
≤ 5 millimeters	23 (95.83%)
> 5 millimeters	1 (4.17%)
3. Duration	
≤ 1 week	16 (66.67%)
> 1 week	8 (33.33%)
4. Frequency	
1 time per year	6 (25.00%)
2 times per years	8 (33.33%)
≥ 3 times per year	10 (41.67%)
5. Location	
Labial mucosa	9 (37.50%)
Tongue	3 (12.50%)
Buccal mucosa	2 (8.33%)
Gingiva	2 (8.33%)
More than 1 site	8 (33.34%)
6. Prodromal symptoms	
No symptoms	8 (33.33%)
Burning sensation	12 (50.00%)
Tingling sensation	4 (16.67%)
7. Stress related RAS	
No	19 (79.17%)
Yes	5 (20.83%)
8. Family history of RAS	
No	5 (20.83%)
Yes	19 (79.17%)

*All subjects were positive for the SLS allergy test.

Discussion

Of the 71 Thai healthy subjects, 16 subjects dropped out of this study. The interpretation of patch testing could not be made in these subjects due to a loss of adhesion of the Fin Chamber® and because patients felt itchy and scratched the area of SLS-patch testing. The finalized self-reported RAS sample size was 24 participants, along with 31 participants with no RAS history. According to Table 3, most of the subjects with a history of RAS responded to the questionnaire that the characteristics of RAS experiences included that they usually had one ulcer with ≤ 5 mm size located on the labial mucosa, presenting prodromal symptoms and relating to their family history. All these characteristics correlated with the previous studies, which demonstrated clinical manifestation and related history of RAS.[1,2,12]

For this study' s main points, we found a prevalence of SLS allergy of about 81.82% in Thai healthy subjects. The prevalence of an SLS allergy was much higher than in previous studies which were conducted in large German populations showing a prevalence of SLS allergy between 22.53% (0.25% SLS),[15] 35.40% (0.5% SLS),[15] and 41.8% (0.5% SLS).[7]

Furthermore, we found that self-reported RAS participants were associated significantly with SLS allergy, as all participants were positive for patch testing. Meanwhile, subjects without RAS history were also found to be 67.74% positive for an SLS allergy test. For the severity of allergic reactions, there was no significant association of the level of allergic reaction between self-reported RAS history and subjects without RAS history. The score of 1+, 2+, and 3+ reactions showed a tendency related to previous studies.[7,16] Moreover, 4+ and 5+ scores were not found in this study, which was also in concordance with previous studies. The previous studies found only 0.1-0.2% in 4+ and 0-0.1% in 5+ scores, respectively.[7,16]

However, the SLS allergy in this present study should be taken into consideration for the above observation. The 1+ score reaction could be due to skin irritability (a false positive reaction) or a genuine allergic reaction, as a previous study demonstrated that the risk of positive reactions caused by skin irritation was as high as 22%.[17] In the present study, the majority of reactions in Thai healthy participants (30 out of 55 participants; 54.55%) was a 1+ score, indicating weak, spotty, or diffuse erythema. Therefore, according to the aforementioned evidence, this study may reveal that the true prevalence of SLS allergy among Thai healthy subjects could be in a range between 27.27% (only 2+ to 3+ scores in 15 out of 55 participants) and 81.82% (1+ to 3+ scores in 45 out of 55 participants). Within this range, the prevalence was in accordance with previous reports on general populations. As aforementioned, the 100% positive SLS allergy in the reported-RAS result revealed that there was no significant difference of SLS allergy between subjects with and without RAS history by considering the 1+ score as a chance of being a false positive (Table 4). The prevalence of SLS allergy in subjects with a history of RAS may range between 29.17% - 100%.

Table 4 The association of SLS-allergy and self-reported RAS history which a 1+ score was considered as a false positive result.

Variables	Thai healthy subjects		p-value*
	With RAS History (N =24)	Without RAS History (N=31)	
Patching test of SLS-allergy			0.509
Negative result [a]	17 (70.83%)	23 (74.19%)	
Positive result [b]	7 (29.17%)	8 (25.81%)	

* Fisher's exact test, α = 0.05

[a] A negative result is determined by the interpretation of a patching test score of 0 and 1+, because a 1+ score could be determined either as irritation (a false positive) or a true allergy.

[b] A positive result is determined by the interpretation of a patching test score of 2+ and 3+.

Additionally, other false positive reactions should also be considered. Other possible causes include increased substance concentration, impure or contaminated test preparation, excessive test preparation use, adhesive tape reactivity, etc.[18] However, we used distilled water covered with the same water-resistance film as the negative control; therefore, we can rule out an adhesive reaction that could result in a false positive reaction. Furthermore, the concentration of the SLS substance and the location of the patch placement may influence a favorable allergic result. Previous studies were usually designed to determine SLS allergy by placing patch-testing on the participants' backs[14,18] One study mentioned that the forearm was more susceptible than the back.[13] However, a study found that performing a forearm test did not differ from results on one's back with an appropriate interpretation time (72 hours).[13] Additionally, one study compared the results from the thigh and the forearm. The result showed that a positive patch testing was more likely obtained from the forearm, because the thicker keratinization of the thigh was greater than the forearm, which led to decrease patch testing positivity.[19] Thus, the arm can be the appropriate site for patch testing in terms of the test result's concordance with the back and thickness of keratinization.

As the discussion above, a possible explanation for a false positive reaction in this study could be the concentration of SLS. Various concentrations of SLS allergy tests were used in previous studies such as 0.25% SLS or 0.5% SLS. One previous study recommended using 0.1% SLS as being an appropriate concentration that could decrease risk of irritation in an atopic dermatitis test.[19] Therefore, using 0.1% SLS patch testing in Thai population may appropriate and could decrease risk of false positive in skin reactions.

According to the aforementioned limitations, further studies should be conducted to determine the appropriate substance concentration, such as varying the concentrations of SLS to 0.1%, 0.25% and 0.5% and comparing the test results. In addition, the test should be repeated to determine whether skin irritation or SLS allergy occurs, as these two reactions share a common mechanism and similar skin manifestations. Moreover, clinical examination and laboratory investigations were not retrieved. From the subjects with a history of RAS who reported and enrolled in the study, it cannot be ruled out that there were other similar ulcerative lesions or possible causes of RAS such as herpetic ulceration, traumatic ulcers, nutritional deficiencies etc. Therefore, a further study should perform an oral examination to ascertain the presence of RAS to eliminate recall bias and exclude other similar ulcerative lesions as well as controlling the possible causes of RAS such as stress, familial history, and nutritional deficiencies in order to determine the actual relationship between SLS allergy and RAS. An appropriate proper sample size is also required as well.

In regard to the strengths of the present study, the results demonstrated the prevalence of SLS allergy in both healthy volunteers and subjects with a history of RAS, regardless of the area of improvements to any further study as mentioned above. Furthermore, in this case 1+ scores were determined as a true allergy. This result also showed a positive association of SLS allergy with subjects with a history of RAS. As in previous studies, while SLS may not directly cause RAS lesions, earlier research has suggested that it may enhance the vulnerability of oral mucosa susceptible to RAS,[1] as well as the number, episode, pain, and healing process of RAS lesions.[8,10] Therefore, if clinicians exclude other possible causes of RAS, an SLS allergy may also be considered to identify patients who will benefit from non-SLS containing toothpaste for SLS-allergy RAS patients in clinical management.

Conclusion

According to this study, there was a high prevalence of SLS allergy in Thai healthy individuals. Furthermore, subjects with a history of RAS were all positive to SLS allergy test, and there was a significant association between subjects with RAS history and SLS allergy.

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ความชุกของการแพ้สารโซเดียมลอริลซัลเฟต และความสัมพันธ์ของการแพ้สารโซเดียมลอริลซัลเฟตกับการรายงานการเกิดแผลร้อนในของอาสาสมัครไทยสุขภาพดี

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บทคัดย่อ

การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาความชุกของการแพ้สารโซเดียมลอริลซัลเฟตหรือเอสแอลเอสในอาสาสมัครไทยสุขภาพดี และศึกษาความสัมพันธ์ของการแพ้สารเอสแอลเอสกับประวัติการเกิดแผลร้อนในของอาสาสมัคร โดยการศึกษานี้เก็บข้อมูลผ่านอาสาสมัครสุขภาพดีทั้งหมด 71 คน ณ คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ซึ่งจะได้รับการทดสอบการแพ้ด้วยสารละลายเอสแอลเอสความเข้มข้นร้อยละ 0.5 และใช้น้ำกลั่นเป็นตัวควบคุมลบ ติดแผ่นทดสอบบนท้องแขนเป็นเวลา 48 ชั่วโมง หลังจากแกะแผ่นทดสอบออก 24 ชั่วโมง ผู้วิจัยอ่านผลการแพ้ สัมภาษณ์อาสาสมัครเกี่ยวกับข้อมูลพื้นฐาน ประวัติการเป็นร้อนใน ได้แก่ จำนวน ขนาด ระยะเวลา ตำแหน่ง ความถี่ อาการนำก่อนเกิดแผล ประวัติครอบครัว และความเครียด ใช้สถิติพรรณนาบรรยายข้อมูลพื้นฐาน ประวัติการเกิดแผลร้อนใน คะแนนผลการทดสอบการแพ้สารเอสแอลเอส และความชุกของอาสาสมัครที่แพ้เอสแอลเอส และใช้สถิติฟิชเชอร์ตรวจสอบความสัมพันธ์ของการแพ้เอสแอลเอสและการมีแผลร้อนใน ผลการศึกษาพบว่าความชุกของอาสาสมัครที่แพ้เอสแอลเอสคิดเป็นร้อยละ 81.82 ในกลุ่มอาสาสมัครที่มีประวัติแผลร้อนในส่วนใหญ่เป็นเพศหญิง มีแผลเดียวโดยมีขนาดน้อยกว่าหรือเท่ากับ 5 มิลลิเมตร มักเกิดในตำแหน่งเยื่อบุผิวช่องปากชนิดไม่มีเคราติน เป็นอยู่ประมาณ 1 สัปดาห์ ความถี่มากกว่า 3 ครั้งต่อปี มีอาการนำก่อนเกิดแผลและมีความเกี่ยวข้องกับประวัติครอบครัว ในอาสาสมัครที่มีประวัติร้อนในพบว่าแพ้เอสแอลเอสร้อยละ 100 ในขณะที่กลุ่มที่ไม่มีประวัติร้อนในพบว่าแพ้ร้อยละ 67.74 พบความสัมพันธ์ของการแพ้เอสแอลเอสและประวัติการเกิดแผลร้อนในของอาสาสมัคร ($p=0.003$) แต่อย่างไรก็ตามไม่พบความสัมพันธ์กับระดับความรุนแรงของการตอบสนองการแพ้เอสแอลเอสและประวัติการเกิดแผลร้อนใน ผลการศึกษาสรุปได้ว่า มีความสัมพันธ์ของการแพ้เอสแอลเอสและประวัติการรายงานการเกิดแผลร้อนใน ดังนั้นอาจจะกล่าวได้ว่าการแพ้เอสแอลเอสอาจเป็นปัจจัยหนึ่งในผู้ป่วยที่มีประวัติแผลร้อนใน

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