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Contact allergy to corticosteroids: Is the European baseline series sufficient?

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Abstract

Background: Patients are consecutively screened for contact allergy to corticosteroids with budesonide and tixocortol-21-pivalate in the European baseline series. Centres using TRUE Test also include hydrocortisone-17-butyrate. A supplementary corticosteroid patch test series is used in case of suspicion of corticosteroid contact allergy or when a marker of corticosteroid contact allergy is positive.

Objective: The aims were to evaluate (1) the efficacy of corticosteroids in the TRUE Test and (2) co-sensitization patterns.

Methods: This retrospective study analysed patients patch tested with TRUE Test corticosteroids plus supplementary corticosteroid series in the period 2006–2020 at the Department of Dermatology and Allergy Centre, Odense University Hospital.

Results: Of 1852 patients tested, 119 were sensitised to TRUE Test corticosteroids and supplementary testing found additional reactions to other corticosteroids in 19 of 119 patients. TRUE Test corticosteroids gave more positive and stronger reactions compared to allergens in petrolatum/ethanol. Fourteen percent of sensitised patients were co-sensitised to multiple corticosteroid groups. Baeck group 3 corticosteroids accounted for 9 of 16 patients not identified by TRUE Test.

Conclusions: Budesonide, hydrocortisone-17-butyrate, and tixocortol-21-pivalate in combination are sensitive corticosteroid markers. In case of clinical suspicion of corticosteroid contact allergy, patch testing with supplementary corticosteroids is highly recommended.

KEYWORDS

allergic contact dermatitis, allergy, contact allergy, corticosteroid, corticosteroid contact hypersensitivity, hypersensitivity reactions, patch test, skin testing

1 | INTRODUCTION

Dermatitis patients are screened for corticosteroid (CS) contact allergy using budesonide and tixocortol-21-pivalate in the European baseline series.¹ Hydrocortisone-17-butyrate is included in the commercially available TRUE Test series used for consecutively testing our

dermatitis patients. All screening CSs are classified as Baeck group 1.² Contact allergy can be to CSs within the same Baeck group, however, the patients often test positive for several CSs (co-sensitization) including CSs from several groups.^{2–4} The routes of contact sensitization to CSs are primarily cutaneous (75%), and secondary by inhalation of aerosols (7%), or by ophthalmic preparations (6%).^{5,6}

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TABLE 1 The prevalence of corticosteroid sensitization among 1852 patch tested patients with suspected or possible allergic contact dermatitis to corticosteroid at Odense University Hospital, Denmark between 2006 and 2020.

Corticosteroid allergens	Concentration	CAS number ^a	Test period (year)	Patch test sensitization, % of tested patients (n)	Clinical relevance of positive patch test ^b , % of sensitised (n)	Baek group ^c
Any corticosteroid sensitization ^d	–	–	2006–2020	7.3 (135/1852)	74.1 (100/135)	–
TRUE Test corticosteroid allergens (µg/cm ²)	–	–	2006–2020	6.4 (119/1852)	71.4 (85/119)	–
Tixocortol-21-pivalate	3	55560-96-8	2006–2020	3.6 (67/1852)	80.6 (54/67)	1
Budesonide	1	51333-22-3	2006–2020	3.0 (56/1852)	76.8 (43/56)	1
Hydrocortisone-17-butyrate	20	13609-67-1	2006–2020	2.8 (52/1852)	88.5 (46/52)	1
Corticosteroids in petrolatum or ethanol (%)	–	–	2006–2020	5.3 (98/1852) ^f	70.4 (69/98)	–
Corticosteroid mix ^g	2.1	–	2006–2020	3.2 (55/1740)	54.6 (30/55)	1
Budesonide	0.1	51333-22-3	2006–2020	2.5 (44/1790)	50 (22/44)	1
Hydrocortisone-17-butyrate ^e	1	13609-67-1	2006–2020	2.4 (43/1795)	72.1 (31/43)	1
Tixocortol-21-pivalate	0.1	55560-96-8	2006–2020	1.8 (33/1797)	72.2 (24/33)	1
Hydrocortisone-17-butyrate	0.1	13609-67-1	2006–2018	1.5 (23/1486)	73.9 (17/23)	1
Amcinonide	0.1	51022-69-6	2006–2018	0.7 (11/1480)	27.3 (3/11)	2
Clobetasol-17-propionate	1	25122-46-7	2006–2020	0.5 (9/1791)	77.8 (7/9)	3
Alclometasone-17,21-dipropionate	1	66734-13-2	2006–2020	0.5 (8/1772)	12.5 (1/8)	3
Hydrocortisone	1	50-23-7	2006–2020	0.4 (8/1812)	75 (6/8)	1
Desoximetasone	1	382-67-2	2011–2020	0.2 (2/1104)	50 (1/2)	3
Triamcinolone acetonide	1	76-25-5	2006–2020	0.1 (2/1798)	50 (1/2)	2
Betamethasone-17-valerate	1	2152-44-5	2006–2020	0.1 (2/1802)	100 (2/2)	3
Betamethasone-17-valerate	0.12	2152-44-5	2006–2020	0.1 (2/1478)	100 (2/2)	3
Dexamethasone-21-phosphate disodium salt	1	2392-39-4	2006–2020	0.1 (2/1786)	50 (1/2)	3
Triamcinolone acetonide	0.1	76-25-5	2006–2020	0.03 (2/1763)	50 (1)	2
Prednisolone	1	50-24-8	2009–2020	0 (0/1341)	–	1

^aCAS-number: Chemical Abstracts Service (CAS) of the American Chemical Society.^bClinical relevance (present or previous) of positive patch tests.^cClassification of corticosteroids according to Baek et al.¹²^dIncluding TRUE Test (SmartPractice) corticosteroid allergens and corticosteroid allergens in petrolatum/ethanol from ChemoTechnique, Trolab, and SmartPractice.^eIn ethanol.^fIn total, 1852 patients were tested with at least one supplementary corticosteroid in petrolatum and/or ethanol.^gIncluding budesonide (0.1%), tixocortol-21-pivalate (1%), and hydrocortisone-17-butyrate (1%).

The prevalence of allergic contact dermatitis (ACD) to CSs is estimated to be 1.5%–4.1%.^{7–10} ACD to CSs is predominantly seen in patients above 40 years of age,¹⁰ possibly due to cumulative

exposure. The diagnosis can be challenging but should be suspected in cases of therapeutically unresponsive inflammatory dermatoses or deterioration of eczema despite optimal topical CS treatment.⁵

Furthermore, the allergic lesions may also manifest as rosacea, exanthema, purpura, or urticaria.¹¹ The clinical appearance represents the balance between a concomitant immunological allergic response conflicting with the pharmacological anti-inflammatory effect of the CSs.^{12,13}

The aims of the present study were to evaluate the frequency of CS sensitizations and associated clinical relevance in patients with possible or suspected CS allergy, to evaluate a possible difference between different test systems (TRUE Test vs. CSs in petrolatum/ethanol [pet/eth]), and finally to assess co-sensitizations between CSs in pet/eth.

2 | METHODS

2.1 | Design and study population

The study was performed at the Department of Dermatology and Allergy Centre, Odense University Hospital, Denmark, and comprised data from 2006 to 2020. A retrospective assessment was performed among all patients with possible or suspected ACD to CSs patch tested with both TRUE Test CSs (included in the baseline series in Odense) and concomitant with CSs in pet/eth as part of aimed testing (extended series). In the case of multiple patch tests, only the latest test was included for analysis.

2.2 | Patch testing

The patients were patch tested with CSs in the European Baseline Series and our centre supplemented with hydrocortisone-17-butyrate (TRUE Test, 20 µg/cm²) (MEKOS Laboratories) (Baeck group 1^{2,4}). All patients were further patch tested with CSs markers in pet/eth from ChemoTechnique Diagnostics, Trolab, and SmartPractice (see Table 1, Baeck group 1–3^{2,4}). All patients were further tested with the supplementary CSs series either at the same time as the baseline series (a priori suspicion of contact allergy to CSs) or either initiated on day 3 (D3), D4, or D7 in case of a positive patch test marker. The CSs included in the supplementary CS series have changed throughout the test period due to availability, different suppliers as well as inclusion and exclusion of allergens throughout time (Table 1). For aqueous allergens, a micropipette was used for the administration of 15 µL CSs into Finn Chamber (8 mm in diameter) corresponding to 30 µL/cm², whereas 20 mg (40 mg/cm²) of CSs in petrolatum was dosed into the chamber.¹⁴ The CSs were applied on the patient's back for 48 h. Patch test reactions were evaluated on D3 or D4 and D7¹⁵ by trained personnel and categorised as negative (–), irritant reaction (IR), doubtful (?+), or positive (intensity: +, ++, or +++) according to the recommendations of the International Contact Dermatitis Research Group (ICDRG).¹⁴ Patch test reactions categorised as –, IR, and ?+ were interpreted as negative. On D7, the consulting dermatologist evaluated the clinical relevance (current, past, or unknown) of the positive patch test based on exposure history and dermatitis pattern.¹⁴

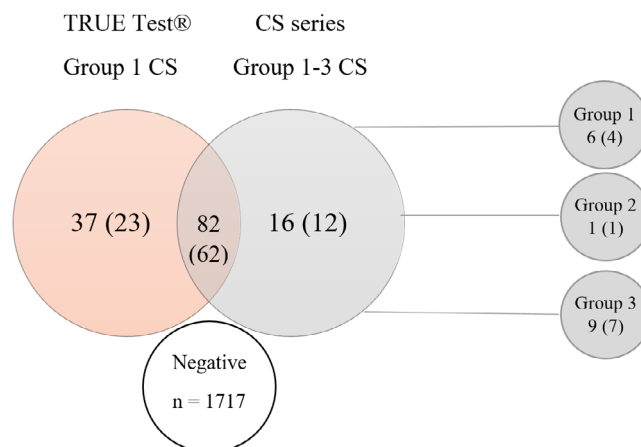


FIGURE 1 Patch test results in patients ($n = 1852$) tested with both Group 1 corticosteroids in TRUE Test and Group 1–3 corticosteroids steroids from the corticosteroid series between 2006 and 2020 at Odense University Hospital, Denmark, presented in a modified Venn Diagram. The clinical relevance (present or previous) of sensitizations is shown in parentheses. CS, corticosteroid. Corticosteroid groups according to Baeck et al.²

2.3 | Statistics

Positive patch tests were presented by frequencies and percentages. Two-sample tests of proportions and χ^2 -test were used for comparisons. The level of statistical significance for the two-sided test was $p < 0.05$. The data analysis was performed with STATA version 17 (StataCorp.).

3 | RESULTS

Overall, 1852 patients were patch tested with TRUE Test CSs and CSs in pet/eth. In total, 119 patients (6.4%) were sensitised to TRUE Test CSs (85/119 clinically relevant), with tixocortol-21-pivalate as the most prevalent allergen (3.6%). A total of 98 patients (5.3%) were sensitised (69/98 clinically relevant) to at least one CSs using the extended series with allergens in pet/eth with reaction to CS mix (3.2%), budesonide (2.5%), and hydrocortisone-17-butyrate (2.4%) as the most prevalent sensitizations (Table 1). No statistically significant difference in clinical relevance between positive reactions in TRUE Test (85/119) and CSs in pet/eth (69/98) was found overall (χ^2 , $p = 0.87$).

The relation between sensitizations to TRUE Test CSs (budesonide, tixocortol-21-pivalate, and hydrocortisone-17-butyrate; Baeck group 1) and supplementary CSs in pet/eth (allergens as presented in Table 1; Baeck group 1–3) are shown in Figure 1. The TRUE Test CSs identified 88.1% (119/135) of all CSs sensitised patients corresponding to 95.2% (119/125) of all patients sensitised to Group 1 CSs of whom 37 patients (23/37 clinically relevant) were only sensitised to TRUE Test CSs. However, by testing with the supplementary CSs series (CSs in pet/eth, see Table 1), in addition, 16 sensitised patients

TABLE 2 Correlation between TRUE Test corticosteroid markers and corresponding allergens in the corticosteroid series (petrolatum/ethanol).

			Hydrocortisone-17-butyrate [20 µg/cm ²] (n = 1795)			
			Positive			Negative
			+	++	+++	–
Hydrocortisone-17-butyrate (1% eth)	Positive	+	13	4	0	6
		++	6	11	0	2
		+++	0	0	1	0
	Negative	–	11	5	0	1736
			Hydrocortisone-17-butyrate [20 µg/cm ²] (n = 1795)			
			Positive			Negative
			+	++	+++	–
Hydrocortisone-17-butyrate (0.1% pet)	Positive	+	13	4	0	0
		++	2	2	1	1
		+++	0	0	0	0
	Negative	–	14	11	0	1438
			Tixocortol-21-pivalate [3 µg/cm ²] (n = 1797)			
			Positive			Negative
			+	++	+++	–
Tixocortol-21-pivalate (0.1% pet)	Positive	+	6	7	0	1
		++	1	13	3	0
		+++	0	1	1	0
	Negative	–	24	9	0	1731
			Budesonide [1 µg/cm ²] (n = 1790)			
			Positive			Negative
			+	++	+++	–
Budesonide (0.1% pet)	Positive	+	16	3	0	3
		++	6	13	0	0
		+++	0	2	1	0
	Negative	–	11	2	0	1733

Abbreviations: eth, ethanol; pet, petrolatum.

(12/16 clinically relevant) were detected (Figure 1). Six patients sensitised to Group 1 (hydrocortisone-17-butyrate, budesonide, hydrocortisone, CS mix), one patient sensitised to Group 2 (amcinonide), and nine patients sensitised to Group 3 (betamethasone-17-valerate, clobetasol-17-propionate, dexamethasone-21-phosphate disodium salt, alclometasone-17,21-dipropionate, desoximetasone) CSs in pet/eth, were not sensitised to any TRUE Test CSs. Furthermore, sensitizations to CSs other than budesonide, tixocortol-21-pivalate, and hydrocortisone-17-butyrate were found in 19 of the 119 patients (12/19 clinically relevant) sensitised to the TRUE Test CSs.

The CSs markers budesonide and tixocortol-21-pivalate, as included in the European baseline series, were positive among 109 patients when testing with TRUE Test compared to 72 patients using allergens in pet/eth. Furthermore, 52 of 1852 (2.8%) had a positive patch to hydrocortisone-17-butyrate in TRUE Test compared to 43 of 1795 (2.4%) sensitizations using hydrocortisone-17-butyrate 1% in eth.

The patch testing results from TRUE Test CSs and equivalent allergens in pet/eth are presented in Table 2. Comparing hydrocortisone-17-butyrate, tixocortol-21-pivalate, and budesonide using the two different test systems, TRUE Test gave rise to more positive patch test reactions than steroids in pet/eth from all three CS markers. All reactions, only positive in one test, were either +1 or +2 in strength. The difference between the two test systems was most pronounced for tixocortol-21-pivalate where TRUE Test identified 24 + 1 and 9 + 2 reactions not found using CSs in pet, whereas only one +1 reaction was not identified using TRUE Test. The clinical relevance where slightly higher using the TRUE Test CSs with the highest difference for budesonide (76.8% vs. 50%; Table 1).

The sub analysis of co-sensitizations of CSs in pet/eth between Groups 1–3 (according to Baek et al.²⁴) is presented in Figure 2. Of all patients sensitised to CSs in pet/eth (n = 98), 73.5% (n = 72), 1% (n = 1), and 10.2% (n = 10) were only sensitised to Groups 1, 2, and

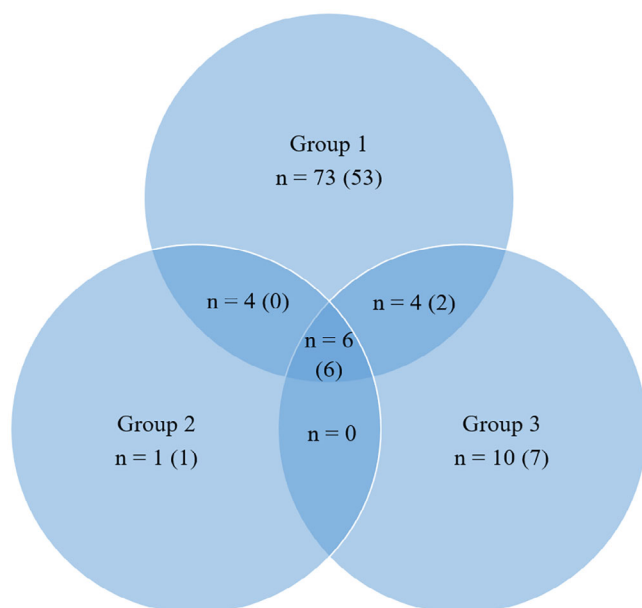


FIGURE 2 A Venn diagram presenting the sensitization patterns of patients sensitised to the corticosteroid series allergens in petrolatum or ethanol between 2006 and 2020 ($n = 98$ of 1852 tested) at the Department of Dermatology and Allergy Centre, Odense University Hospital, and stratified by groups according to Baeck et al. The clinical relevance (present or previous) of sensitizations is shown in parentheses. Corticosteroid groups according to Baeck et al.²

3, respectively. Concomitant sensitizations were present for 4.1% ($n = 4$) of Groups 1 and 2; 4.1% ($n = 4$) of Groups 1 and 3. No patients were sensitised only to Groups 2 and 3, but six patients (6.1%) were concomitantly sensitised to CSs from all three Baeck groups. The clinical relevance of sensitizations to CSs from Baeck group 1 and 3 were about 70%, whereas all patients ($n = 6$) with concomitant sensitization to CSs from all three Baeck groups had anamnestic relevant sensitizations.

4 | DISCUSSION

In total, 135 of 1852 patients (7.3%) suspected of CS contact allergy had positive patch tests with TRUE Test and/or the supplementary series with CSs in pet/eth.

The TRUE Test markers budesonide and tixocortol-21-pivalate, as included in the European patch test baseline series, and supplemented with hydrocortisone-17-butyrate detected 80.7% (109/135) and 88% (119/135), respectively, of patients sensitised to any CS. By further testing with Groups 1–3 CSs in pet/eth, sensitizations to CSs other than the CS allergens included in the TRUE Test CSs were found in 19 of 119 patients. Among the 16 patients not detected by TRUE Test steroids, sensitization was primarily to Group 3 CSs (nine patients); secondary to Group 1 (six patients), and Group 2 CSs (one patient).

Budesonide and tixocortol-21-pivalate as screening markers detected approximately 56% (30/54) of patients sensitised to any CSs

in a Spanish cohort.⁷ In this population, patch testing with hydrocortisone-17-butyrate yielded no further information.

According to our knowledge, in contrast to budesonide and tixocortol-21-pivalate, the diagnostic equivalency between hydrocortisone-17-butyrate in TRUE Test and corresponding CSs in pet/eth has not been verified.¹⁶ Budesonide and tixocortol-21-pivalate in petrolatum were detected in 53.3% of all patients sensitised to any CSs in the study population, whereas the corresponding allergens from TRUE Test found in 80.7% of all CSs sensitised patients. Thus, the proportion detected by budesonide and tixocortol-21-pivalate in petrolatum is significantly lower than that of the corresponding allergens in the TRUE Test. A previous study by Boffa et al. reported a combination of tixocortol-21-pivalate (1% pet) and budesonide (1% pet) detected about 91% of all patients allergic to CSs,¹⁷ but the subjects included in our study were tested with allergens in a 10-fold lower concentration (0.1% pet), whereas budesonide in the European baseline patch test series is in a hundredfold lower concentration (0.01% pet).

The association between exposure to CSs and the development of dermatitis, that is, ACD, was approximately 70% for the two test systems. Thus, the clinical relevance of sensitizations was equally distributed between the two test systems and may be equal in detecting ACD. The overall proportion of clinical relevance of sensitizations of any CSs (if co-sensitised to multiple CSs) was about 74% being, as expected, higher compared to consecutively tested dermatitis patients.¹⁰ The assessment of clinical relevance is done on the day of the patch test reading. The classification of CSs is based on clinical observations of co-reactivity, and cross-reactivity to some extent, in patients with allergic contact allergy to CSs.^{2,5} Furthermore, as only a few CSs included as markers are available as a topical treatment, the classification is used in clinical practice to assist the anamnestic relevance. Changing the internationally acknowledged classification of CS allergy within the test period might have had an impact on the evaluation of clinical relevance, as sensitization to a CS within the same group as the CS(s) the patients were exposed to (culprit), might misclassify the clinical relevance if the previous CS classification is used.^{2,18}

Sensitizations to tixocortol-21-pivalate in TRUE Test created a stronger test reaction in about 30% of sensitised patients compared to the allergen in petrolatum, whereas budesonide and hydrocortisone-17-butyrate produced comparable test strengths regardless of the test system. Furthermore, all CSs in TRUE Test detected more sensitised patients compared to the CS in pet/eth regardless of concentration. Thus, TRUE Test preparation of tixocortol-21-pivalate might be more sensitive in diagnosing sensitization to CSs despite previously reported diagnostic equivalency between tixocortol-21-pivalate in TRUE Test and petrolatum.¹⁶

Detection of Group 3 CSs sensitization has previously been a diagnostic issue if using the TRUE Test and European baseline series.^{7,19} Sommer et al. reported an overall miss of 81% of sensitizations to clobetasol propionate and betamethasone valerate if the patients are only patch tested with budesonide and tixocortol-21-pivalate.¹⁹ The group 3 CSs clobetasol-17-propionate (in Dermovate) and betamethasone-17-valerate (in Betnovate) are frequently used in the treatment of various inflammatory dermatoses

such as eczema and cutaneous psoriasis in Denmark. In total, only nine patients sensitised to Group 3 CSs are missed in 1852 patch-tested patients, and clobetasol-17-propionate being a potential Group 3 CS marker,^{7,9,20} inclusion of clobetasol-17-propionate in consecutively screening panel might optimise the overall sensitivity.

CSs were previously grouped into A-D2,^{18,21} but a renewed classification into three groups was proposed by Baeck et al. based on the clinical patterns of patch test co-reactions and molecular structure.^{2,4,5} The existence of co-sensitization within one group is expected, but sensitization to multiple groups is well-described.²⁻⁴ The patients showed an overall co-sensitizations of 14% between CS Baeck groups of which about 2/3 were sensitised to all three groups. Previously, our study group reported a co-sensitization of 34% between Group 1 CS markers budesonide, tixocortol-21-pivalate, and hydrocortisone-17-butyrate from the TRUE Test.¹⁰ The sensitization proportion being approximately 2.5 times higher across the Baeck group 1-3 than within Group 1 is in accordance with the most recent classification.²

The data further support the hypothesis concerning two clinical profiles of CS-sensitised patients²; some patients are only sensitised to one group of CSs due to immunological recognition of the lateral chain of the CS (thus the electrostatic fields), whereas others show wide co-reactivity between the CS groups due to recognition of the skeletal ring structure.^{22,23} This classification should be considered when patients sensitised to CSs are advised in the clinics. Patients with co-reactivity across groups might be at greater risk of skin reactions after exposure to systemic CSs due to shared chemical basic structure, but the clinical relevance of this classification remains unknown.

Limitations to our study include the retrospective design, which limits the workup of sensitised patients to identify the culprit. The pattern of sensitization in our highly selected Danish population may be due to local demographics and prescribing habits²⁴; and the diagnostic procedure such as patch test readings, differences in vehicle concentrations, manufacturers, and types of CSs used for patch testing vary according to local practicability.^{15,25} The CSs in the supplementary CS series have changed throughout the test period, either due to commercial availability or clinical irrelevance, and may inflict on the estimates of prevalence. Furthermore, in some patients, only selected CSs in pet/eth were used in supplementary patch testing. The supplementary test series should preferably contain all CSs present in the country. Varying concentrations of CS in patch test materials, for example, budesonide in TRUE Test corresponds to 0.001 mg/cm², may affect the outcome of positive patch test reactions when comparing the same culprits in pet/eth, as lower concentrations of CS show less anti-inflammatory potency. Assessment of the clinical relevance of sensitization is based on different clinicians. The intrinsic dual effect of anti-inflammatory potential and allergenic, inflammatory potential entails challenging patch test readings often being in a spectrum of doubtful to weak positive, thus the experiences of clinicians are important and a delayed patch test reading must happen.²⁰

In conclusion, this retrospective study of 1852 patients patch-tested concomitant with TRUE Test CSs and CSs in pet/eth over a 28-year period, found that 88% of all CS-sensitised patients were

detected by TRUE Test CS markers. Group 3 CSs accounted for 56% (9/16) of undetected sensitised patients. Therefore it is important to use supplementary tests if CS allergy is suspected or in chronic dermatitis patients.

AUTHOR CONTRIBUTIONS

Sebastian Vigand Svendsen: Conceptualization; writing – original draft; writing – review and editing; formal analysis. **Carsten Bindlev-Jensen:** Writing – review and editing. **Charlotte G. Mortz:** Conceptualization; writing – review and editing; supervision.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data are not available due to ethical restrictions.

ETHICS STATEMENT

The Allergen database (journal no. 21/14482) and the present project (journal no. 21/27686) were approved by the Danish Data Protection Agency.

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