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# Prospective study of consecutive patch testing in patients with contact dermatitis using an adapted Latin American baseline series

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## KEY WORDS

Contact dermatitis; patch test; allergy; Latin American; COVID-19.

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## IMPACT STATEMENT

The current research presents the clinical and epidemiological characteristics of a population with suspected allergic contact dermatitis. The adapted Latin American baseline series represents an important update of patch test in Brazil.

## Summary

**Background.** Contact dermatitis is characterized by pruritic skin lesions with high prevalence rates. Our objective is to describe the clinical and epidemiological characteristics of a population with suspected contact dermatitis who underwent to a patch testing using an adapted Latin American baseline series. **Methods.** Observational, descriptive, analytical clinical study with prospective data collection was performed. 208 participants who underwent patch testing using an adapted Latin American baseline series containing 40 allergens were analyzed. The prevalence of contact allergies was compared with data from the literature. Pearson's chi-square test was used for qualitative variables. Quantitative variables were compared using the Mann-Whitney U test. The significance of the regression parameters was tested using the Wald statistical test. **Results.** A total of 69.7% had one or more positive tests. Among those, 82.8% were women (OR 1.371;  $p = 0.398$ ). The hands were the most commonly affected site at 43%. An occupational history was detected in 19.2%. The most common allergens were nickel sulfate (32.2%), sodium tetrachloropalladate (19.7%), fragrance mix I (15.4%), and methylisothiazolinone (13.5%). In multivariate logistic regression models, nickel was significantly related to female sex, as well as palladium. Fragrance mix I was related to a family history of allergy ( $p < 0.05$ ). Methylisothiazolinone was statistically significantly related to face and hand lesions. **Conclusions.** This study demonstrated a detailed profile of a population with suspected allergic contact dermatitis. Our patch test results, using an adapted Latin American baseline series, represent a significant update of this important diagnostic tool.

## Introduction

Contact dermatitis (CD) is an inflammatory cutaneous reaction induced by an external triggering substance in direct contact with the skin and is characterized by pruritic eczema. Irritant contact dermatitis accounts for approximately 80% of cases due to direct damage to the skin, either by physical agents or chemicals, without prior sensitization. Allergic contact dermatitis

(ACD) is a delayed type IV hypersensitivity reaction that occurs in susceptible individuals with previous exposure to subsequent sensitization (1). Additionally, an overlap of these two types of dermatitis may occur (2). ACD affects 20% of individuals regardless of age in general population, and, when added to cases of irritant contact dermatitis, the sum of the two is responsible for more than 90% of occupational skin lesions (3). Furthermore, the prevalence of ACD in the general population is in-

creasing (4). ACD development is determined mainly by individual susceptibility, allergen physicochemical properties, and allergen exposure (dose and frequency of contact) (5).

Patch testing is the gold standard for diagnosing CD. During testing, the individual is exposed to various allergens, which cause a skin reaction in sensitized individuals (5). It is an investigative method with well-established foundations and internationally accepted standards (4). The patch tests combined with a well-conducted clinical history and specific examination of the lesion helps the specialist to make the etiological diagnosis of the ACD-related substance (6). The allergens used vary across different countries and over the years, depending on the target population, the products of interest, or the emerging substances reported as potential allergens in scientific publications (6). A baseline patch test series is a collection of the most frequent or important contact allergens applied nonselectively to all tested participants (*i.e.*, a series of substances most commonly associated with ACD in a target population) (7). The baseline patch test series should constantly evolve with new relevant allergens being identified and added and others becoming less relevant and removed (8). The Brazilian baseline series has been available since 1996 (9). It's outdated and data about that series are scarce. It's necessary more studies in this field in our country.

The objective of the present study was to describe the clinical and epidemiological characteristics of a population with suspected contact dermatitis who underwent patch testing using an adapted Latin American baseline series.

## Materials and methods

Observational, descriptive and analytical clinical study with prospective data collection was performed in consecutively evaluated patients at a referral center. The institution's Ethics Committee approved the study, in accordance with the ethical standards established in the Declaration of Helsinki and the participants signed an informed consent form before inclusion in the study.

Two hundred and fifty-two participants with suspected ACD or other types of chronic dermatitis refractory to usual treatment were selected; among those, 44 decided to withdraw for fear of the COVID-19 pandemic, despite the institution undertaking all the protocols determined by the health authorities. Thus, 208 participants were evaluated and fully completed the patch testing in the departments of allergy and dermatology of a referral center in Brasília – Hospital Regional da Asa Norte, Brazil – from March to December 2020.

Participants using systemic corticosteroids and/or immunosuppressants (three weeks prior), topical corticosteroids or calcineurin inhibitors on the back (one week prior), or exposed to solar irradiation on the back (two weeks prior) were excluded. Children under 18, pregnant women, and nursing mothers were also excluded.

ACD is very important in children, but they were excluded because only adult patients are evaluated in our department.

All participants were tested with the adapted Latin American baseline series with 40 allergens proposed by the Colegio Ibero-Latinoamericano de Dermatología (CILAD) (10). This series was chosen because it represents an updated and modern version of the current Brazilian series (11). Some modifications were made to this series: 1) two new allergens were added: 10% propolis in petroleum jelly (following a proposal to the European baseline series) and 1% hydrocortisone acetate in petroleum jelly (same corticosteroid class and available in Brazilian market); and 2) the following allergens were removed: primin (it is suggested that primin should be deleted, owing to reduced environmental exposure) (12) and tixocortol-21-pivalate (it isn't marketed in Brazil) (**table I**). The allergens were handled, following the Chemical Abstracts Service (CAS) number, by the company IPI ASAC Brasil. Patch testing was performed using four previously prepared containers Alergochamber<sup>®</sup> hypoallergenic adhesive tapes (Neoflex Biotecnologia Ltda) with ten allergens each.

Patch testing was conducted using the standard technique following recommendations of the International Contact Dermatitis Research Group (13). Readings were taken at 48 and 96 hours. The results were graded as mild (+), strong (++), or very strong (+++), based on the degree of induration, erythema, papules and/or vesicles. A single researcher performed all questionnaires and test interpretations, and the same researcher supervised the preparation and application of the tests.

The qualitative variables are presented as frequencies (n) and percentages (%). For the association of the variables, Pearson's chi-square test was used with continuity correction or simulation and Monte Carlo when necessary (at least one cell expected a frequency lower than five). In  $2 \times 2$  tables without empty cells, it was possible to calculate the odds ratio with the respective 95% confidence interval. For quantitative variables, the Kolmogorov-Smirnov test was initially used to assess the normality of the data. As the null hypothesis of normality was rejected, the Mann-Whitney U test was used to compare these variables. Four multiple binary logistic regressions were performed to identify the main explanatory variables associated with the most prevalent allergens: nickel sulfate, fragrance mix I, sodium tetrachloropalladate, and methylisothiazolinone (MI). Initially, all independent variables were included in the model as explanatory variables to investigate the main factors associated with the four most prevalent allergens. Then, statistical techniques for variable selection were used based on the insertion of the variables (forward stepwise method: conditional, likelihood ratio, and Wald) and the removal of variables (backward stepwise method: conditional, likelihood ratio, and Wald). The techniques for removing variables showed better adjustments and predictive power, and the likelihood ratio method was chosen as it was the most appropriate. Finally, the significance of the regression parameters was tested using the Wald statistical test.

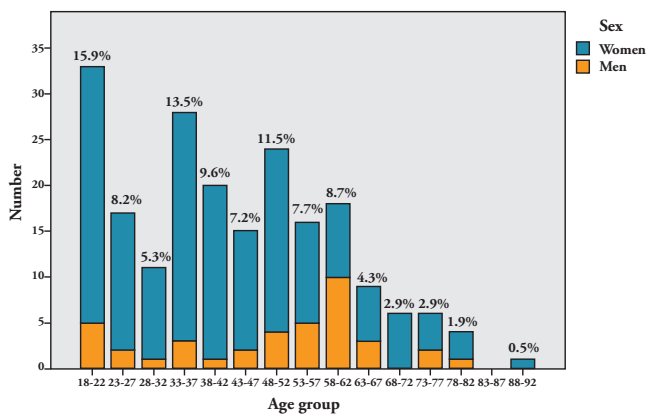
**Table I** - Latin American baseline series (9).

n	Allergens - Concentration %	n	Allergens - Concentration %
1	Potassium dichromate – 0.5	21	Quaternium-15 – 1.0
2	p-phenylenediamine – 1.0	22	Propolis – 10.0
3	Thiuram mix – 1.0	23	Methylisothiazolinone / methylchloroisothiazolinone – 0.01
4	Neomycin sulfate – 20.0	24	Budesonide – 0.01
5	Cobalt(II)chloride hexahydrate – 1.0	25	Hydrocortisone acetate – 25.0
6	Caine mix – 10.0	26	Methyldibromo glutaronitrile – 0.5
7	Nickel(II)sulfate hexahydrate – 5.0	27	Fragrance mix II – 14.0
8	Clioquinol – 5.0	28	Hydroxyisohexyl 3-cyclohexene carboxaldehyde – 5.0
9	Colophonium – 20.0	29	Toluenesulfonamide formaldehyde resin – 10.0
10	Paraben mix – 16.0	30	Cocamidopropyl betaine 1.0
11	N-Isopropyl-N-phenyl-4-phenylenediamine – 0.1	31	Diazolidinyl urea – 2.0
12	Lanolin alcohol – 30.0	32	Propyl gallate – 1.0
13	Mercapto mix – 2.0	33	Sodium tetrachloropalladate(II) hydrate – 3.0
14	Epoxy resin, Bisphenol A – 1.0	34	Thimerosal – 0.1
15	Peru balsam – 25.0	35	Disperse Blue mix 106/124 – 1.0
16	4-tert-Butylphenolformaldehyde resin – 1.0	36	Mixed dialkyl thiourea – 1.0
17	2-Mercaptobenzothiazole – 2.0	37	Methylisothiazolinone – 0.2
18	Formaldehyde – 1.0	38	Carba mix – 3.0
19	Fragrance mix I – 8.0	39	Hydrocortisone-17-butyrate – 1.0
20	Sesquiterpene lactone mix – 0.1	40	Imidazolidinyl urea – 2.0

## Results

Two hundred and eight participants between 18 and 89 years of age were analyzed, including 39 men (18.75%) and 169 women (81.25%). The mean age was 42.6 years, with a predominance of the age groups from 18 to 22 years and 33 to 37 years (**figure 1**). Most participants were white (66.3%), followed by mixed-race (26.9%) and black (6.7%). A time of disease evolution (CD) of more than three years was the most frequent (36.5%). The time period between one and three years and that with less than

six months had frequencies of 23.6% and 26%, respectively, while dermatitis lasting from six months to one year represented 13.9%. The subjects were characterized according to the MOAHLFAP index (male; occupational; atopic, hands, legs or face dermatitis;  $\geq 40$  years; and  $\geq 1$  positive reaction) (**table II**). Participants were grouped into 12 categories according to their profession: administrative, agriculture, retired, civil construction, household, student, teacher, beauty salon professional, health care worker, security, commerce worker, and others (**table III**).

**Figure 1** - Number of patch test by age group and sex.**Table II** - Characteristics of the assisted population according to the MOAHLFAP index.

Characteristics	n (%)
Male	39 (18.7)
Occupational*	40 (19.2)
Atopic triad	
Rhinitis	76 (36.5)
Atopic dermatitis	24 (11.7)
Asthma	23 (11.2)
Hand dermatitis	86 (43.0)
Leg dermatitis	51 (25.5)
Face dermatitis	54 (27.0)
Age $\geq 40$ years	110 (52.9)
Positivity (at least 1 positive reaction)	145 (69.7)

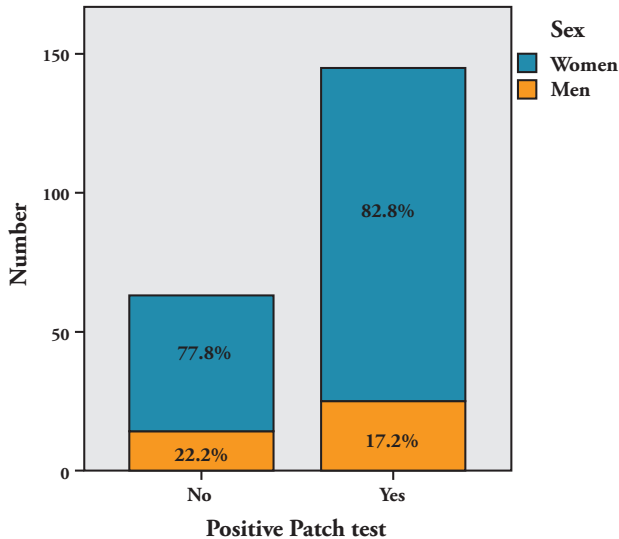
\*Includes any skin injury that is deemed to be occupational.

Patch testing was positive in 145 participants (69.7%). The median age of those who had a positive test was 41 years, with no statistically significant difference compared to participants with a negative result ( $p = 0.930$  – Mann-Whitney U test). Despite having a clinical suspicion, 63 cases (30.3%) showed no reactivity. Among the positive tests, 82.8% were women (OR 1.371,  $p = 0.398$ ,  $n = 120$ ) (**figure 2**); 25 men had positive tests (64.1%). There was significant variation in anatomical sites, and many had multiple areas involved. The hands were the most commonly affected (43.0%), followed by the upper limbs (33.0%) and the face (27.0%) (**figure 3**). Areas such as the lower limbs, trunk, and neck also showed considerable involvement, while the anogenital region had the least involvement (3.5%).

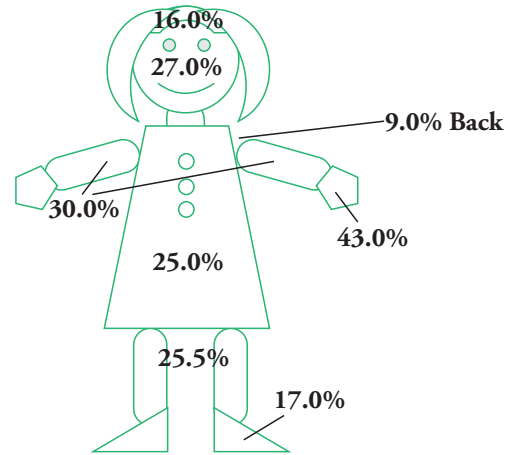
**Table III - Occupation of the participants.**

Occupation	n (%)
Administrative	56 (27.0)
Household	34 (16.4)
Student	33 (15.9)
Health care worker	23 (11.1)
Retired	20 (9.7)
Commerce worker	9 (4.3)
Teacher	7 (3.4)
Security	6 (2.9)
Civil construction	3 (1.4)
Beauty salon professional	3 (1.4)
Agriculture	2 (1.0)
Others	12 (5.8)

**Figure 2 - Positive patch test by sex.**



**Figure 3 - Percentages of main body parts affected.**



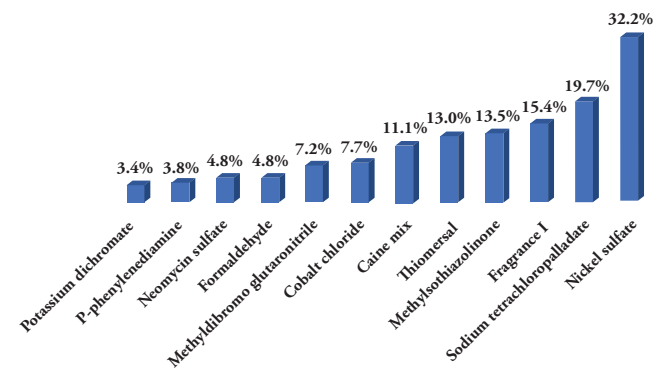
Among participants with a positive patch test, 57.3% (OR 0.793,  $p = 0.457$ ) reported a personal history of atopy and 58.74% (OR 1.208,  $p = 0.539$ ) reported some family history of atopy. Of the hypersensitivity reactions in these participants 8.39% (OR 0.425,  $p = 0.051$ ) reported asthma, 35.86% reported allergic rhinitis (OR 0.909,  $p = 0.759$ ), and 11.19% (OR 0.850,  $p = 0.726$ ) reported atopic dermatitis. However, there was no statistically significant correlation between these comorbidities and a positive patch test. Regarding the number of positive reactions, most participants had one to three reactions; only 29 (13.9%) showed four or more (**table IV**). They were not considered as a sign of the “angry back syndrome”, due to lack of close proximity to each other (14).

The ten main allergens with positive reactions to patch testing according by their percentages were nickel sulfate (32.2%,  $n = 67$ ); sodium tetrachloropalladate (19.7%,  $n = 41$ ); fragrance mix I (15.4%,  $n = 32$ ); methylisothiazolinone (MI) (13.5%,  $n = 28$ ); thiomersal (13.0%,  $n = 27$ ); caine mix (11.1%,  $n = 23$ ); cobalt chloride (7.7%,  $n = 16$ ); methylidibromo glutaronitrile (7.2%,  $n = 15$ ); and neomycin sulfate and formaldehyde each (4.8%,  $n = 10$ ) (**figure 4**).

Four multiple binary logistic regressions were performed to identify the main explanatory variables associated with the most prevalent allergens: nickel sulfate, fragrance mix I, sodium tetrachloropalladate, and MI. No variable showed statistical significance after inserting the explanatory variables; thus, variable selection techniques improved the mathematical models. For the nickel sulfate variable, women were 2.683 times more likely to have a positive test than men ( $p = 0.038$ ). Participants with an allergy to fragrance mix I were 2.786 times more likely to have a family history of allergy ( $p = 0.026$ ). Participants sensitive to sodium tetrachloropalladate were 5.071 times more likely to occur

**Table IV** - Number of positive reaction per participant.

Number of positive reaction	n (%)
0	63 (30.3)
1	47 (22.6)
2	45 (21.6)
3	24 (11.5)
4	19 (9.1)
5	8 (3.8)
6	2 (1.0)
<b>Total</b>	<b>208 (100.0)</b>

**Figure 4** - Main allergens presenting positive reaction.

in women ( $p = 0.034$ ). Those who tested positive for MI were 2.826 ( $p = 0.047$ ) and 6.802 ( $p < 0.001$ ) times more likely to have lesions on the face and hands, respectively.

## Discussion

This study was peculiar in aiming to reduce the number of influencing variables. Specifically, we used a single researcher as the patch reader who was also responsible for preparing all patch tests throughout the entire study in order to minimize variability between observers, which has occurred in other published studies. A similar methodology was found in only one previous study (3). Furthermore, to our knowledge, this is the first prospective study to evaluate the Latin American baseline series proposed by CILAD (15) in a wide selection of Brazilian participants with suspected CD.

Understanding the epidemiological aspects of a specific population suffering from a particular pathology is essential for an appropriate approach, especially concerning CD, as management can often be as simple as removal of the etiological agent. Therefore, this study constitutes an initiative, including a pop-

ulation from a single center in which the main clinical and sociodemographic characteristics and the main allergens involved are described (5). In the present research, variables, such as age, sex, occupation, personal and family history of atopy, site of involvement, among others, and their correlation with the patch test results were analyzed.

Patch testing, history, and typical clinical features are important aspects in identifying the specific causative allergen in individuals with ACD (4). The frequency of positive patch tests in the present research was 69.7%. In a study using the European baseline series, it was 62.2% (4). In another paper using the North American baseline series with 50 substances, one or more positive reactions was 60.2% (3). However, a comparison among studies using different series is not adequate, as other allergens are used. In an Argentine study using the same series as ours, the test was positive in 82.4% (16). We do not have other Brazilian data using the Latin American baseline series to compare with our results.

In the present study, the mean age was 42.6 years. This age is lower than that reported in other countries. In an American study performed in Massachusetts, the mean age was 47.7 years (3). In a North American Contact Dermatitis Group (NAC-DG) multicenter study, the mean age was 47 years (17). Our research was carried out during the COVID-19 pandemic, which may be a possible explanation for the lower mean age, in that the older population was afraid to undergo the procedure, despite the institution undertaking all the protocols determined by the health authorities. The age groups from 18 to 22 years and 33 to 37 years correspond to the age groups in whom more tests were performed. It is usual to observe a higher prevalence in adults after 30 years of age, and a possible explanation could be the need for a prolonged time to develop sensitization to allergens due to repeated exposure (5).

Women were the majority of participants at 81.3% and had a more positive reactions 82.8%; however, the difference between sexes was not statistically significant ( $p = 0.398$ ). In a retrospective study over six years, in which 585 individuals were tested, 73% of positive results occurred in women (1). A reason for the female predominance might be a greater exposure to personal care products, cosmetics, and jewelry. Hormone influence could also be an explanation (1, 5). On the other hand, the difference between the sexes could relate to cultural factors, as women seek medical assistance more often and have better control over their health, and, therefore, they have a greater chance of being correctly diagnosed (5).

A personal history of allergic disease was found in 57.3%, while a family history of atopy was noted in 58.7% of patients with a positive patch test. This is in contrast to a scientific study published in 2021, in which only 16% of participants reported a personal history of atopy (18). In another recent study, a history of hypersensitivity was found in one-third of participants (5). The association with allergic diseases is probably multifactorial,

including family and environmental predisposition and inherent factors related to individual behavior and lifestyle (5).

Occupation-related dermatitis was detected in 19.2% of study participants. Another study showed a discrepant prevalence of only 5.4% (18). However, another research showed that an occupational history associated with skin lesions was observed in 21.1%, demonstrating that there is usually significant variability in this prevalence (4). The epidemiological characterization showed the professional profile of the participants submitted to patch tests. In the present study, participants who held administrative positions (civil servants) were the most affected group, representing 27%. This result differs from that of another study in which housework was the most common activity associated with CD (5). We believe this result is due to the study being carried out in the capital of Brazil, where there is a higher concentration of civil servants.

Hand involvement was the most frequent site at 43%, followed by the upper limb involvement at 33%. In another study, the main anatomical site was also the hands, followed by the upper limbs at 64.8% and 44.6%, respectively (16). Similar results were also found in a Turkish study with hand involvement at 49.3% (18). The hands' predominance is due to daily activities, repeatedly exposing hands to various allergens. This high prevalence has a considerable impact on work-related aspects, a substantial economic burden on society, and the quality of life of individuals (19).

The main allergens causing CD vary depending on the geographic region analyzed. Large countries may have differences in allergens across their regions. Thus, our study, which was carried out in Brasília, may not reflect the whole country of Brazil, which has continental dimensions. The top ten most frequent positive allergens were comprised four preservatives (MI, thiomersal, methylidibromo glutaronitrile, and formaldehyde), three metals (nickel, palladium, and cobalt), two drugs (caine mix and neomycin), and one fragrance (fragrance mix I).

The most frequent allergen in this sample was nickel sulfate at 32.2%. The same finding occurred in the NACDG study, with nickel reaching a prevalence of 16.2% and also being the most commonly positive allergen (17). In another paper, using the standard European series, 27.8% of participants had an allergic response to nickel sulfate (4). A systematic review showed a prevalence of 11.4% among 34,102 individuals, which was 4.3% among men and 15.7% among women (20). In the present research multivariate analysis revealed that women were 2.7 times more likely to have a positive test for nickel than were men ( $p < 0.05$ ). These data are also corroborated when using a specific metal series. Women have earlier and more intense exposure to jewelry (21). This element is ubiquitous in metals. It is increasing in sensitivity and is the most common allergen found worldwide (2). It is also frequently used in eyeglass frames, metal buckles and fasteners, coins, tools, braces, and toys (1, 2). Thus, especially concerning nickel, patch testing is

imperative to ensure early diagnosis of this specific allergy and adequate intervention (3).

The metal group was the most significant cause of sensitivity in the present study. Palladium, represented by sodium tetrachloropalladate, had a high sensitivity and was positive in 19.7% of the tests, relating to regular jewelry use. The same was found in another paper that used the Latin American series, with palladium being the second most frequently positive hapten at 41.9% (16). Importantly, palladium is not part of the standard European and American series. Palladium exposure can also come from braces and electronics. In addition, it is speculated that other metals, such as palladium and cobalt, may replace nickel in popular products, increasing the presence of these metals (21). Furthermore, positive reactions to palladium salts are commonly associated with positive reactions to the nickel sulfate patch test (16). Cross-reactivity between nickel and palladium has been attributed to both elements belonging to the same group on the periodic table (22). These facts help to explain the high sensitization to palladium (19.6%) observed in a scientific study that evaluated individuals with suspected metal allergy, using a specific series, especially in females (25.9%) (21). Our study also demonstrated, through multivariate analysis, a significant relationship between palladium and women ( $p < 0.05$ ). There is evidence that polysensitization to metals occurs in women (23). Allergy to fragrance mix I was also observed in a large proportion and was the third substance with the most positive results at 15.4%. Multivariate analysis also revealed a significant association between sensitivity to fragrance mix I and a family history of atopy ( $p < 0.05$ ). Fragrances are widely added to cleaning products, topical medicaments, and cosmetics (24). In a systematic review, fragrance mix I was the second most common allergen in the general population, suggesting that its occurrence is becoming an endemic phenomenon (20). In an important European multicenter study, contact allergy to fragrance mix I was seen in 6.9% (25). On the other hand, the NACDG found 9.2%, with fragrance mix I, being the fourth most commonly involved allergen in CD (17). A comparative study observed increased contact sensitivity to fragrance allergens between 2013 and 2019 compared to 1998 to 2005 (18). Furthermore, these data about prevalence may underestimated the probability of contact allergy to fragrances, as these results cover only eight of 82 haptens known to cause this allergy (20). Thus, the need for a newly expanded fragrance mix was recognized in the 1990s, when it was found that 15% of fragrance allergies were not identified by fragrance mix I. Fragrance mix II is able to identify additional individuals with undiagnosed fragrance sensitivity to fragrance mix I (26). The series in the present study used also fragrance mix II, with a prevalence of contact allergy of 2.4%. Similar data were also observed in another paper, with a prevalence of 2.1% (18).

Isothiazolinone derivatives are widely used as preservatives, mainly in personal, domestic, and industrial products (27). The mixture

of methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) in a 3:1 ratio caused severe sensitization rates in the past. With MI as an isolated preservative in cosmetics, a pandemic of dermatitis to this substance has emerged in recent years (28). For this reason, MI was named “allergen of the year” in 2013 by the American Contact Dermatitis Society (26). It is a potential primary sensitizing substance that has been used at a higher concentration to be effective, which explains the explosion of cases worldwide (29). In this study, MI reached a prominent place, ranking fourth, with 13.5% positivity. However, the MCI/MI association showed only 0.5% positivity. The data in this research regarding MI were very similar to those found in important international studies. The NACDG group, in their latest paper, found a sensitization rate of 15.3% for MI and 11% for MCI/MI (17). The American group use a higher concentration (0.02%) of MCI/MI than the Latin American series (0.01%). This fact may partly explain the different positivity in the association. Another group using the Mayo Clinic standard series found that MI was the second substance with the highest positive reaction rate (13.6%), being surpassed only by nickel sulfate (8). In another prospective study similar to ours, contact allergy to MI was diagnosed in 13.2% (30). In Brazil, in a specific study to detect allergies with the main isothiazolinones, MI was positive in 26.7% of patients, with a clinical relevance of 93.8%. Those authors found that 35.7% of the participants who tested positive for MI had negative results for MCI/MI at 0.02% (31).

Through multivariate analysis, a significant relationship especially between MI and involvement of the hands ( $p < 0.001$ ), but also of the face ( $p < 0.05$ ) was observed. Frequently, in ADC, MI mainly affects the face and hands due to chemical product handling. Airborne exposure to MI containing paints and household detergents is commonly described with intense involvement of the face (27). Other authors also reported that the most frequent involvement was the hands (33.3%), followed by the face (26.5%) (32). In a study that evaluated the Brazilian series, with a 0.5% sensitization to MCI/MI, it was also found that the hands were the most affected site (58.6%), followed by the head, face, and neck (48.3%) (33).

This study reveals a detailed profile of a population with suspected ACD observed in our region. Adequate anamnesis with careful physical skin examination, associated with a well-performed patch test, can lead to significant success in diagnosing individuals with suspected CD. Patch testing using an updated baseline series remains the gold standard for identifying relevant allergens and is considered to be a safe and practical method. This research is the first to analyze the Latin American baseline series in the Brazilian population. The use of this adapted baseline series represents a significant update of this important diagnostic tool.

### Fundings

None.

### Contributions

PESB, CMSR: conceptualization. PESB: data collection. PESB, PGB, RZFB: writing - original draft. MRCGB, CMSR: supervision. All authors: writing - review & editing.

### Conflict of interests

The authors declare that they have no conflict of interests.

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