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Natural Rubber Latex:: Glove Use, Sensitization, and Airborne and Latent Dust Concentrations at a Denver Hospital

[Original Articles]

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Abstract

Exposure to natural rubber latex may cause immediate hypersensitivity reactions. Published latex sensitization prevalence rates range from 2.9% to 22% among health care workers, and from 0.12% to about 20% of occupationally unexposed populations. In this study, self-administered questionnaires addressed job and personal characteristics, glove use, and symptoms in two groups of hospital workers: those who regularly used latex gloves and those who did not. Serum was tested for latex-specific immunoglobulin E. Air, surface, and air-filter dust samples for natural rubber latex were collected. The prevalence of latex sensitization was 6.3% in the non-users and 6.1% in the latex glove users (P = 0.9); 81.3% of sensitized workers were atopic compared with 59.5% of non-sensitized workers (P < 0.05). Reporting of work-related hand dermatitis was more common in the latex glove users (23.4%) than in the non-users (4.9%), as were rhino-conjunctivitis (16.3% and 7.9%, respectively, [P < 0.01]),

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and hand urticaria (9.9% and 2.1%, respectively, [P < 0.01]). There was no significant difference in work-related symptoms between the sensitized and non-sensitized workers. Environmental concentrations of latex were higher in the work areas of the non-sensitized workers, but higher in the clinical than in the non-clinical areas. Occupational latex glove use was not a risk factor for sensitization.

Natural rubber latex (NRL) is contained in the milky fluid from the *Hevea brasiliensis* tree. It contains a variety of proteins capable of inducing antibody-mediated allergic reactions. Routes of exposure include dermal, mucosal, percutaneous, and inhalation. There are three main types of reaction to latex-containing objects: irritant contact dermatitis, allergic contact dermatitis, and immediate hypersensitivity. 1

Immediate hypersensitivity (type I, immunoglobulin E [IgE] -mediated reaction) from latex was first reported in the English literature in 1979, when Nutter described contact urticaria in a housewife who used rubber gloves. 2 Type I hypersensitivity reactions may manifest as urticaria, asthma, allergic rhino-conjunctivitis, and anaphylaxis. 3 Persons thought to be at risk of developing latex allergy include health care workers, latex product manufacturing workers, children with spina bifida, and persons who have had multiple operations. Atopy is also a risk factor, as is allergy to foods such as banana, kiwi, avocado, and chestnut, 3 which may contain allergens that cross-react with antibodies to latex proteins. The estimated prevalence of sensitization to latex, manifested by either a positive skin-prick test (SPT) or the presence of antibodies to latex in serum, among health care workers has been reported to range from 2.9% to 22%. 4–19 Prevalences ranging from 0.12% to about 20% have been reported in a variety of occupationally unexposed populations, such as adults attending health screening or allergy clinics, children admitted for allergy testing, blood donors, or in the general population. 19–29 Thus, it has been difficult to determine the magnitude of the occupational risks faced by health care workers (HCWs). These wide ranges in prevalence may be due to differences in the methods and/or reagents used to estimate prevalence in a study. In 1998, the National Institute for Occupational Safety and Health (NIOSH) received a confidential employee request for a health hazard evaluation to investigate a hospital in Denver, Colorado, and determine if a health hazard existed for HCWs from occupational exposures to NRL. The objectives of this study were to determine the prevalence of sensitization (IgE antibodies to latex proteins) among latex glove using and non-using hospital staff utilizing a single assay and protocol, determine risk factors for sensitization, and determine whether work-related symptoms were associated with latex sensitization or latex glove use.

Methods

Study Population

Two employee groups, regular users of latex gloves and non-users, were recruited to participate in the study. Employees in Human Resources, Finance, Marketing, and a variety of other administrative areas were the non-user group. Labor and Delivery, the Emergency Department, and the Laboratory Service, were selected as the latex-glove–using group.

Questionnaire

Questionnaires were self-administered and consisted of questions concerning demographics (age, race, gender, job title, years worked, etc) and information about personal history of allergic disorders, surgical procedures, latex allergy, and smoking, as well as about glove use, symptoms, and possible symptom triggers. For analysis, latex glove exposure was determined by two questions: "Do you usually wear gloves when working in your current position?" and "What type of gloves do you wear most often?" Persons answering the first question affirmatively and specifying that they wore either powdered or non-powdered latex gloves were categorized as wearing latex gloves, whereas those answering the first question negatively, or in the affirmative but specifying non-latex gloves, were classified as not using latex gloves.

Work-related symptoms were defined as either those present at work but not at home, or those present both at work and at home that improved when away from work. Asthma was defined as wheezing, or any two of the following three symptoms: cough, shortness of breath, and chest tightness. Rhino-conjunctivitis was defined as the presence of two of three of the following: itchy, runny nose (with or without sneezing); stuffy nose; and itchy, watery eyes. Hand dermatitis was defined as the presence of dermatitis, eczema, or other red, inflamed rash on the hands, whereas urticaria was defined as red, raised, itchy swellings (called hives, wheals, or urticaria), either on the hands or elsewhere (general urticaria). Participants were asked if they had any of these symptoms or diagnoses in the preceding 12 months. Atopy was defined as having a history of hay fever or other allergies (not including allergies to medications), eczema or atopic dermatitis, or asthma.

Antibody Testing

Blood was drawn by venipuncture , and sera was separated and stored frozen and then shipped on dry ice to the NIOSH Health Effects Laboratory Division in Morgantown, West Virginia. The sera were analyzed for latex-specific IgE and total IgE by using the Pharmacia CAP® system (Pharmacia and UpJohn AB Diagnostics, Uppsala, Sweden). A negative latex-specific IgE was defined as <0.35 kU_A/L (no detectable antibodies) and positive as $>=0.35$ kU_A/L (presence of detectable antibodies). All data collection, including questionnaires, blood collection, and environmental sampling, were conducted in July and August of 1998.

Occupational Hygiene

To evaluate environmental concentrations or occult reservoirs of NRL protein, air samples, surface dust samples, and accumulated dusts from the hospital's central air handling unit (AHU) air filters were collected. A total of 23 area air samples were collected by using two high-volume samplers operated at 5.7 L/sec) and at 6.1 L/sec. Sampling time was 8 hours and 17 minutes. Samplers were located at a height of 52 inches (approximate seated breathing zone height). NRL was collected on bilaminate (glass fiber and polytetrafluroethylene) membrane filters.

Plenum spaces (the interstitial space above suspended ceiling tiles), which in some buildings serve as return air pathways, can collect and retain dust. Latent dust accumulated in the plenums

can be released during construction or routine maintenance activities. To evaluate for reservoirs of occult NRL-containing dust, surface dust samples were collected from the backsides of ceiling tiles by using microvacuuming techniques described in American Society for Testing and Materials method D 5755–95. [30] Areas were masked by using disposable 100-cm ^{2} clear plastic masking templates. A high-volume sampling pump, operated at 28.3 L/min, and 37-mm sampling cassettes connected in-line with Tygon® tubing were used to collect the samples; 100-cm ^{2} areas were microvacuumed for 2 minutes or until no visible dust remained. Ceiling tiles adjacent to a return air grille in the room or area where air sampling was conducted were selected for surface sampling. Dust samples were also collected from the insides of AHUs and AHU pre-filters by using the same technique as for the collection of ceiling tile surface dust samples. All samples were sent to the Mayo Clinic, Rochester, Minnesota, for analysis for latex proteins by radioallergosorbent inhibition assay by using IgE antibodies from latex-sensitive individuals. [31]

Statistical

Statistical Analysis System software (SAS Institute, Cary, N.C.) was used for statistical analysis. Univariate associations between categorical outcome and exposure variables were assessed with contingency tables by using chi-squared or Fisher's exact test (two-tailed). Univariate associations between categorical outcome and continuous exposure variables were evaluated by comparing group means using the *t* test, or for non-parametric data, the Mann-Whitney test. A *P* value of <0.05 was considered statistically significant. Logistic regression was also used to evaluate associations between exposure and outcome variables. Odds ratios (OR) were used as a measure of association. Along with the OR, a 95% confidence interval (CI) was calculated. A CI excluding 1 was considered significant. All participants were included in the analyses unless specific necessary data were missing; therefore, the denominators vary for some analyses. Values for sampling results that were below the limit of detection were estimated by dividing the limit of detection by the square root of two. [32] Geometric means were calculated for area air samples, surface samples, and filter samples by department.

Results

Medical

Five hundred thirty-two of 640 (83.1%) eligible employees participated in the study. Participation rates were 80% in the non-clinical areas and 86% in the clinical areas. Demographics were similar for the latex glove users and non-users, with the exception of age: glove non-users were older by an average of 4.6 years (Table 1). There was a significant difference in the number of hours worked weekly. Latex glove non-users worked more hours per week than the latex glove users (Table 1), but there was no difference in the length of time working in either the current department ($P = 0.9$) or in the hospital ($P = 0.4$).

Table 1. Demographics and Selected Characteristics by Exposure Group*$P < 0.05$.

TABLE 1
Demographics and Selected Characteristics by Exposure Group

	No Latex Gloves (n = 239)	Latex Gloves (n = 248)
Mean age (y)	44	39*
Gender (%)		
Male	25	26
Female	75	74
Race (%)		
White	79	83
Black	7	6
Hispanic	11	7
American Indian or Alaskan native	0	1
Asian or Pacific islander	3	3
Other	1	1
History of atopy (%)	60	61
Smoking Status (%)		
Current	17	15
Former	27	24
Never	56	61
Years worked in current department (%)		
<1	22	23
1–5	34	31
6–10	18	22
11–20	19	17
>20	7	8
Average no. of hours worked per week (%)		
1–40	55	78
40+	45	22*

* $P < 0.05$

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The overall prevalence of latex sensitization (defined by the presence of latex-specific IgE) was 6.2% (33 of 531). There was no statistically significant difference in the prevalence of sensitization between employees who wore latex gloves (6.1%, or 16 of 264) and those who did not (6.3%, or 16 of 255) ($P = 0.9$). There was also no statistically significant difference in the prevalence of latex sensitization between employees who reported current latex glove use or having worn at least one pair of latex gloves per day at another job or in training (ie, ever having occupational latex glove use) (6.3%), and those who reported never having occupational latex glove use (5.1% [$P = 0.6$]).

Reporting of work-related hand dermatitis was more common among latex glove users (23.4%) than in the non-users (4.9%), as were rhino-conjunctivitis (16.3% and 7.9%, respectively, [$P < 0.01$]) and hand urticaria (9.9% and 2.1%, respectively, [$P < 0.01$]). There was no significant difference in the reporting of work-related asthma or general urticaria (Table 2). Employees who reported rhino-conjunctivitis, hand or general urticaria, and hand dermatitis

reported a significantly higher median number of gloves used per day (Table 3). Findings were similar for median number of pair-hours, a variable calculated by multiplying the number of gloves worn daily by the average duration of wear of each pair (results not shown). There was no difference between those who were sensitized and those who were not sensitized in median number of gloves used per day (1.5 vs 1.0, respectively, $P = 0.8$) or median number of pair-hours (0.4 and 0.3, respectively, $P = 0.7$). There was no significant association between work-related asthma, rhino-conjunctivitis, general urticaria, hand urticaria, or hand dermatitis and latex sensitization, although prevalences of hand urticaria and hand dermatitis were higher in those who were sensitized (Table 4). Twenty-four percent of those with latex sensitization reported no immediate hypersensitivity symptoms either at work or home, compared with 38% of the non-sensitized workers ($P = 0.1$), whereas 62.1% of the sensitized workers reported no work-related symptoms, compared with 71% of the non-sensitized ($P = 0.3$) (not shown).

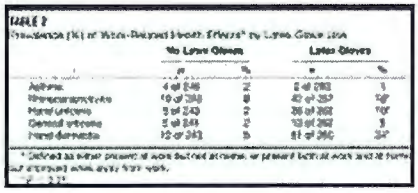

Table 2. Prevalence (%) of Work-Related Health Effects[a] by Latex Glove Use[a] Defined as either present at work but not at home, or present both at work and at home but improved while away from work.*$P < 0.01$.

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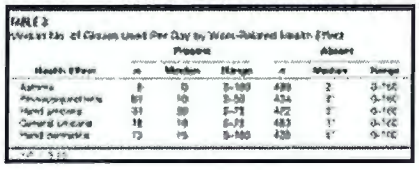

Table 3. Median No. of Gloves Used Per Day by Work-Related Health Effect*$P < 0.05$.

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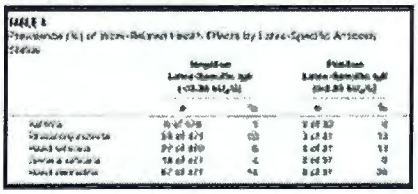

Table 4. Prevalence (%) of Work-Related Health Effects by Latex-Specific Antibody Status

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The prevalence of atopy was similar in both exposure groups, 60.2% in the latex glove non-users and 61.1% in the latex glove users. The mean total IgE level in atopic workers was 96.6 kU/L, compared with 58.1 kU/L in non-atopic workers ($P = 0.06$). Atopy was significantly associated with latex sensitization, with 81.3% of those with latex sensitization being atopic, compared with 59.5% of those who were not sensitized ($P < 0.05$).

Self-reported respiratory and dermatologic allergic reactions related to avocados, kiwis, peaches, chestnuts, or bananas were not significantly associated with latex sensitization ($P = 1.0$). The number of surgical procedures undergone ranged from 0 to 30 and were not significantly associated with latex sensitization ($P = 0.3$). There was no association between sensitization and the number of gloves worn daily (eg, those who wore more than 18 pairs of latex gloves daily [the highest quartile] were as likely as those who wore no latex gloves [the lowest quartile] to be sensitized [OR, 0.9; 95% CI, 0.3 to 2.3]). Similarly, those who reported more than 7 pair-hours of latex glove use daily (the highest quartile) were not more likely to be sensitized than those who reported 0 pair-hours (the lowest quartile) (OR, 0.8; 95% CI, 0.3 to 2.2). There was no significant difference in the prevalence of sensitization between those who reported wearing powdered latex gloves and those who reported wearing powder-free latex gloves (4.7% vs 7.0%, $P = 0.4$)

Male workers were significantly more likely to have latex sensitization than female workers (12.1% vs 4.1%, [$P < 0.01$]). Gender, however, was not related to atopy. Women predominated in all job categories except facilities maintenance worker, physician, and physician assistant, but sensitization was not associated with job category ($P = 0.3$).

Environmental

Air sampling.

Seven area samples were collected in non-clinical areas of the hospital (Table 5). Five of seven samples had no detectable amounts of NRL allergen, and one sample had a trace amount (detectable but below the limits of quantification). Only one sample had a quantifiable amount of NRL allergen, 0.26 ng/m³. The geometric mean concentration in the non-clinical areas was 0.10 ng/m³.

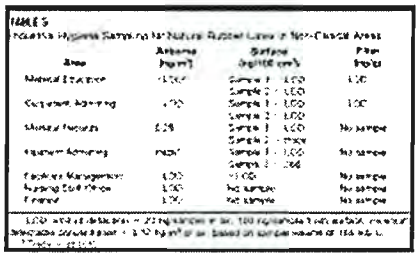

Table 5. Industrial Hygiene Sampling for Natural Rubber Latex in Non-Clinical Areas* LOD, limit of detection = 20 ng/sample in air, 100 ng/sample from surface; minimum detectable concentration = 0.12 ng/m³ of air, based on sample volume of 165,402 L.† Trace = at LOD.

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In the clinical areas, 16 area air samples were collected. The concentrations of NRL ranged from not detected (three samples) to 3.33 ng/m³. Four samples contained trace concentrations (Table 6). The geometric mean concentration of NRL was 0.52 ng/m³. The laboratory that provided the analysis reported differences in limits of detection for the sets of air samples from the non-clinical areas (approximately 20 ng/sample) and the clinical areas (approximately 40 ng/sample). The reason for these differences was a different amount of buffer used to extract NRL from the filters in the two sets of samples (total sample extraction volumes of 250 µL and 500 µL, respectively).

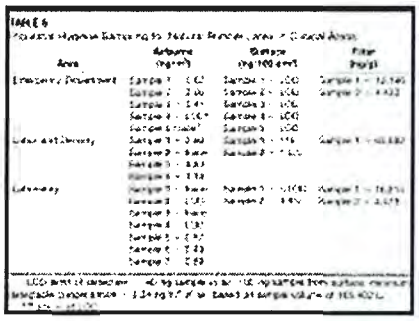

Table 6. Industrial Hygiene Sampling for Natural Rubber Latex in Clinical Areas* LOD (limit of detection) = 40 ng/sample in air, 100 ng/sample from surface; minimum detectable concentration = 0.24 ng/m³ of air, based on sample volume of 165,402 L.† Trace = at LOD.

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Surface dust samples.

Nine samples were collected in clinical areas and nine in non-clinical areas (Tables 5 and 6). In the non-clinical areas, seven of the samples had no detectable NRL protein, one surface dust sample from the AHU serving the medical records area had a trace concentration, and one sample had 368 ng/100 cm²). In the clinical areas, six of the nine samples had no detectable NRL antigens. Three samples had quantifiable results ranging from 118 ng/100 cm² to 3952 ng/100 cm².

Filter dust samples.

Two filter dust samples were collected from the pre-filters of AHUs serving non-clinical areas of the hospital; neither had detectable NRL antigens (Table 5). Six samples of filter dust were collected from AHUs serving clinical areas of the hospital (Table 6). The concentrations of NRL antigens ranged from 4433 ng/g (from an AHU serving the emergency department) to 83,682 ng/gm (from an AHU serving the labor and delivery area).

Geometric mean concentrations of NRL in air, on surfaces, and from air filters were calculated for each of the departments studied. Individual participants were assigned the mean concentration for their department. Mean concentrations were compared between the sensitized and the non-sensitized workers. For airborne, surface, and filter samples, mean concentrations were higher in the work areas of the non-sensitized workers (Table 7). This was statistically significant for airborne

concentrations.

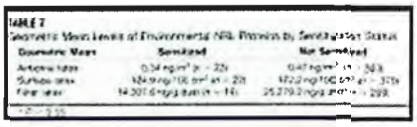

Table 7. Geometric Mean Levels of Environmental NRL Proteins by Sensitization Status*$P < 0.05$.

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Discussion

We found that neither current nor past occupational use of latex gloves was associated with latex sensitization in this study population. The prevalence rate of latex sensitization in this hospital is at the lower end of the range reported in the medical literature for other hospitals and within the range reported in non-occupationally exposed populations.

There was a significant association between latex glove use and rhino-conjunctivitis, hand urticaria, and hand dermatitis. However, there was no difference in the prevalence of these conditions by sensitization status. Such an association would not be expected for hand dermatitis inasmuch as neither irritant nor allergic contact dermatitis is a type 1 reaction. There are several potential reasons for this apparent discrepancy. First, the serum test may not be as sensitive as reported, and thus we may have missed cases of sensitization. However, the test sensitivity should not differ between exposure groups, and therefore this is an unlikely explanation. Second, glove use may be a proxy for other workplace exposures that cause allergic or irritant symptoms. Because there were only 32 sensitized individuals in this study, there may have been insufficient statistical power to detect a significant association between sensitization and certain health effects. Finally, because latex allergy is a high-profile issue among HCWs, and because the request for a NIOSH study came from employees, symptom reporting may have been subject to an awareness bias.

A significant proportion of sensitized individuals reported being asymptomatic. It is not uncommon to be sensitized to a substance but not have clinical symptoms of allergy. For example, about 60% of positive SPT results do not reflect symptomatic food allergy. [33] In other studies, one-third [34] to one-half [35] of patients with positive SPT results to latex are asymptomatic.

Atopy is an established risk factor for latex allergy, and this was supported by our study. The significant association of latex sensitization with male gender [20,36–38] has been reported elsewhere, but other studies have found a female predominance, [39–41] or no difference between genders. [5–8,10,11,16,18] The lack of an association with age has been previously reported. [5,7–9,11,18,20,25]

Other risk factors for latex sensitization identified in previous studies include allergies to kiwi, avocado, banana, chestnut, and other foods. We found no association between these allergies and

reported respiratory and dermatologic type I allergic symptoms, but we did not ask about oral symptoms, which may be more common when the route of exposure is ingestion. Having multiple surgical procedures has been hypothesized to be a risk factor, especially in children with spina bifida, because of the extensive mucosal exposure to latex gloves. Some studies have found an association with increasing numbers of surgical procedures;[29,42] others have not.[7,25,36,43] In this study, the number of surgical procedures was not associated with the presence of latex-specific IgE. The lack of association between sensitization and number of gloves worn daily or pair-hours of glove use per day and sensitization was not unprecedented. Others have documented a lack of association between measures of glove use and sensitization.[4,5,9] However, retrospective self-reports of glove use as a measure of exposure are subject to error. The lack of association with job title/category has also been documented in other studies.[5,7,17]

One hospital in the United States adopted an in-house guideline of a time-weighted average concentration of 10 ng/m 3 for total NRL allergen,[44] on the basis of extensive industrial hygiene sampling, which suggested that 10 ng/m 3 is a concentration seldom, if ever, exceeded when powder-free gloves were used. A recent article proposed that a critical threshold for development of latex IgE antibodies, conjunctivitis, rhinitis, and asthma in HCWs is a time-weighted average concentration of 0.6 ng/m 3 of NRL aeroallergen.[45] Another study[46] reported that when powdered latex gloves were used, NRL concentrations ranged from 39 to 311 ng/m 3, but concentrations of NRL were less than 0.02 ng/m 3 when powder-free gloves were used. A study in a large medical center reported concentrations ranging from 0.3 to 1.8 ng/m 3 in areas where powdered gloves were never or seldom used, and from 13 to 208 ng/m 3 in areas where powdered gloves were used frequently.[47] Air sampling during our investigation revealed very low levels of airborne NRL proteins at the locations sampled. As expected, airborne NRL was more commonly detected and in higher concentrations in clinical areas than in non-clinical areas. It is difficult to interpret the finding that airborne concentrations of NRL proteins were statistically significantly higher in the work areas of non-sensitized employees than in those of sensitized employees. Airborne area NRL concentrations were very low overall, and air sampling was not conducted at the time when sensitization occurred. Awareness of a latex-allergic worker could result in less powdered glove use by coworkers, hence less airborne NRL. Housekeeping vigilance in the area(s) of sensitized employees may also have had an impact on airborne NRL concentrations. It has been noted that latex allergen concentrations vary markedly between different types of latex gloves (powdered vs powder-free, surgical vs examination), by manufacturer, and even among gloves from the same manufacturer.[48] Gloves that were lower in protein and allergen content may have been used in the areas studied. We did not determine allergen content in the gloves in use at the time of the study but noted only whether powdered or powder-free gloves were used. Although this hospital had not made efforts to use only powder-free, low-protein latex gloves, glove manufacturers have been working to reduce protein and allergen levels in gloves in response to the heightened awareness of latex allergy. This may have resulted in the low concentrations of airborne latex noted in this study and could have affected sensitization rates.

One limitation of this study is its cross-sectional nature. It is possible that sensitized workers who were symptomatic left the workplace. This did not seem to be a major factor, however, because there was no difference in years worked in the department or in the hospital either by

exposure classification or latex sensitization status. In addition, we asked if employees had ever had another job or training position in which they wore at least one pair of latex gloves daily, but we were unable to quantify levels of previous exposure. We found no difference in prevalence of sensitization between those who had ever had occupational exposure to latex gloves and those who never had. We did not inquire about non-occupational exposures to latex other than surgery, but there is no reason to suspect that they would differ between the two occupational/exposure groups. Health conditions and exposure were self-reported, but sensitization status was based on an objective test: measurement of latex-specific IgE. Serologic testing may be diagnostically less accurate than SPT. This limitation would apply to both exposed and non-exposed populations and would not account for the lack of difference in prevalence rates observed. However, the Pharmacia CAP has been demonstrated to have a sensitivity of 97% and a specificity of 83%, compared with clinical history, whereas SPT demonstrated a sensitivity of 97% and a specificity of 100%. [49] Another study found the sensitivity and specificity of the CAP to be 100% compared with clinical history and a positive SPT to define latex allergy. [50] A recently published multicenter study of latex sensitization showed that the CAP had a sensitivity of 76.3% and a specificity of 96.7% compared with SPT. [51] We chose to use serum testing because of the high sensitivity and specificity noted above, and because it is a widely used, [6,8,11,15,19–21,25,29,33] Food and Drug Administration–approved diagnostic method. Moreover, there is no FDA-approved, standardized SPT available in the United States, and anaphylaxis has been reported with the use of SPT to latex.

In summary , the large sample size, high participation rates, use of area air sampling to quantify airborne exposure to latex, inclusion of a virtually unexposed comparison group, and utilization of a single assay and protocol are strengths of this study. We found that occupational use of latex gloves was not a risk factor for sensitization. Glove use was associated with hand urticaria, hand dermatitis, and rhino-conjunctivitis.

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