Title: How good is the Australian Baseline Series at detecting allergic contact dermatitis?

Running Title: Australian Baseline Series

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Title:

How good is the Australian Baseline Series at detecting allergic contact dermatitis?

Abstract:

Background:

Patch testing is the gold standard for the diagnosis of allergic contact dermatitis (ACD). The Australian Baseline Series (ABS) was formulated by our group to include the 60 most common and relevant allergens in our patient population.¹ The aim of this study was to assess the efficacy of testing with the Australian Baseline Series in order to diagnose ACD.

Methods:

We conducted a retrospective study of 964 patients with ACD diagnosed at our centre from 1st January 2012 to 31st December 2018. Patients with at least one relevant positive reaction contributing to ACD were stratified into three groups: 1) reactions only to allergens in the Australian Baseline Series; 2) reactions to allergens in the Australian Baseline Series and to additional allergens; and 3) reactions only to allergens not present in the Australian Baseline Series.

Results:

The Australian Baseline Series alone was successful in identifying the cause of ACD in 63.4% (611/964) of patients. In 23.0% (222/964), the Australian Baseline Series detected at least one relevant allergen but there were relevant allergens outside of the Australian Baseline Series as well. In 13.6% (141/964), no relevant allergens were detected in the Australian Baseline Series but allergens were detected in additional series or by testing patients' own products. The most frequently occurring allergens not included in the Australian Baseline Series were citral, ammonium persulfate, geraniol, oakmoss absolute and chlorhexidine diacetate.

Conclusions:

The Australian Baseline Series is an adequate screening tool for identifying patients with ACD. Nevertheless, females should be additionally routinely tested with the fragrance series. Patients with suspected occupationally related dermatitis should always be tested with additional allergens and own products.

Key words: allergic contact dermatitis, baseline series, allergens, fragrances

Main text:

Introduction

Contact allergy refers to the presence of skin sensitisation and is a common condition with a prevalence of 20% in the general population.¹ However, making a diagnosis of allergic contact dermatitis (ACD) requires three components: the patient's typical clinical course, a positive patch test to an allergen and a history of exposure to that allergen, denoting its relevance. An early and accurate diagnosis can lead to improved quality of life and prevent refractory disease.^{2,3}

The baseline or standard series refers to a minimum set of allergens used for patch testing every patient and should reflect the most common allergens in a given population.² Multiple baseline series have been proposed internationally, reflecting the diverse allergens found in regional patient groups. The Australian Baseline Series was first formulated in 2012 by our group and includes the 60 most common and relevant allergens in our patient population.²

Alongside this, specialised patch testing clinics generally supplement their baseline series with additional allergen series as well as patients' own products, based on the occupational and specific environmental exposures for each patient. The aim of this study was to assess the efficacy of the Australian Baseline Series in diagnosing ACD in a tertiary setting.

Methods

We conducted a retrospective study of patients who were patch tested at our tertiary referral centre at the Skin Health Institute (formerly the Skin and Cancer Foundation Inc). Patients were included from both Occupational Dermatology and Contact Dermatitis clinics. Data were collected from patients tested from January 2012 when the Australian Baseline Series was first implemented to 31st December 2018 and included detailed histories and examinations.

All patients were routinely patch tested to the Australian Baseline Series, as well as additional allergen series as assessed by the clinician, together with their own products which were tested at appropriate dilutions.

Allergens were supplied by Chemotechnique Diagnostics® (Malmö, Sweden) and were applied to patients' backs using SmartPractice allergEAZE chambers® (Phoenix, Arizona, USA). Readings were performed on day 2 and day 4 according to the International Contact Dermatitis Research Group guidelines. The diagnosis of ACD was based on the patients' clinical course, positive patch test(s) and history of exposure to allergen(s), denoting a relevant reaction.

Patients were included if their primary diagnosis was ACD, with relevant reactions demonstrated. Exclusion criteria included patients who did not have ACD as their primary diagnosis, patients who were not patch tested to the complete Australian Baseline Series, and those with any unknown or old reactions. House dust mite patch test reactions were also excluded and were considered in retrospect to be mostly irritant in nature. Patients who were referred from our Oral Mucosal Clinic for specific testing of cheilitis and/or oral lichen planus and those assessed for prosthetic joint reactions were also excluded, as it was considered that allergens tested in their situations were outside the normal range of allergens used in routine testing.

Patients with at least one positive reaction were stratified into three groups: 1) reactions only to allergens on the Australian Baseline Series; 2) reactions to allergens on the Australian Baseline Series and to additional allergens; and 3) reactions only to allergens not present on the Australian Baseline Series. For patients in Group 1, the Australian Baseline

Series was said to “solve the problem”, for patients in Group 2, the Australian Baseline Series was said to “partially solve the problem” and for patients in Group 3, the Australian Baseline Series was said to “not solve the problem”.

If a patient reacted to a mix in the Australian Baseline Series as well as to the individual allergens, then it was usually considered that the mix would diagnose ACD and these patients would be classified into Group 1. If the patient reacted to p-phenylenediamine (PPD) in the Australian Baseline Series but also to other hair dyes such as toluene 2,5 diamine sulphate, p-aminophenol or 2-nitro-4-phenylenediamine, then it was classified that the positive reaction to p-phenylenediamine had diagnosed their ACD. If the patient reacted to hydroxyethyl methacrylate (HEMA) and other acrylates, then it was classified that HEMA had diagnosed their ACD. If a patient reacted to carba mix in the Australian Baseline Series as well as tetramethylthiuram disulphide or diphenylguanidine then it was assumed that the carba mix diagnosed their ACD. Finally, if a patient reacted to fragrance mixes 1 and/or 2, this was also regarded as diagnosing their ACD, although there are specific limitations with testing with the fragrances mixes, which will be addressed below.⁴

Statistical analysis was performed using Excel (Microsoft Corporation, Redmond, WA, USA) using the chi-square test and differences were considered to be statistically significant at $p < 0.05$.

Results

A total of 2836 patients were patch tested from 1 January 2012 to 31 December 2018. Of these, 1090 patients (38.4%) were given a primary diagnosis of ACD. The 126 patients excluded included 97 patients with cheilitis/oral problems, 8 patients investigated for prosthetic joint reactions and 21 patients not tested to the full Australian Baseline Series, leaving a total of 964 patients. Approximately one third of the cohort (331/964, 34.3%) attended the Occupational Dermatology clinics and the remainder of the cohort (633/964, 65.7%) attended the general Contact Dermatitis clinics.

The MOAHLFA criteria (male, occupational dermatitis, atopic dermatitis, hand, leg, face and age >40) is shown in Table 1. The demographics of our cohort revealed a 3:1 female to male ratio (73.3% (707/964) females and 26.7% (257/964) males). The mean age was 44.5 years (range 8-86). The most common site of rash was on the hands which was reported in 28.6% (276/964) of patients, the face (24.5%, 236/964), anogenital (16.0%, 154/964) and the arms (8.2%, 79/964). There was often more than one site affected per patient. ACD was deemed to be fully work related in 20.2% (195/964) patients, and partially work related in 4.0% (39/964) patients. Patients were assessed by the examining clinician to be atopic in 24.9% of cases (240/964). Patients self-reported a history of atopic eczema in 31.0% (299/964), history of asthma in 24.8% (239/964) and a history of hay fever in 40.4% (389/964).

Testing with the Australian Baseline Series alone was successful in identifying the relevant allergen causing ACD and hence “solving the problem” in 63.4% (611/964) of patients. The Australian Baseline Series partially solved the problem in 23.0% (222/964) of patients. The Australian Baseline Series did not solve the problem in 13.6% (131/964) of patients (see Table 2). There was no significant difference between the ability of the Australia Baseline Series to fully detect relevant allergens in the Occupational Dermatology clinics compared to the Contact Dermatitis clinics ($p = 0.195$).

The top ten allergens in Group 1 (Australian Baseline Series allergens) associated with ACD (and their respective relevant-positive reaction rates) are shown in Table 3 and include methylisothiazolinone (MI) (21.2%), methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) (19.8%), fragrance mix 1 (14.5%), nickel (8.2%), p-phenylenediamine (6.3%), fragrance mix 2 (6.2%), *Myroxylon pereirae* (Balsam of Peru) (5.7%), potassium dichromate (5.0%), cocamidopropyl betaine (4.7%) and thiuram mix (3.9%). The top allergens not included in the Australian Baseline Series but were most frequently positive and relevant either in Group 2 or Group 3 included citral (although present in fragrance mix 2), ammonium persulfate, geraniol and oakmoss absolute (although both present in fragrance mix 1) and chlorhexidine diacetate (Table 4).

The most common relevant positive allergens in Group 2 and Group 3 that were not present in the Australian Baseline Series, were in males, epoxy resin bisphenol F ($n=10$), 2-n-octyl-4-

isothiazolinone (n=6), citral (n=5) and chlorohexidine diacetate (n=4). In females, they were ammonium persulfate (n=22), citral (n=21), geraniol (n=19), oakmoss absolute (n=13), and lavender spike oil (n=13).

Discussion

The ongoing dynamic evaluation of a baseline series is crucial in order to monitor trends, identify emerging allergens, allow comparison between populations and assess the diagnostic efficacy of the baseline series itself.^{2,5} This study demonstrates that when used alone, the Australian Baseline Series will successfully diagnose ACD in almost two thirds of patients who are ultimately diagnosed with ACD. It is possible of course, that some people had ACD where the allergen was not identified, although every patient was tested as comprehensively as possible with additional series where relevant and their own samples.

Only 13.6% of patients were positive for a supplementary allergen alone. However, 23.0% were positive for at least one Australian Baseline Series allergen and one supplementary allergen. Therefore, if patients had not been tested with supplementary allergens, 36.6% would have had one or more allergens missed. Overall, 86.4% of patients with ACD had at least one positive reaction picked up from the Australian Baseline Series.

The components of baseline series vary between regions and over time, meaning that direct comparisons can be difficult. Reports have suggested that baseline series fully evaluate ACD in 23.0 - 85.8% of cases, clearly a wide range, and likely to be dependent on the size of the series.⁶⁻¹¹

Previous studies have shown a greater detection rate of allergens with the use of larger series.¹² Examples of large baseline series include the North American Contact Dermatitis Group series of 70 allergens. Despite this, 23% of patients had a relevant positive allergic reaction not on the North American Contact Dermatitis Group series.¹³ In contrast, smaller series such as the Thin-layered Rapid Use Epicutaneous (TRUE) Test (Smart-Practice, Phoenix, AZ®) currently contains 35 allergens plus a negative control (3 panels). In the past, this has been reported to have been used by nearly half of Australian practising

dermatologists.^{14,15} It has been associated with a detection rate as low as 27.6% in fully diagnosing ACD.^{6,8} Furthermore, up to 50% of allergens causing occupational dermatitis are missed when the TRUE test® is used.¹³ Other shortfalls include the inability to customise the panel to potential allergens encountered in an individual's workplace and hobbies. However, TRUE test® is currently the FDA-approved standard for diagnosing ACD in the United States.¹⁵

The most significant allergen missing in TRUE test® is MI, which caused an epidemic of ACD during the time that this study was performed.¹⁶ In the TRUE test®, only MI/MCI (also known as Kathon CG®) is tested, which may underestimate MI allergy. The TRUE test® also only screens for fragrance mix 1 and has the potential to miss other fragrance allergies, such as citral, the most common allergen in our study not included in the Australian Baseline Series.⁶

The efficacy of the European Baseline Series (now 30 allergens) in diagnosing ACD was assessed in a multicentre European study of 4824 patients in 1992, where there was a large range 37- 73% of patients reacting to allergens in the series from different centres.¹⁰

Of the relevant reactions from testing with the Australian Baseline Series in our study, the top 10 most frequent allergens in Group 1 were MI, MCI/MI, fragrance mix 1, nickel, p-phenylenediamine, fragrance mix 2, *Myroxylon pereirae*, cocamidopropyl betaine, potassium dichromate, and thiuram mix. These top allergens are largely similar to those described by Toholka et al (2015) who prior to the introduction of the Australian Baseline Series, reported the top allergens (out of all allergens tested) in a patient population from the same institution between 2001 and 2010. Differences include the increased frequency of MI, MI/MCI, and formaldehyde reactions seen in this present study.²

When choosing additional allergens to test, it is important to take a comprehensive history including occupational and environmental exposures. Our study found that in 36.6% of cases, at least one relevant allergen was detected on supplementary series. In 13.6% of cases, no allergens were detected on the Australian Baseline Series but relevant allergens

were detected only from the additional series. This is a similar figure to that reported by Zug et al in 2008 who found that 15% of children had relevant allergens that were not included in the North American Contact Dermatitis Group baseline series.¹⁷ Higher figures have been reported showing that up to a quarter of ACD diagnoses would be missed by the North American Contact Dermatitis Group series without the use of additional allergens.^{13,18,19}

The most common relevant allergen that was detected from additional allergen testing was citral, a component of fragrances and flavourings which was prevalent in both females and males in our study. Of the patients who had a positive citral reaction on supplementary testing (26 patients), nearly half of these patients (46.2%) tested negative for fragrance mix 2 on the Australian Baseline Series.

It has been shown by a study in Sweden that more than a third of patients who have positive reactions to components of fragrance mix 2, do not react to fragrance mix 2 itself. Similarly, 27% of patients with positive reactions to fragrance mix 1 ingredients did not have a reaction to fragrance mix 1 itself.²⁰ In this particular study in Sweden, citral was also the most commonly encountered individual fragrance allergen from fragrance mix 2 with a positive reaction rate of 1.2%. In our study, we had a greater relevant-positive reaction rate of 3.6%.

Other important allergens in females not included in the Australian Baseline Series in females were geraniol, oakmoss absolute and lavender spike oil. All these allergens are fragrances which likely explains their increased frequency in females, who traditionally have used more cosmetics than males. In light of these findings, we agree with recent suggestions that all females should routinely be tested with the fragrance series.^{21,22}

Ammonium persulfate was another common allergen that is not included in the Australian Baseline Series. Ammonium persulfate is found in hairdressing bleach where it is added as a booster to hydrogen peroxide. It was not added to the Australian Baseline Series despite having a relevant positive rate of 6% in those tested between 2001 and 2010, as it was thought that ACD to ammonium persulfate was likely to be overrepresented in the patient population used to formulate the Australian Baseline Series, given that most patients

allergic to ammonium persulphate were hairdressers attending the Occupational Dermatology clinic.² In this present study, it was the most common allergen not included in the Australian Baseline Series to be found in females, yet 65% (15/23) of those with an ammonium persulfate allergy were hairdressers. It is likely that the majority of positive reactions to ammonium persulfate would have been found by testing these hairdressers with the hairdressing chemicals series, again highlighting the importance of testing with additional series based on occupational exposures.

In males, the most common allergens not included in the Australian Baseline Series were epoxy resin bisphenol F, 2-n-octyl-4-isothiazolinone, citral and chlorhexidine diacetate, also mostly reflecting occupational exposures.

The main limitation to our study is that it is limited to one tertiary referral centre in Melbourne. In addition, nearly all patients were referred from the state of Victoria, and thus may not accurately represent the general population in Australia. This was the same population studied when the Australian Baseline Series was introduced. Pooling data from other centres throughout Australia would allow for a more national perspective.

Furthermore, 34% of our study cohort were seen in the Occupational Dermatology clinic, where patients may be exposed to and react to more specialised and unusual allergens, less reflective of allergens seen in general dermatology practice. It is also possible that there were cases where the diagnosis of ACD was missed, as a relevant allergen was not identified. Finally, several different dermatologists were involved in reading the patch tests and assessing whether the reaction was relevant to the patient's history, so there may be a degree of investigator bias. However, all variables collected were standardised whenever possible.

Conclusion

The benefits of patch testing are considerable. Appropriate patch testing can lead to improved diagnoses, thereby reducing the morbidity and economic impact of ACD. Overall, our study shows that the Australian Baseline Series detected relevant allergens in 63% of patients with ACD and at least one relevant allergen in 86% of cases. This should reassure

dermatologists that the Australian Baseline Series is an appropriate screening series with a likelihood of finding a culprit allergen in approximately two thirds of cases. However, using the Australian Baseline Series alone has the potential to miss a relevant reaction in 36.6% of cases. This study highlights the importance of testing patients to additional series and their own products in order to obtain a higher yield of reactions and hence a more accurate diagnosis. Based on our findings, we concur with recent international recommendations to routinely test all females with the fragrance series as well as the Australian Baseline Series. In addition, cases of occupational dermatitis may require testing with additional allergen series.

These results will also be used to update the constituents of the Australian Baseline Series, as it is important that baseline series are dynamic and regularly subject to review.

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Tables

Table 1: MOAHLFA (male, occupational dermatitis, atopic dermatitis, hand, leg, face and age >40) characteristics in 964 subjects patch tested at our institution from 2012 to 2018

Index	Patients (n)	Percentage of study population (%)
Male	257	26.7
Occupational dermatitis	234	24.3
Atopic dermatitis	240	24.9
Hand dermatitis	276	28.6
Leg dermatitis	49	5.1
Face dermatitis	236	24.5
Age above 40	599	62.1

Table 2: The ability of the Australian Baseline Series (ABS) to fully or partially detect allergens (patients with all relevant allergens in ABS in Group 1, patients with some allergens detected in ABS and some in supplementary series in Group 2, and patients with all relevant allergens detected in supplementary series in Group 3)

	Occupational Dermatology clinic Number (%)	Contact Dermatitis clinic Number (%)	Clinics combined Number (%)
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<i>ABS fully detected relevant allergens (Group 1)</i>	219 (66.2) Work related: 140 (64.0%)	392 (61.9) Work related: 5 (1.3%)	611 (63.4) Work related: 145 (23.7%)
<i>ABS partially detected relevant allergens (Group 2)</i>	58 (17.5) Work related: 50 (86.2%)	164 (25.9) Work related: 4 (2.4%)	222 (23.0) Work related: 54 (24.3%)
<i>ABS did not detect relevant allergens (Group 3)</i>	54 (16.3) Work related: 35 (64.8%)	77 (12.2) Work related: 0 (0.0%)	131 (13.6) Work related: 35 (26.7%)

Table 3: The most frequent relevant reactions to

allergens in the Australian Baseline Series that fully diagnosed allergic contact dermatitis at our institution from 2012 to 2018

Number	Allergen	Number (n)	Relevant/tested %
1	Methylisothiazolinone	204	21.2
2	Methylchloroisothiazolinone/ methylisothiazolinone	191	19.8
3	Fragrance mix 1	140	14.5
4	Nickel	79	8.2
5	P-phenylenediamine (PPD)	61	6.3
6	Fragrance mix 2	60	6.2
7	<i>Myroxylon pereirae</i>	55	5.7
8	Potassium dichromate	48	5.0
9	Cocamidopropyl betaine	45	4.7
10	Thiuram mix	38	3.9
11	Hydroperoxides of limonene	36	3.7
12	Formaldehyde	32	3.3
13	Carba mix	32	3.3
14	Hydroperoxides of linalool	28	2.9

15	Cobalt chloride	23	2.4
16	Colophony	21	2.2
17	Amerchol	21	2.2
18	2-hydroxyethyl methacrylate	20	2.1
19	Hydroxyisohexyl 3 cyclohexene- Lyrall	16	1.7
20	Iodopropynyl butyl carbamate	14	1.5

Table 4 : Most frequent relevant reactions to allergens not in the Australian Baseline Series in patients patch tested at our institution from 2012 to 2018

	Allergen	Series	Number (n)	Relevant/ Tested %
1	Citral	Cosmetic/Frag mix 2	26	3.9
2	Ammonium persulfate	Hairdressing chemicals	23	21.7
3	Geraniol	Fragrance common/Frag mix 1	20	7.5
4	Oakmoss absolute	Cosmetic/Fragrance common/Frag 1	16	2.5
5	Chlorhexidine diacetate	Antiseptics/nurses	15	13.0
6	Chlorhexidine digluconate	Antiseptics/nurses	13	8.2
7	Lavender spike oil (8% in petroleum)	Fragrance common	13	11.6
8	Citronellol	Fragrance common/Frag 2	12	4.1
9	Isoeugenol	Fragrance common/Frag 1	11	6.9
10	Abitol	Cosmetic	11	1.8
11	Propolis	Cosmetic	11	1.8
12	Epoxy resin, bisphenol F	Epoxy	10	27.0

13	Toluene 2, 5 diamine sulfate	Hairdressing chemicals	9	34.6
14	Hexyl cinnamic aldehyde	Fragrance common/Frag 2	9	4.1
15	Benzoic acid	Cosmetic	9	6.4
16	Grevillia extract (20% in acetone)	Plant extract	9	30.0
17	p-Aminophenol	Hairdressing chemicals	8	5.2
18	Anise alcohol	Fragrance common	7	6.8
19	Dodecyl gallate	Cosmetic series	7	1.2
20	Lavender angustifolia	Fragrance common	7	4.9
21	Cinnamic alcohol	Fragrance common/Frag 1	7	3.7
22	2-n-octyl-4-isolthiazolinone	Plastic and glues	7	8.9
23	Benzyl salicylate	Fragrance common	6	2.4
24	Hydroxy citronellol	Fragrance common/Frag 1	6	3.2
25	Lillial	Fragrance common	6	2.8
26	Phenoxy ethanol	Cosmetic	6	0.9
27	Eugenol	Fragrance common/Frag 1	6	2.2

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