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Rolls, S.; Owen, E.; Bertram, C. G.; Bourke, J. F.; Buckley, D. A.; Chowdhury, M. M. U.

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DR SOPHIE ROLLS (Orcid ID : 0000-0002-4139-7193)

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What's in? What's out? Updating the British Society for Cutaneous Allergy Facial Series

S. Rolls,¹ E. Owen,¹ C.G. Bertram,² J.F. Bourke,³ D.A. Buckley,⁴ M.M.U. Chowdhury,⁵ S.M. Cooper,⁶ S.A. Ghaffar,⁷ C.M. Green,⁷ T.M. Hughes,¹ G.A. Johnston,⁸ C.M. Reckling,⁹ D.A. Thompson,¹⁰ S.H. Wakelin,¹¹ M. Wilkinson¹² and N.M. Stone¹

1. Royal Gwent and Nevill Hall Hospitals, Newport, U.K
2. Royal Infirmary of Edinburgh
3. South Infirmary Victoria University Hospital, Cork, Ireland
4. Royal United Hospital Bath, U.K.
5. University Hospital of Wales, Cardiff, U.K.
6. Oxford University Hospital, U.K.
7. Ninewells Hospital, Dundee, U.K.
8. Leicester Royal Infirmary, Leicester, U.K.
9. Kent and Canterbury Hospital, Canterbury, U.K.
10. Sandwell and West Birmingham Hospitals NHS Trust, U.K.
11. Imperial College Healthcare NHS Trust, London, U.K.
12. Leeds Teaching Hospital NHS Trust, Leeds, U.K.

Corresponding author: Sophie Rolls

Email: sophie.rolls@nhs.net

ORCID: 0000-0002-4139-7193

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Summary

Background Allergic contact dermatitis (ACD) to cosmetics is widely reported. To ensure we are accurately diagnosing ACD, patch test series should be continually reviewed to identify relevant and emerging allergens and highlight those which are outdated. The current British Society for Cutaneous Allergy (BSCA) facial series recommends 26 allergens and was last modified in 2012.

Objectives To review and update the BSCA facial series.

Methods We retrospectively reviewed the results from 12 U.K. and Ireland patch test centres' facial series from January 2016 to December 2017. We recorded the number of allergens tested in each centre and the detection rate for each allergen. Using a 0.3% positive rate as the inclusion threshold, we established those allergens in the BSCA facial series with a positive patch test rate $<0.3\%$ and $>0.3\%$. Allergens not in the BSCA facial series which had a positive patch test rate $>0.3\%$ were identified.

Results 4224 patients were patch tested to the facial series. The number of allergens included in individual centres' facial series ranged from 24 to 66 with a total of 103 allergens tested across all centres. Twelve of the 26 allergens in the BSCA facial series had a positive patch test rate $<0.3\%$ and 14 had a rate $>0.3\%$. Twenty-five allergens not recommended in the BSCA facial series had a positive patch test rate $>0.3\%$.

Conclusion This audit has highlighted the significant variation in practice that exists amongst patch test centres, despite a recommended facial series. The BSCA facial series has been updated and now contains 24 allergens. Fifteen allergens remain, 11 allergens have been dropped and 9 new allergens have been added.

Key words: allergic contact dermatitis; facial series; cosmetic allergens, patch testing.

Background

Allergic contact dermatitis (ACD) to cosmetics is widely reported, with many key ingredients of facial cosmetics being potent contact allergens. Facial dermatitis is recognised as one of the dominant presenting complaints, as the face is exposed to the greatest number of cosmetics. Facial ACD has a significant impact on a patient's quality of life.¹ To ensure accurate diagnosis of contact allergy, it is important that patch testing is performed with relevant allergens. Hence, patch test series need to be continually reviewed to identify relevant, outdated and new emerging allergens.

The current British Society for Cutaneous Allergy (BSCA) facial series recommends 26 allergens and was last modified in 2012.

Our aim was to review the 2012 BSCA facial series to identify which allergens were being tested in facial series in the United Kingdom (U.K.) and Ireland, and to document the detection rate of individual allergens. Using this information, we intended to create an updated, 2019 BSCA facial series.

Methods

We retrospectively reviewed the results for the facial series patch tested in 12 U.K. and Ireland centres for the 2 year period from January 2016 to December 2017. We recorded the number of allergens tested in each centre and the frequency of positive patch tests to each allergen.

The European Society of Contact Dermatitis (ESCD) suggests that for an allergen to be included in the baseline patch test series, and hence tested in consecutive patients, it should have a positive patch test rate of 0.5-1%.² Using the ESCD recommended 0.5% threshold for inclusion retrospectively on our data, a significant number of allergens would have been removed from the facial series. In contrast, using a lower 0.2% threshold for inclusion, few allergens would have been removed and the facial series would still contain a large number of cosmetic allergens.

Selecting an appropriate number of allergens to include in a facial series is a difficult task. There is an overwhelming number of cosmetic chemicals which increases continually as new products appear on the market. The authors wanted to avoid including too many allergens in the facial series, since patch testing with many allergens is time consuming, costly, wasteful and can increase the risk of active sensitisation. Equally, choosing too few allergens could result in failing to identify pertinent allergens and missing treatable cases of allergic contact dermatitis to cosmetic, which defeats the aim of a facial series. Therefore, the authors reached a consensus that this balance was met using a threshold for inclusion of 0.3%.

Using the 0.3% inclusion threshold we identified those allergens in the current BSCA facial series with a positive patch test rate of <0.3%, to be considered for removal. Allergens *not* currently recommended in the BSCA facial series and with a positive rate of >0.3%, were discussed for inclusion into an updated facial series. The positive patch test rate of allergens already in the BSCA facial series was also identified.

Results

Over the 2-year period, 4224 patients were patch tested to a facial series in 12 centres. The number of allergens included in individual centres' facial series varied, ranging from 24 to 66. Despite the BSCA recommending only 26 allergens in the 2012 facial series, a total of 103 different allergens were being tested.

Of the 26 allergens in the current BSCA facial series, 12 had a positive patch test rate of less than 0.3%. These allergens include (listed in order of lowest to highest detection rate): 2,6-di-tert-butyl-4-cresol (BHT) 2.0% petrolatum (pet.); chloroacetamide 0.2% pet.; sorbic acid 2.0% pet.; 2-tert-butyl-4-methoxyphenol (BHA) 2.0% pet.; triclosan 2.0% pet.; benzophenone-3 10.0% pet.; 0.2% pet.; DMDM hydantoin 2.0% aqueous (aq.); ethylenediaminetetraacetic acid disodium salt dihydrate (EDTA) 5.0% pet.; triethanolamine 2.0% pet.; cocamide DEA 0.5% pet. and butyl methoxydibenzoylmethane 10.0% pet. The rate of positive patch tests ranged from 0.07% to 0.24%.

Of the 26 allergens in the current BSCA facial series, 14 had a positive patch test rate of greater than 0.3%. These allergens include (listed in order of lowest to highest detection rate): benzyl alcohol 10.0% pet.; cocamidopropyl betaine 1.0% aq.; lauryl glucoside 3.0% pet.; melaleuca alternifolia (tea tree) 5.0% pet.; tosylamide/formaldehyde resin 10.0% pet.; sorbitan sesquioleate (Arlacel® 83) 20.0% pet.; oleamidopropyl dimethylamine 0.10% aq.; tert-butylhydroquinone (TBHQ) 1.0% pet.; propyl gallate 1.0% pet.; lanolin alcohol 50.0% pet.; hydroabietyl alcohol 10.0% pet.; glyceryl thioglycolate 1.0% pet.; propolis 10.0% pet. and sodium metabisulfite 1.0% pet. The rate of positive patch tests ranged from 0.35% to 3.14%.

There were 25 allergens not in the current BSCA facial series which had a positive patch test rate greater than 0.3%. These allergens include (listed in order of lowest to highest detection rate): methenamine 2.0% pet.; benzyl salicylate 10.0% pet.; mentha piperita 2.0% pet.; panthenol 5.0% pet.; sodium benzoate 5.0% pet.; propylene glycol 5.0% pet.; phenylmercuric acetate 0.01% aq.; phthalic anhydride 1% pet.; octyl gallate 0.25% pet.; vanillin 10.0% pet.; benzophenone-4 2.0% aq.; tocopherol acetate 10.0% pet.; ethylhexylglycerin 5.0% pet.; hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine 1.0% aq.; shellac 20.0% alcohol (alc.); decyl glucoside 5.0% pet.; dodecyl gallate 0.25% pet.; 3-(dimethylamino)-1-propylamine 1.0% aq.; octylisothiazolinone 0.1% pet.; thiomersal 0.1% pet.; benzoic acid 5.0% pet.; carvone 5.0% pet.; sodium thiosulfate 2.0% pet.

and benzalkonium chloride 0.10% aq. The rate of positive patch tests ranged from 0.32% to 3.96%.

Of the 103 allergens tested, 14 were tested in a single patch test centre. Four of these gave no positive reactions. Four had a high rate of positive reactions: benzoic acid (3.02%), benzisothiazolinone (2.26%), sodium thiosulfate (3.9%) and carvone (3.66%).

Discussion

Despite there already being a recommended facial series, this audit has highlighted the significant variation in practice that exists amongst U.K. patch test centres. Whilst individual centres can and should test with whichever allergens they consider locally important, a standardised series which is regularly updated is of value. It allows centres to keep up to date, eliminating allergens with low yield and of questionable importance, whilst including relevant and emerging allergens, improving diagnosis and facilitating audit of results.

From the current BSCA facial series, 14 of the 26 allergens had positive patch test rates $>0.3\%$. The BSCA agreed to keep 11 of these allergens in the modified facial series (Table 1). Sodium metabisulfite and lanolin alcohol were not included as they are already present in the BSCA standard series. Glyceryl thioglycolate remains in the hairdressing series. Not all patch test centres had tested all the previously recommended allergens in their facial series, since some were included in individual centres' baseline series, for example propolis and lauryl glucoside. Both these allergens are currently in the European Baseline series.^{3 4}

Almost half of the allergens currently in the BSCA facial series had a positive patch test rate of $<0.3\%$ questioning their diagnostic value. The BSCA reviewed these allergens and removed 8 of them (Table 2) whilst agreeing to keep 4 in the facial series: EDTA, iodopropynyl carbamate, cocamide DEA and triethanolamine. Their positive rate was just below the 0.3% threshold but all four allergens were felt to be relevant when positive.^{5 6 7} In particular iodopropynyl butyl carbamate was judged to be of importance as a potential commercial alternative to methylisothiazolinone.⁸

Of the 25 allergens not currently recommended, but which had a high positive rate $>0.3\%$, the BSCA agreed that 8 allergens were relevant: tocopherol, panthenol, benzophenone-4, 3-(dimethylamino)-1-propylamine, dodecyl gallate, octyl gallate, decyl glucoside and propylene glycol. Tocopherol (vitamin E) and panthenol (vitamin B) are ubiquitously found in cosmetic

products and wet wipes. Benzophenone-4 had the highest detection rate of the sunscreen allergens and is present in many shampoos and make ups. 3-(dimethylamino)-1-propylamine, also known as (dimethylaminopropylamine, DMAPA), is a reagent in the formation of cocamidopropyl betaine (CAPB), a common additive in liquid soaps, shampoos and other cleansing products due to its utility as a surfactant.⁹ Gallates are commonly used antioxidant preservatives and gallate allergy is frequently reported in the literature, with propyl gallate being the most commonly reported gallate contact allergen and a frequent cause of facial ACD.^{10 11} Alkyl glucosides are nonionic surfactants formed through the condensation of glucose with fatty alcohol derived from palm, coconut and rapeseed oil. They are found in rinse off products and leave on cosmetics including sunscreens and moisturisers. Reports of ACD to these emergent allergens: decyl glucoside, the original alkyl glucoside, and lauryl glucoside, have increased in recent years.¹² Propylene glycol is an emollient and emulsifier found in cosmetics, medications and food. It is an emerging allergen which is ubiquitous in cosmetics.¹³ These allergens have been added to the 2019 modified facial series.

The allergen with the highest detection rate was benzalkonium chloride at 3.96%, which the BSCA recommended in its medicament rather than facial series. Octocrylene is an ultraviolet-B absorbing agent, frequently used in sunscreen cosmetics: creams, lotions, lipsticks and oils, which is considered to belong to the family of cinnamates. There is compelling evidence in the literature identifying it as an emerging photo allergen, where the majority of positive reactions are thought to result from previous photo contact sensitisation to topical ketoprofen preparations.^{14 15} ¹⁶ The BSCA have therefore agreed to include octocrylene in the updated facial series.

Of the remaining 17 allergens: 8 allergens were placed in other series which were felt to be more appropriate (Table 3). Three allergens were not currently recommended for inclusion in any series: hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine, phthalic anhydride and methenamine.

Phthalic anhydride, a film former used in nail polish, is an emerging cause of cosmetic dermatitis,¹⁷ but is not yet commercially available for patch testing.

Three allergens were not deemed cosmetic allergens: benzisothiazolinone, octylisothiazolinone and sodium thiosulfate. Benzisothiazolinone and octylisothiazolinone are not permitted in cosmetics, and are currently being trialled in the European Baseline Series. Sodium thiosulfate is known to be an irritant and its relevance often questioned.¹⁸ 2-hydroxyethyl methacrylate (HEMA) was removed as it is used as a screening allergen in the BSCA baseline series.¹⁹ Ethylhexylglycerin, a new cosmetic ingredient used for its surfactant, emollient and antimicrobial

properties which has a low allergenic risk but is usually relevant when positive,²⁰ and sodium benzoate were included in an extended (supplementary) 2019 facial series. This series contains 7 allergens of less proven importance which require further analysis over the next year by the BSCA. The additional 5 allergens within the extended series include: 2,6-ditert-butyl-4-cresol (BHT), 2-tert-butyl-4-methoxyphenol (BHA), methoxybenzophenone (oxybenzone), DMDM hydantoin and shellac.

Four allergens tested in only one patch test centre which had significant positive rates: sodium thiosulfate (3.9%), benzoic acid (3.02%),²¹ benzisothiazolinone (2.26%) and carvone (3.66%). Benzisothiazolinone is not considered a cosmetic allergen. Carvone, a mint flavour in spearmint oil and an oxidation product of D-limonene, is considered a mild sensitiser. Sensitisation may be linked to oral/perioral signs, although studies are sparse.²² Whilst we cannot draw any reliable conclusion, since these allergens were tested in an individual patch test centre, further studies are suggested to assess their importance.

This study collected data retrospectively over a 2 year period, which the authors recognise is a limitation. We aim to collect data over a 5 year period in our next review, to give more perspective data and be better placed to more accurately assess the evolution of each allergen.

Conclusion

The BSCA facial series has been updated in response to the results of our multicentre audit. Reviewing current literature and auditing practice is a vital requirement to ensure that patch test series are kept up to date with the most relevant allergens, and to ensure that treatable cases of facial dermatitis are not missed.

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Allergen	Conc.	Base	No. Of patients tested	Positive patch test rate	95% confidence interval
Panthenol*	5.00%	pet.	1903	0.47%	0.25-0.89
Decyl glucoside*	5.00%	pet.	1432	1.89%	1.30-2.73
Tosylamide/formaldehyde resin	10.00%	pet.	4180	0.48%	0.31-0.74
Octyl gallate*	0.25%	pet.	1423	0.77%	0.43-1.38
Cocamidopropyl betaine	1.00%	aq.	4224	0.38%	0.20-0.62
Propylene glycol*	5.00%	pet.	872	0.57%	0.24-1.33
Tert-Butylhydroquinone (TBHQ)	1.00%	pet.	4224	0.62%	0.42-0.91
Dodecyl gallate*	0.25%	pet.	839	2.15%	1.36-3.37
Propyl gallate	1.00%	pet.	4224	0.80%	0.57-1.12
Hydroabietyl alcohol	10.00%	pet.	4224	1.16%	0.88-1.53
Benzyl alcohol	10.00%	pet.	2601	0.35%	0.18-0.66
3-(dimethylamino)-1-propylamine	1.00%	aq.	872	2.18%	1.40-3.38
Triethanolamine	2.00%	pet.	4224	0.24%	0.13-0.44
Benzophenone-4*	2.00%	pet.	1390	0.79%	0.44-1.41
Ethylenediaminetetraacetic acid disodium salt dihydrate (EDTA)	1.00%	pet.	3853	0.23%	0.12-0.44
Melaleuca alternifolia (tea tree)	5.00%	pet.	4224	0.45%	0.29-0.70
Octocrylene*	10.00%	pet.	-	-	-
Iodopropynyl butyl carbamate	0.20%	pet.	4224	0.17%	0.08-0.35
Oleamidopropyl dimethylamine	0.10%	aq.	3831	0.60%	0.40-0.90
Sorbitan sesquioleate (Arlacel® 83)	20.00%	pet.	4033	0.52%	0.34-0.79
Cocamide DEA	0.50%	pet.	3787	0.24%	0.13-0.45
Propolis	10.00%	pet.	3338	2.45%	2.01-3.08
Lauryl glucoside	3.00%	pet.	2775	0.43%	0.25-0.75
Tocopherol acetate*	10.00%	pet.	839	0.83%	0.04-1.71

Table 1. The 2019 updated British Society for Cutaneous Allergy facial series.

Concentration, Conc; petrolatum, pet.; aqueous, aq. * Cosmetic allergens added to this facial series.

Allergen	Conc.	Base	No. Of patients tested	Positive patch test rate	95% confidence interval
DMDM hydantoin	2.00%	aq.	4224	0.19%	0.01-0.37
Triclosan (Ingrasan DP 300)	2.00%	pet.	4224	0.17%	0.08-0.35
Benzophenone-3	10.00%	pet.	4224	0.17%	0.08-0.35
2,6-di-tert-butyl-4-cresol (BHT)	2.00%	pet.	4224	0.07%	0.02-0.21
2-tert-butyl-4-methoxyphenol (BHA)	2.00%	pet.	4224	0.07%	0.05-0.28
Sorbic acid	2.00%	pet.	4224	0.07%	0.03-0.24
Chloroacetamide	0.20%	pet.	4224	0.07%	0.02-0.21
Butyl methoxydibenzoylmethane	10.00%	pet.	3036	0.07%	0.02-0.25

Table 2. Allergens with a positive patch test rate <0.3% which have been removed from The British Society for Cutaneous Allergy (BSCA) facial series, last modified in 2012.

Concentration, Conc; petrolatum, pet.; aqueous, aq.

Allergen	Conc.	Base	Series moved to	No. Of patients tested	Positive patch test rate	95% confidence interval
Benzalkonium chloride	0.10%	aq.	Medicaments	1188	3.96%	2.99-5.23
Thiomersal	0.10%	pet.	Eyes	1232	2.68%	1.91-3.74
Benzyl salicylate	10.00%	pet.	Fragrances	1938	0.36%	0.17-0.74
Mentha piperita	2.00%	pet.	Fragrances	559	0.36%	0.10-1.30
Vanillin	10.00%	pet.	Fragrances	515	0.78%	0.30-1.98
Carvone	5.00%	pet.	Fragrances	191	3.66%	1.78-7.36
Benzoic acid	5.00%	pet.	Bakery series	795	3.02%	2.04-4.45
Phenylmercuric acetate	0.01%	aq.	Eyes	1232	0.57%	0.28-1.17
Glyceryl thioglycolate	1.00%	pet.	Hairdressing	1973	0.71%	0.42-1.19

Table 3. A table displaying 9 allergens not in the 2012 British Society for Cutaneous Allergy (BSCA) facial series , which had a positive patch test rate >0.3% and have been added to more relevant series.

Concentration, Conc; petrolatum, pet; aqueous, aq.