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Original Article

Patch testing: clinical relevance and successful recall of allergens in local Chinese patients

斑貼試驗：本地華裔患者的臨床相關性和致敏原的成功憶述率

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Objectives: To investigate the clinical relevance of contact allergens identified in patch testing, and the successful recall rate of these allergens. ***Methods:*** This was a single-centre study performed in Hong Kong. Local Chinese patients were invited for interviews. ***Results:*** There were a total of 146 patients with valid patch tests performed from 2009 to 2012. One hundred patients were interviewed, of which 68 patients had positive patch test reactions, resulting in a total of 122 allergen reactions. Nickel sulphate, fragrance mix, 5-chloro-2-methyl-4-isothiazolin-3-one+2-methyl-4-isothiazolin-3-one (3:1 in water) and paraphenylenediamine (PPD) were the commonest allergens identified in this study. Among these sixty-eight patients, 80.3% of the identified allergens were clinically relevant (45.9% definitely relevant, 34.4% probably or possibly relevant). 75.4% of the allergens were successfully recalled, either in their full names or substance groups. Patients with a lower education level were less likely to recall the allergens identified in patch testing. ***Conclusion:*** The clinical relevance of allergens and the recall rate were satisfactorily high.

目標：要找出在斑貼試驗確定的接觸性致敏原的臨床相關性及其成功憶述率。**方法**：這是在香港進行的單中心研究。本地華裔患者會被邀請會面。**結果**：由2009至2012年，總共有146名患者進行有效的斑貼試驗。一百名患者接受了採訪。 六十八名有陽性斑貼試驗反應，共導致122次致敏原反應。在此研究中，硫酸鎳，混合香料，五 - 氯 - 二 - 甲基 - 四 - 異噻唑啉 - 三 - 酮 + 二 - 甲基 - 四 - 異噻唑啉 - 三 - 酮（在水中3:1）和對苯二胺是最常見的致敏原。在六十八名患者中，其致敏原標識的臨床相關性爲80.3%（45.9%肯定有關，34.4%或許或可能有關）。患者能成功憶述75.4%的致敏原全名或物組群。教育程度較低的患者比較少能憶述在斑貼試驗確定的致敏原。**結論**： 致敏原的臨床相關性和憶述率令人滿意。

Keywords: Patch test, allergic contact dermatitis, clinical relevance, recall

關鍵詞：斑貼試驗，過敏性接觸性皮炎，臨床相關性，憶述

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Introduction

Allergic contact dermatitis and patch testing

Allergic contact dermatitis (ACD) is an inflammatory skin condition resulting from a delayed hypersensitivity reaction after contacting foreign substance(s). Patch testing is a valuable, objective, *in vivo* diagnostic tool for identifying

causative allergens in patients with allergic contact dermatitis. It carries a sensitivity and specificity of 70-80%.[1,2] Two major standard series have been developed in the United States (US) and Europe. The European standard series is commonly employed in Hong Kong.

Common patch test allergens in Hong Kong

Lee et al. reviewed 490 local patients with patch testing done in a local private dermatology clinic between 1987 and 1988 and found that fragrance mix, nickel sulphate and cobalt chloride to be the most common allergens identified in the European standard series.[3]

The most frequently identified allergens by patch testing from 1995 to 1999 in the Social Hygiene Service (SHS), a major local provider of public dermatology services, were nickel sulphate, fragrance mix, cobalt chloride, paraphenylenediamine (PPD) and Balsam of Peru.[4]

With the emergence of new allergens that were found to be associated with allergic contact dermatitis, the SHS introduced the 28-item European series patch testing (Trolab®) in 2009 and replaced the previous 24-item European series.

Clinical relevance of patch test allergens

Patch testing can identify many contact allergens, but a positive reaction to a specific allergen *per se* may not correlate well with clinical symptoms (clinical relevance).[5] On their own, results of patch testing can neither confirm a relationship between a specific exposure and induction of contact dermatitis, nor can it predict what specific exposure can be safely tolerated.[5] Establishment of clinical relevance should be based on the clinical history with evidence of relevant exposure.[5,6] Certain allergens identifiable in patch testing were reported as most likely to be clinically relevant in a Singaporean study.[7] Data on clinical relevance in Hong Kong is, however, not available.

Recall of allergens

Many of the allergens identified in patch testing are forgotten by the patients afterwards. In a study in the US, patients were able to remember only a mean of 51% of the allergens identified by patch testing.[8] The patient's ability to recall the results of patch testing and the adoption of suitable avoidance behaviour might influence the ultimate benefits of patch testing.[9]

The ability of patients to recall allergens identified by patch testing correlated negatively with the number of identified allergens, years elapsed after patch testing and a male gender.[9] In one study, 29% of patients reported the correct names of the allergens and 20% remembered the substance group.[9] It is not certain if a similar recall problem is prevalent among local Chinese patients.

Objectives

In the present study, we sought to 1) evaluate the clinical relevance of allergens that were identified by patch testing and 2) evaluate the recall rate of positive allergens.

Methods

Study design

This was a single-centre study performed at the Fanling Integrated Treatment Centre (FLITC), Social Hygiene Service. All Chinese patients who had patch testing performed after the introduction of the 28-item European standard series from 2009 to 2012 were eligible for inclusion into the study. Exclusion criteria included failure of the patch testing procedure, failure to establish contact with the patient for an interview, patients' refusal to participate in any part of the study and patients' mental incompetence in understanding questions or giving answers. Patients with positive patch test reactions were requested to recall the allergen(s) that were identified. The investigator would then remind the patient on his/her identified allergens

and asked questions on clinical relevance. The study was approved by the Ethics Committee, Department of Health, Hong Kong Special Administrative Region.

For the patch testing procedure, Finn chambers containing the 28 allergens in the European standard series were applied on the upper back (Table 1). The patients were requested to return after 48 hours for the first reading and the second reading was made at 96 hours after the test. The results of patch testing were classified according to the International Contact Dermatitis Research Group (ICDRG) recommendations (Table 2).[10, 11]

Table 1. The 28 items of the European standard series

	Test substance	Common source
1.	Potassium dichromate 0.5%	Metal, cement, paint
2.	Neomycin sulphate 20%	Medication
3.	Thiuram mix 1%	Rubber chemical
4.	Fragrance mix II 14% hard paraffin 14%	Fragrance
5.	Cobalt chloride 6 H_2O 1%	Metal, building, decoration trades
6.	Paraphenylenediamine free base	Dyes
7.	Benzocaine 5%	Medication
8.	Formaldehyde in water 1%	Disinfectant or preservative
9.	Colophony 20%	Paper, plasters, adhesive tapes, make-ups
10.	Clioquinol 5%	Vioform medication
11.	Balsam of Peru 25%	Medicaments, fragrance in cosmetics
12.	*N*-Isopropyl-*N*-phenyl-paraphenylenediamine 0.1%	Rubber chemical
13.	Wool alcohols 30%	Topical medicaments, lanolin eucerin
14.	Epoxyl resin 1%	Plastic and glue
15.	Mercapto mix 1%	Rubber chemical
16.	Budesonide 0.1%	Steroid
17.	Paraben mix 16%	Preservative in pharmaceutical, foodstuff, cosmetics
18.	Paratertiarybutyl-phenol-formaldehyde resin 1%	Glue, leather products
19.	Fragrance mix 8%	Perfumes, cosmetics
20.	Quaternium-15 1%	Preservative in topical medicaments, cosmetics
21.	Nickel sulphate 6H_2O 5%	Metal
22.	5-chloro-2-methyl-4-isothiazolin-3-one+ 2-methyl-4-isothiazolin-3-one 0.01% (3:1 in water)	Preservative in cosmetics, glues, detergents, moisted toilet paper
23.	Mercaptobenzothiazole 2%	Rubber
24.	Sesquiterpene lactone mix 0.1%	Plant
25.	Tixocortol pivalate 1%	Steroid
26	Dibromodicyanobutane 0.3%	Preservative
27.	Hydroxymethypentylcyclohexene-carboxaldehyde 5%	Synthetic fragrance
28.	Primin 0.01%	Plant

Table 2. Interpretation of patch testing results according to the International Contact Dermatitis Research Group

Score	Interpretation
–	Negative reaction
? +	Doubtful reaction; faint erythema only
+	Weak (non-vesicular) reaction: erythema, slight infiltration
++	Strong (oedematous or vesicular) reaction: erythema, infiltration, vesicles
+++	Extreme (bullous or ulcerative)

During the interviews, patients who tested positive were asked to recall the allergens that were identified. Short or long forms of an allergen name, in Chinese or English, were all acceptable answers. For patients who could not name the allergen exactly, they would be asked if they could name the group that this specific allergen belonged to (Table 1). The ability to name the correct allergen or substance group was regarded as successful recall.

In this study, clinical relevance of an allergen was classified as follows:

- Definite relevance was defined when the allergen was found to be present in the patient's environment, the dermatitis corresponded to the point(s) of contact with the allergen and the dermatitis significantly improved upon isolation of the allergen or recurred with re-challenge.[6] Probable relevance was defined when the criteria for definite relevance was met except that no follow-up information was available and thus any improvement with isolation of allergen or condition after re-challenge could not be assessed.[6]
- Possible relevance referred to an allergen that only fulfilled one of the three criteria that defined definite relevance.[6]
- No relevance was defined when there had been no evidence of past or present exposure to a specific allergen.

In our study, sub-division of clinical relevance into past and current relevance was not made given the variable time lag from patch testing to interview.

Statistical analysis

Continuous data was presented as mean ± standard deviation or median with inter-quartile ranges (25th to the 75th percentiles) unless otherwise specified. Percentages were calculated for dichotomous variables. Group comparisons were made by Fisher's exact test or Pearson's chi-squared (χ^2) test for nominal variables and by Student's t-test or Mann-Whitney U test for continuous variables. All p-values were two-sided, values of less than 0.05 were considered statistically significant. SPSS for Windows version 20.0 (SPSS Inc., Chicago, IL, USA) was used for all statistical calculations.

Results

One hundred and forty-six valid patch testing reports and clinical records were reviewed. Successful interviews were made with 100 of them. For the remaining 46 cases, two refused interviews, one failed to understand the questions due to mental incompetency and 43 of them could not be contacted.

Of the 100 patients interviewed, the median age was 45.29 (standard deviation 15.28) and 74% of them were female. Sixty-eight patients (68%) had positive patch testing results (Table 3). Out of those sixty-eight patients who had positive patch testing results, 33 patients (48.5%) were reactive to one allergen only and 24 patients (35.3%) reacted to two allergens (Table 4). Patients tested positive did not differ in their age, gender, occupation, past medical history, personal or family history of atopy or drug allergy (Table 5). Face and hands were most commonly involved in our patch-tested subjects.

Clinical relevance and recall of allergens

A total of 122 allergens were identified in 68 patients who were interviewed and had at least one allergen identified in patch testing. They were asked to recall the allergens on the date of interview. The median time elapsed from patch testing to the date of interview was 22.37 months (inter-quartile range = 9.15-32.25). Ninety-two (75.4%) of the 122 allergic items were successfully recalled. Fifty-six (45.9%) were definitely clinically relevant while forty-two (34.4%) were probably or possibly clinically relevant (Table 6).

Factors associated with successful recall of allergens

Among the 68 patients (Table 7), fifty-seven had a successful recall. Forty-eight (70.6%) recalled all positive allergens identified in patch testing, nine (13.2%) recalled at least one of the identified allergens while eleven (16.2%) failed to recall any of the allergens found in patch testing. Despite similar time lag from patch testing to interview and similar number of allergens being identified

Table 3. Number of positive patch test in the 100 patients who were interviewed after patch testing

Characteristic	All (n=100)	Female (n=74)	Male (n=26)	p
Positive patch testing	68 (68%)	49 (66.2%)	19 (73.1%)	0.628

Table 4. Number of allergens identified in the 68 patients who had positive patch tests

Number of allergens identified	(n=68)	Female (n=49)	Male (n=19)	p
Median (IQR)[range]	2 (1-2)[1-7]	1 (1-2)[1-7]	2 (1-2)[1-4]	0.236
Absolute				0.639
1	33 (48.5%)	26 (53.1%)	7 (36.8%)	
2	24 (35.3%)	16 (32.7%)	8 (42.1%)	
3	6 (8.8%)	4 (8.2%)	2 (10.5%)	
4	4 (5.9%)	2 (4.1%)	2 (10.5%)	
7	1 (1.5%)	1 (2%)	/	

IQR=interquartile range

Table 5. Characteristics of the 100 patients who were interviewed after patch testing

		Patch testing results		
Characteristic	All (n=100)	Positive (n=68)	Negative (n=32)	p
Age (year)	45.29±15.28	46.63±14.10	42.44±17.43	0.202
Female gender (%)	74 (74%)	49 (72.1%)	25 (78.1%)	0.628
Occupation				0.093
Cleanser	8 (8%)	7 (10.3%)	1 (3.1%)	
Construction	3 (3%)	2 (2.9%)	1 (3.1%)	
Driver	6 (6%)	3 (4.4%)	3 (9.4%)	
Hairdressing or beauty salon	4 (4%)	4 (5.9%)	0 (0%)	
Health worker	8 (8%)	7 (10.3%)	1 (3.1%)	
Housewife	20 (20%)	13 (19.1%)	7 (21.9%)	
Office worker	25 (25%)	18 (26.5%)	7 (21.9%)	
Retired or unemployed	5 (5%)	3 (4.4%)	2 (6.2%)	
Student	9 (9%)	2 (2.9%)	7 (21.9%)	
Others	12 (12%)	9 (13.2%)	3 (9.4%)	
Past medical history	36 (36%)	29 (42.6%)	7 (21.9%)	0.127
Personal history of atopy	41 (41%)	27 (39.7%)	14 (43.8%)	0.747
Family history of atopy	49 (49%)	34 (50%)	15 (46.9%)	0.739
History of drug allergy	10 (10%)	7 (10.3%)	3 (9.4%)	0.365

Table 6. Recall and clinical relevance of 122 allergens identified in 68 patients

Allergens 1-28 (European standard series)	Number of positive reactions	Number of allergens able to recall (%)	Clinical relevance (%)		
			Definite	Probable or possible	No
1. Potassium dichromate 0.5%	1	1 (100%)	1 (100%)	/	/
2. Neomycin sulphate 20%	6	2 (33.3%)	/	3 (50%)	3 (50%)
3. Thiuram mix 1%	7	6 (85.7%)	6 (85.7%)	/	1 (14.3%)
4. Fragrance mix II 14% hard paraffin 14%	6	6 (100%)	5 (83.3%)	1 (16.7%)	/
5. Cobalt chloride $6H_2O$ 1%	7	6 (85.7%)	3 (42.9%)	3 (42.9%)	1 (14.3%)
6. Paraphenylenediamine free base	8	6 (75%)	6 (75%)	2 (25%)	/
7. Benzocaine 5%	/	/	/	/	/
8. Formaldehyde in water 1%	4	1 (25%)	1 (25%)	1 (25%)	2 (50%)
9. Colophony 20%	6	4 (66.7%)	1 (16.7%)	4 (66.7%)	1 (16.7%)
10. Clioquinol 5%	/	/	/	/	/
11. Balsam of Peru 25%	3	2 (66.7%)	1 (33.3%)	1 (33.3%)	1 (33.3%)
12. *N*-Isopropyl-*N*-phenyl-paraphenylenediamine 0.1%	2	1 (50%)	1 (50%)	/	1 (50%)
13. Wool alcohols 30%	/	/	/	/	/
14. Epoxyl resin 1%	/	/	/	/	/
15. Mercapto mix 1%	1	1 (100%)	1 (100%)	/	/
16. Budesonide 0.1%	2	2 (100%)	/	2 (100%)	/
17. Paraben mix 1%	3	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)
18. Paratertiarybutyl-phenol-formaldehyde resin 1%	1	1 (100%)	/	1 (100%)	/
19. Fragrance mix 8%	20	13 (65%)	9 (45%)	7 (35%)	4 (20%)
20. Quaternium-15 1%	/	/	/	/	/
21. Nickel sulphate $6H_2O$ 5%	30	29 (96.7%)	14 (46.7%)	11 (36.7%)	5 (16.7%)
22. 5-chloro-2-methyl-4-isothiazolin-3-one+ 2-methyl-4-isothiazolin-3-one 0.01% (3:1 in water)	10	7 (70%)	4 (40%)	3 (30%)	3 (30%)
23. Mercaptobenzothiazole 2%	1	1 (100%)	1 (100%)	/	/
24. Sesquiterpene lactone mix 0.1%	/	/	/	/	/
25. Tixocortol pivalate 1%	/	/	/	/	/
26. Dibromodicyanobutane 0.3%	3	1 (33.3%)	/	2 (66.7%)	1 (33.3%)
27. Hydroxymethypentylcyclohexene-carboxaldehyde 5%	1	1 (100%)	1 (100%)	/	/
28. Primin 0.01%	/	/	/	/	/
All of allergens 1-28 (European standard series)	122	92 (75.4%)	56 (45.9%)	42 (34.4%)	24 (19.7%)

Table 7. Differences in patients who could and could not recall the allergens identified in patch testing

		Recall of the allergen(s) identified		
	All (n=68)	**Partially or all (n=57)**	**None (n=11)**	**p**
Female gender (%)	49 (72.1%)	44 (77.2%)	5 (45.5%)	0.061
Age (year)	46.63±14.10	45.95±12.92	50.18±19.53	0.503
Median months (IQR) from test to interview	22.37 (9.15-32.25)	19.17 (8.72-33.24)	24.60 (22.27-29.73)	0.355
Number of allergen(s) identified				0.656
1	33 (48.5%)	26 (45.6%)	7 (63.6%)	
2	24 (35.3%)	21 (36.8%)	3 (27.3%)	
3	6 (8.8%)	6 (10.5%)	/	
4	4 (5.9%)	3 (5.3%)	1 (9.1%)	
7	1 (1.5%)	1 (1.8%)	/	
Education				0.040
Primary	12 (17.6%)	7 (12.3%)	5 (45.5%)	
Secondary	38 (55.9%)	34 (59.6%)	4 (36.4%)	
Tertiary	15 (22.1%)	14 (24.6%)	1 (9.1%)	

IQR=interquartile range

in patch testing, patients who were unable to recall the allergens were more likely to be of a lower educational level. Notably, age and gender did not appear to be predictive factors.

Discussion

Common allergens noted in our patch testing study

Nickel, fragrance, preservative and PPD are the commonest allergens found in patch testing.

Nickel has consistently been the commonest contact allergen detected in patients patch-tested for suspected allergic contact dermatitis.[12,13] It is present in drinking water, coins, spectacle frames, dental fillings and prostheses, buttons, zippers, jewellery, tools, alkaline batteries, insecticides, fuel additives, dyes, nickel plated items and some foods.

Some ingredients of cosmetic products were frequently labelled as "perfumes", "colognes" "aroma chemicals" or "essential oils" instead of the specific names. In addition, a quote of "unscented", "hypoallergenic" or even "fragrance-free" in product labels does not really guarantee that the product is truly free of all fragrances.[14] Some companies label their products as "fragrance-free" though they still contain natural fragrances.[15] A knowledge of these facts is important when educating our patients on allergen avoidance.

For preservatives, Kathon CG, a cosmetic preservative containing 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one as active ingredients, was identified as an important allergen in local Chinese patients[16,17] and Taiwan hairdressers.[18] It exists in cosmetics and toiletries, causing contact sensitisation.[19] Even moisturising cream may contain this ingredient that causes contact dermatitis.

Paraphenylenediamine is an organic aromatic amine present in hair dyes.[20] It is used for restoring dark hair colour[21] and is chemically related to other para-amino compounds.[22] A positive patch test reaction to PPD should alert the physician of the possibility of cross reactivity with a group of

immunochemically-related substances such as local anaesthetics and other chemicals with an amino group in the "para" position and therefore caution is needed.

Clinical relevance

Exploring the clinical history including exposure, time course, relapse, and locations of the patient's current dermatitis are crucial in determining the clinical relevance of the patch result. A detailed review of the presence of the allergen in the patient's home and working environment should be done as well as a thorough review on the use of cosmetics or skin-care products, occupation and hobbies.[14]

Clinical relevance may differ between identified allergens. In a study performed in Singapore, the allergens most likely to have present or past relevance were nickel sulphate (79% relevance), PPD (76% relevance), colophonium (73%), cobalt chloride (68%) and potassium dichromate (67%).[7]

In our study, due to the small sample size, we were not able to make a conclusive comment on the 'most relevant' allergen(s). However, for the most common allergens identified, all of them were associated with high clinical relevance (either definite or probable/possible relevance). More importantly, the overall clinical relevance was as high as 80.3%. This figure implies that the current, 28-item European series suits the local purpose of performing patch testing, though inevitably as in elsewhere, we may miss allergens that are not included in the series.

It is prudent to assess the significance or relevance at the time of final reading and provide the patient with a list of allergens to avoid. Extended follow-up may be necessary for accurate determination of the clinical relevance of allergens, especially in those circumstances in the patient's condition has not improved.[23] In this study, the median duration from patch testing to interview was 22.37 months. This time interval was likely to be long enough for patients to observe the relevance of the identified allergen(s) to the dermatitis.

Some patients do not have dermatitis upon exposure to an allergen despite a positive patch test reaction.[7,21] The absence of clinical relevance may be explained by the concept of clinical tolerance in which repeated exposures to low concentration of an allergen for short durations do not elicit dermatitis.[21] On the contrary, longer contact time and exposure to higher concentration of an allergen, as in patch testing, can trigger an elicitation response that results in a positive reaction.

Another possible explanation for doubtful clinical relevance of allergens is a false positive reaction. False positive reactions can be due to positive reaction against test vehicles or adhesive tape, pressure effect of tapes, impurities of the test substances, too high a concentration of the test substances and "angry back syndrome".[24,25]

Recall of allergens

Patch testing loses its value if education is not complete. A knowledge of established contact allergies is crucial to the patients in order to improve the prognosis.[9] In our study, patients with lower educational level were noted to have poor recall of the allergens. This patient group may be specifically targeted for education and periodic review.

The names of most allergens are difficult to remember.[14] On average, only 50% of the relevant allergens found in patch testing could be successfully recalled by patients.[8] It is possible that patients can only remember the more well-known allergens or those allergens proven to be clinically relevant to their skin condition. It is natural for a patient to forget the allergens to which he/she was not exposed to since these would be irrelevant.

Giving handouts detailing the names of the identified allergens, their synonyms, and common routes of encounter in daily life is often helpful.

Such a written reminder is the starting point that enables a patient to search for the allergens in their homes and working environment.[26] In some instances, it may be better for the patients to remember the substance group rather than the specific chemical name which may not appear in commercial product labels.[9]

Nevertheless, a written information sheet should never substitute a face-to-face education, which is a foundation for successful allergen avoidance. Relevant allergens should be discussed in detail. Practical, tailor-made avoidance strategies should be formulated. In fact, patients perceived verbal advice to be better understood than written information.[27] A thorough review of the products used by the patient in the office can be very helpful. This process helps the patients to practise label-reading and in identifying products with causative allergens.

Limitations

This study was a retrospective analysis of patch testing in a single public dermatology clinic, thus there is an inherent limitation when attempting generalisation of the results to the whole territory. However, as FLITC serves a population of ~1,300,000 in the Eastern and Northern districts of the New Territories, this study should provide a fair estimate of the situation in Hong Kong.

Many factors influenced the accuracy of our data of patch testing in Hong Kong. Among those was how a dermatologist selects patients for patch testing.[28,29] Case selection in our study was at the full discretion of the attending clinician. Furthermore, the recruitment of subjects for interview in this study was on a voluntary basis and report bias was inevitable. Conversely, some patients who had patch testing done a number of years ago were not included into this study since they had defaulted follow-up and could not be traced. In addition, the long time lag between patch testing and interview was a possible source of recall bias.

Conclusion

In this study, nickel sulphate, fragrance mix, 5-chloro-2-methyl-4-isothiazolin-3-one+ 2-methyl-4-isothiazolin-3-one 0.01% (3:1 in water) and PPD were the commonest allergens identified.

The overall 80.3% clinical relevance of the tested allergens suggested that the current European series is a suitable baseline panel in our service. Patients with persistent symptoms after patch testing might be the potential candidates for testing with other screening series after excluding other causes of dermatitis. The recall rate of 75.4% of allergen items was satisfactory but there was reduced recall rate in patients with a lower educational level. Extra work and alternative strategy should be focused on this group of patients to enhance recall so as to achieve a better avoidance of the allergens.

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