

Original article

Allergic contact dermatitis to preservatives: prevalence and associated factors

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Abstract

In recent years, preservatives have caused a global epidemic of allergic contact dermatitis, mainly because of their ubiquitous presence. The purpose of the study was to establish the sociodemographic and occupational profile of the patients sensitized to preservative allergens included in the European standard Series and to identify their outcomes. A retrospective descriptive epidemiological study was conducted among all the patients sensitized to preservative allergens included in the European standard Series, diagnosed in the Dermatology-Allergy Unit Department of Occupational Medicine ward in the Farhat Hached University Hospital of Sousse, Tunisia, during 2006-2015. During the study period, 140 cases of sensitization to preservative allergens were collected, with a prevalence of 8.4% of all patch-tested patients during the same period. Among the studied population, 110 patients (78.6%) were professionally active. Hands were the preferred initial site for contact dermatitis lesions (58.6%), followed by the face (37.1%). Formaldehyde has been the most frequently positive preservatives with 37.1% of cases. Formaldehyde sensitization was significantly associated with the initial site of feet lesions, the initial erythematous-squamous aspect of the lesions, and the weeping aspect of the lesions. In conclusion, contact dermatitis is frequent with preservatives, hence the need for appropriate preventive measures.

Keywords: Contact Dermatitis, Preservatives, Sensitization, Allergy.

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1. Introduction

Allergic contact dermatitis (ACD) is a common disease that leads to high health costs and a decrease in quality of life. Its risk factors include atopic dermatitis and wet work, while the role of mutations in the complex filaggrin gene (FLG) remains to be clarified [1]. In recent years, preservatives and especially isothiazolinone have caused a global epidemic of ACD, mainly because of their ubiquitous presence [2]. It is estimated that preservatives sensitization all allergens combined is in the range of 3 to 4% [2].

A preservative is a natural or synthetic chemical or substance added to food, pharmaceuticals, cosmetics, paints, woods, or biological samples to prevent decomposition due to microbial proliferation or adverse chemical changes. The ideal preservative should be colorless, odorless, water soluble, non-toxic, non-allergenic, non-irritating and effective on a wide range of bacteria at very different pH [2].

The positive diagnosis of ACD to one or more preservatives is based mainly on: interview, physical examination and allergy assessment including patch tests. In the European Standard Battery (ESB), preservatives are represented by parabens, formaldehyde, methyl glutarnitrile/phenoxyethanol, quaternium 15, clioquinol and

CI methylisothiazolinone/methylizothiazolinone (MCI/MI better known as Kathon CG) [3].

The objectives of this study were to identify the sociodemographic, clinical, and occupational characteristics of patients with sensitization to one or more ESB preservative allergens, to determine the most implicated allergens and to identify the measures initiated after the diagnosis of these sensitizations.

2. Patients and methods

Study design

This is a retrospective descriptive study conducted over a period of 10 years, from January 1st, 2006, to December 31st, 2015, among all patients who consulted the Dermato-Allergology Unit of the Occupational Medicine Department of Farhat Hached University Hospital in Sousse (Tunisia) for patch tests to allergens of the European Baseline Series (EBS).

In this study, we included all the data of patients who were patch tested by the European Baseline Series (EBS) allergens (26 haptens until 2008 and then 28 haptens from 2008 to 2015) and who had a positive patch-test to one or more preservative allergens included in the European Baseline Series (EBS).

During the survey period, all cases of sensitization to one or more preservatives have been collected. The following

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products were considered as preservatives contained in the EBS [3]:

- Paraben: is a biocide composed of 4 esters of the acid parahydroxybenzoic.
- Formaldehyde: is a very reactive and easily polymerizable aldehyde which appears at room temperature as a colorless gas with an acrid and suffocating odor.
- Quaternium 15: is a formaldehyde releaser, widely used as preservative in cosmetics, industrial and household products.
- Methyl glutarnitrile/phenoxyethanol (Dibromodicyanobutane): is glycol ether used as a chemical preservative in hygiene products and in particular baby wipes, due to its anti-microbial effect.
- Clioquinol: is used as an antibacterial and antifungal. It's not generally an occupational allergen. Cross-reactions are possible with chloroquinadol and quinolone antibiotics.
- Methylisothiazolinone/methylizothiazolinone CI (MCI/MI better known as Kathon CG): is a mixture of methylchloroizothiazolinone and methylizothiazolinone with a weight ratio of 3:1. It is a biocide widely used in cutting oils, detergents, cosmetics.

The data were collected through a pre-established synoptic sheet covering socio-demographic characteristics, personal and family allergic and non-allergic history, initial and progressive clinical appearance of skin lesions, professional and extra-professional reactogenic products.

Patch-tests were applied to our patients according to the protocol recommended by the International Contact Dermatitis Research Group (ICDRG) [4]. The technique includes the application of the product diluted in a neutral and non-allergenic substance (acetone or vaseline) using Finn Chamber patches. The patch tests were applied on the upper back of patients with a hypoallergenic plaster and are left in situ for 48 hours. The skin should not be prepared in advance, especially not degreased by solvents such as ether. The reading and interpretation of test results, whether positive or negative, were done at 48 hours and at 72 hours with a late reading for certain allergens. Test results were coded based on the intensity following the criteria from the International Contact Dermatitis Research Group [5].

The specialist in charge of reading the tests should determine the relevance of the obtained results. This relevance may be current, and the physician should attempt to link the results of positive tests of an allergic nature to the pathology presented by the patient, and then tries to establish a relationship between the results of positive allergy test patches and the skin condition presented recently by the patient.

Determining relevance can be complex in some cases. Additional tests may be required to support the diagnosis of occupational allergic contact dermatitis such as use tests or open tests [4].

Statistical analysis

Data analysis was performed using SPSS 24.0 software. For the descriptive study, numbers and percentages were calculated for qualitative variables and means, standard deviations, medians, and modes for quantitative variables. For the analytical study, the significance level was set at 0.05. Comparison of frequencies was done using the Pearson Chi-Square test. Comparison of means was carried out by the "student t" test and the one-way ANOVA test. The study of the link between two quantitative variables

was carried out using the Pearson correlation coefficient.

Regarding the multivariate analysis, a multiple binary logistic regression was performed when the dependent variable is qualitative and a linear logistic regression when the dependent variable is quantitative. Multivariate analysis was realized with a significance level at 0.2 in the univariate study as the inclusion criterion for independent variables.

The study protocol was reviewed and approved by the Research Council and the Medical Ethics Committee of the Sousse Medical School. We do not declare any conflict of interest.

3. Results

During the study period, 140 preservative sensitization cases were collected, representing 8.4% of all patch patients tested during the same period. Table 1 summarizes the yearly prevalence of this sensitization over the 10 years of the survey. The average age of the participants was 45.05 ± 13.67 years old. The sex ratio was 1.05 (72 males/68 females). Among the participants, 110 cases (78.6%) were professionally active. Most workers were employed in the clothing sector (15.5%), followed by the administration (14.5%) and the healthcare sector (10%). The average occupational seniority of our workers was 6 years ± 2.91 years with extremes of 1 and 42 years.

Table 1. Distribution of study population by year of study.

Year	n	%
2006	22	15.7
2007	4	2.9
2008	7	5
2009	15	10.7
2010	11	7.9
2011	9	6.4
2012	17	12.1
2013	16	11.4
2014	18	12.9
2015	21	15
Total	140	100

Only 34 patients (26.4%) had a personal history of cutaneous and respiratory allergy, and 29 patients (20.7%) had an allergic family history. The most common functional sign reported by 127 patients (90.2% of cases) was pruritus. Hands were the preferred initial location for ACD lesions in 58.6% of cases followed by the face (37.1%) (Table 2).

Table 2. Distribution of study population by initial site of lesions.

Initial site of cutaneous lesions	n	%
Face	52	37.1
Neck	9	6.4
Trunk	15	10.7
Hands	82	58.6
Wrists	12	8.6
Forearm	32	22.9
Arm	14	10
Feet	37	26.4
Legs	47	33.6
Thighs	20	14.3
Buttocks	8	5.7
Folds	5	3.5
External genitalia	1	0.7
Total	140	100

Semiological analysis of the initial lesions had often

revealed various aspects where erythema, vesicles and scales were both entangled. More than half of our patients (55.7%) had initial erythematous vesicular lesions while 35% of cases had initial erythemato-squamous lesions. The average duration of progression of clinical lesions at the time of patch testing was 35.73 ± 59.71 months (1-396 months).

Hands remained the preferred site of progressive ACD lesions to preservative allergens in our patients with 97.1% of cases, followed by feet with 33.6% of cases and legs in 32.1% of cases. Semiological analysis of the evolution of the skin lesions at the time of the patch testing showed the predominance of the erythemato-squamous aspect (35% of cases) followed by the erythemato-vesicular aspect (22.1% of cases) and oozing (4.3% of cases).

All our patients were tested with ESB allergens. Formaldehyde has been the most frequently positive preservative with 37.1% of cases of which 1.4% had a positive intensity of 3 crosses, followed by dibromodicyanobutane in 20% of cases (Table 3). Table 4 summarizes the distribution of patch reaction intensity by allergen.

Table 3. Results of ESB patch tests among study population.

Allergens	Sensitization			
	Yes		No	
	n	%	n	%
Formaldehyde	52	37.1	88	62.9
Kathon CG	20	14.3	120	85.7
Quaternium 15	19	13.6	121	86.4
Dibromodicyanobutane	28	20	112	80
Paraben mix	13	9.3	127	90.7
Clioquinol	8	5.7	132	94.3

Occupational origin was retained in 94 patients among the 110 employed patients, representing 85.5% of cases. The removal of ACD-containing preservatives was indicated in all patients. Recognition of the occupational origin of their disease, was done for 8 of the 52 patients with formaldehyde ACD.

Preservatives sensitization was significantly associated with several variables (Table 5). After the binary logistic regression, formaldehyde sensitization was significantly associated with the initial site of the foot lesions, the initial aspect of erythmato-scaly lesions, the oozing aspect of lesions at the time of patch testing, and the influence of plastic handling. Sensitization to dibromodicyanobutane was significantly associated with the localization of skin lesions in the right hand and the notion of pruritus. Kathon CG sensitization was significantly associated with DIY as an extra-professional leisure activity (OR=6.8 CI [1.69-27.23]; $p=0.007$). Skin reactivity to clioquinol, paraben mix and quaternium 15 was not associated with any of the study variables.

4. Discussion

Allergic manifestations are frequent in the workplace and their incidence is constantly increasing in connection with the intensive exposure to various chemical nuisances due to industrial development, the placing on the market of new chemical substances with insufficient training of workers and prevention. Preservatives are the second most common class of substances responsible for allergy to cosmetics and cleaning products [1,2]. In our study, 140 cases of preservatives contact dermatitis were collected over 10

years, representing 8.4% of all patch-tested patients during the same period. According to a Korean study conducted in 2012, the prevalence of contact dermatitis with cosmetic preservatives reached 41.1% of patients with cosmetic ACD [7]. A North American study of 39,332 patch tested patients showed that preservatives were the 2nd most common allergen source of occupational ACD [8]. A recent Spanish literature review has shown that preservatives (and at the top of the list isothiazolinone) still rank first among the most ACD-producing allergens in Europe and the United States despite the ban on the use of several of them in professional and extra-professional environments, namely dibromodicyano-butane [9].

The main determinant in the development of contact dermatitis is the interaction between individual susceptibility or endogenous factors and the characteristics of exposure or exogenous factors. Age is among the endogenous factors that influence the pathogenesis of contact dermatitis. In our study, the average age was 45.5 years and 66.4% of patients were between 21 and 60 years of age. Our results corroborate those of the literature. Indeed, in Denmark, occupational ACD to preservatives appears to be more common in patients over the age of 40 (71.6%) [10]. Another Danish study assessing the changing profile of ACD to occupational and non-occupational custodians between 1985 and 2008 estimated that the most affected age group was between 41 and 60 [11].

However, the relationship between gender-ACD and preservatives remains a controversial issue and the use of cosmetics and detergents and cleaners by women and industrial products in various occupational sectors by men may explain the lack of gender difference. The sex ratio in our survey was 1.05 and no statistically significant differences between the two genders were noted for sensitization to different preservative allergens. However, in Denmark, a female predominance was observed with a sex ratio varying between 0.5 and 0.7 [10,11]. A Turkish study also showed that women were more sensitized of cosmetic preservatives while men were aware of industrial preservatives [12].

Hands were the preferred site of ACD lesions to preservative allergens in our patients with 58.5% of cases followed by the face with 37.1% of cases, which corroborates the results of various international studies. According to a Canadian study of mechanics with occupational ACD, 59.5% of workers' hands were affected [13]. In North America, hands are also the preferred location for occupational ACDs of all allergens combined with 53.8% of cases followed by arms with 29.4% of cases [8].

Several occupational factors are involved in the genesis of contact dermatitis, including wet work, as well as exposure to irritants such as detergents, cleaning agents, disinfectants, cutting oils and abrasives [14]. The occupational category appears to influence the epidemiology of contact dermatitis by determining the type and frequency of exposures. However, the relationship between profession and preservatives sensitization, especially those used in cosmetic and cleaning products, remains discussed [15]. In a study in London, the prevalence of preservatives contact dermatitis appears to be more common among blue-collar workers [16]. The authors suggested that occupations in this class are more frequently exposed to industrial chemicals.

Formaldehyde is a powerful ubiquitous sensitizer found in both professional and extraprofessional use. It appears in

free form or in formaldehyde-releasing preservatives [17].

Table 4: Distribution of allergy cases according to the intensity of the patch-tests reaction.

Allergens	Reaction									
	Negative		Doubtful		1 cross		2 cross		3 cross	
	n	%	n	%	n	%	n	%	n	%
Formaldehyde	83	59.3	5	3.6	31	22.1	19	13.6	2	1.4
Kathon CG	118	84.3	2	1.4	11	7.9	9	6.4	0	0
Quaternium 15	117	83.6	4	2.8	10	7.14	7	5	2	1.42
Dibromodicyanobutane	108	77.1	4	2.9	18	12.9	8	5.7	2	1.4
Paraben mix	127	90.7	0	0	8	5.7	5	3.6	0	0
Clioquinol	131	93.6	1	0.7	5	3.6	1	0.7	2	1.4

Table 5. Multiple binary logistic regression: Variables associated with formaldehyde sensitization.

Variable	p	OR	CI (95%)
Initial localization at foot level	0.001	4.698	[1.870-11.802]
Initial erythematous-squamous appearance	0.004	3.667	[1.507-8.926]
Current oozing appearance	0.039	13.891	[1.140-169.310]
Influence of plastics	0.045	6.766	[1.040-44.035]

OR: Odds Ratio, CI: Confidence interval

In our study, formaldehyde ranked first among ESB preservatives responsible for sensitization with 37.1% of cases. This sensitization was independently associated with the location of skin lesions in the feet, and this could be explained by the fact that this allergen is contained in many types of work shoes. Similarly, the influence of the handling of plastic products on the aggravation of skin lesions in the context of sensitization to formaldehyde may be due to cross-allergies between formaldehyde and plastic components such as resins. The prevalence of formaldehyde sensitization has been estimated at 1.3% in Turkey, 0.9% in Czech Republic, 2.5% in France and 2.3% in Greece [12,14,18,19]. In North America, formaldehyde ranked 4th among the most ACD-producing allergens between 1998 and 2014 with 6.3% of cases [8]. A multi-center study of 1,787 patch tested patients with industrial preservatives, antimicrobials and biocides estimates that formaldehyde sensitization affects 2% of these patients [20].

The Kathon CG, a biocide widely used, is also found in the professional environment, including agriculture, agri-food, painting, wood industry, construction, and printing. The prevalence of sensitization to Kathon CG has passed in Spain from 2.3% in 2009 to 3.9% in 2011, despite the legislative restriction of its use in professional settings and as a preservative of cosmetics [21]. This prevalence would be underestimated because it is present in very diluted form in patch-tests. In Switzerland, the prevalence of ACD in Kathon CG was estimated in 1994 at 5.5%, leading to a ban on its use in many sectors of activity [22]. Another multicentric study estimated that sensitization to Kathon CG occurred primarily among young women due to its presence in cosmetics, cleaners, and detergents [23]. In our series, the automotive, textile and DIY industries were the variables associated with the skin response to Kathon CG, but only the DIY activity was independently associated with this sensitization after binary logistic regression.

Quaternium 15 is a formaldehyde deliverer found in cosmetics, medical products including lens care products, and household products such as detergents. In an occupational environment, it is frequently encountered in the agri-food sector due to the use of soaps, detergents and disinfectants, the hairdressing and aesthetic sector, in metallurgical and mechanical construction due to its use as a preservative of cutting oils [3]. In our study population,

13.57% of patients were sensitized to quaternium 15 and. In Europe, preservative allergy varies between 0.6 and 1.7% [24]. In France, this prevalence remains stable and is estimated at 1% and in Spain it was around 1.27% [15,21].

In North America, it is the 5th allergen responsible for ACD in hairdressers [25].

Dibromodicyanobutane is used as a bactericide and fungicide and was banned for use in cosmetics in Europe in 2008 [3]. It is the 2nd most preservative responsible for ACD in our population with 20% of cases. Its possible sources therefore remain «underground» cosmetic products (not complying with European regulations), and liquids from the metallurgical industry (coolants) [26], dyes, paints, and adhesives (water based), wood preservatives, industrial and household cleaning products, photographic development solutions, seed disinfectants and paper industry.

In our study, the recognition of the occupational origin of the ACD to preservatives was done for only 8 of the 52 patients with formaldehyde ACD. This can be explained by the fact that the best-known activity sectors of promoting this contact dermatitis to preservatives are poorly represented in our study population. In addition, most of our workers were not covered by the National Health Insurance Fund such as hairdressers, mechanics working for themselves. This lack of reporting could also be related to the fact that it is based on a voluntary approach by the patient to obtain official recognition of the professional character of his/her pathology with the fear of losing the job for some workers or because the compensation is perceived as low, which inhibits the reporting since the rate of permanent partial disability is generally less than 10%.

In Tunisia, the increasing level of awareness of the various preservatives and the lack of explicit regulation remain a matter of concern that requires preventive measures to be taken to mitigate their scale. However, we used oral and written information through fact sheets that record the sources of allergen exposure to which our patients were sensitized. We have also indicated the removal, if possible, in the occupational environment, of any contact with preservative allergens that may trigger or aggravate their contact dermatitis.

Preservative ACDs are common and can be caused by both occupational and extra-occupational sources. Over the years, changes in the spectrum of allergens, which differ

greatly from one country to another, have been observed [14]. The ubiquitous and increasing use of preservatives create the need to put in place measures to prevent contact dermatitis such as reducing the level of occupational and non-occupational exposure, the reorganization of work so that workers have the same low level of exposure, regular and periodic monitoring of exposure levels, the automation of work, and good ventilation.

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Conflict of Interest Disclosures

All authors declare that they have no conflict of interest.

Authors' contributions

All authors have read and agreed to the published version of the manuscript.

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