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Latex allergy

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Latex allergy continues to be an important medical problem. In this review we re-examine the definition of latex allergy, the offending allergens, the factors that enhance sensitization, the threshold levels that sensitize and elicit reactions in sensitized individuals, current diagnostic techniques, avoidance measures, the barrier properties of nonlatex alternatives, and the roles of premedication and immunotherapy. Twenty years after its resurgence, latex allergy is a well-defined condition with established diagnostic criteria and rational treatment and prevention strategies. However, in spite of advances associated with molecular studies of latex allergens and improved understanding of immunotherapy, avoidance remains the only effective treatment. (J Allergy Clin Immunol 2000;105:1054-62.)

Key words: *Latex, rubber, immediate hypersensitivity, allergen, immunotherapy, skin testing*

Latex allergy continues to be a feature of allergy practice worldwide. In the 20 years since its resurgence,[1] latex allergy has become a well-defined condition with recognized risk groups, established diagnostic tests, and rational treatment and prevention strategies.[2-4] The circumstances that have generated numerous judicial and legislative efforts will not be addressed in this review, nor will broad preventative remedies be proposed; these have been discussed elsewhere.[2,5] Rather, we will focus on unanswered specific questions of clinical significance for the patient with latex allergy: (1) How do we define latex allergy? (2) What specific allergens cause latex allergy? How are these allergens absorbed? Are all patients sensitized by the same allergens? (3) Given constant exposure, are there specific factors that enhance a person's likelihood of being sensitized? (4) What are threshold levels for sensitization in a naive individual? For reaction in a sensitized individual? (5) What are the strengths and weaknesses of the currently available diagnostic techniques? (6) How do the barrier properties of nonlatex alternative gloves compare with those of latex gloves? (7) What specific avoidance measures have been shown to work? (8) What is the role of medication and immunotherapy in the treatment of latex allergy?

HOW DO WE DEFINE LATEX ALLERGY?

The diagnosis of latex allergy is based on the identification of individuals with latex-specific IgE *and* symptoms consistent with IgE-mediated reactions to latex-containing devices. *The diagnosis of latex allergy should not be made on the basis of either of these criteria alone.* Patients who have laboratory findings indicating the presence of latex-reactive IgE antibody without clinical reactivity may have cross-reactive antibodies of no clinical significance. Likewise, patients with frankly anaphylactoid symptoms but no evidence of latex-specific IgE on serologic or skin testing may be reacting to other environmental allergens, and the diagnosis of latex allergy should be entertained only after an exhaustive evaluation of other possibilities.[3,6]

How then should we interpret epidemiologic studies and surveys that base their conclusions on determinations of latex-specific IgE alone? In principle, these studies remain valuable because, although the presence of latex-specific IgE is not equivalent to the presence of latex allergy in an individual patient, *the seroprevalence of latex-specific IgE in a population is directly proportional to the risk of latex allergy in that population.* However, the performance characteristics of the test used to measure latex-specific IgE must also be considered. At this time no single available test or combination of tests or challenge procedures is sufficient for the accurate diagnosis of latex allergy in all cases. Thus comprehensive and well-designed challenge studies will be needed to define true positives, true negatives, and the limits of the testing regimens.

WHAT ARE THE SPECIFIC LATEX ALLERGENS?

Several latex allergens have been cloned and sequenced; others have been partially characterized. Molecular studies have largely supplanted previous attempts to identify latex allergens by immunoblot and inhibition

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studies. We are now able to identify, with reasonable certainty, most of the bands that appear on electrophoretic analysis of latex extracts (Fig 1). However, it is important to recognize that recombinant proteins derived from sequences cloned from *Hevea* plant material—even those that bind to IgE from latex-allergic individuals—may not represent naturally expressed proteins or proteins that are present in finished products. The identity of the cloned products, or even products derived directly from native plant material, with authentic allergens in latex products must be determined experimentally for each allergen.

Table I lists currently identified latex allergens. Most of these (Hev b 1, Hev b 3, Hev b 5, Hev b 6, Hev b 7, hevamine, and prenyltransferase) are fully characterized and sequenced; for others, only partial sequences are available. Current information suggests that Hev b 1[7] and Hev b 3 are major allergens for children with multiple congenital anomalies.[8] Hev b 3 has 47% homology to Hev b 1.[9] Hev b 2 and Hev b 4 are more important for health care workers with latex allergy.[10] Hev b 5 is recognized by IgE from a majority of both health care workers and latex-allergic children.[11]

Several reports have highlighted clinical and immunochemical cross-reactivity between latex and banana, chestnut, avocado, and other fruits.[12-20] Beezhold et al[21] found that, among 47 latex-allergic adults (mostly health care workers), 17 (36%) had clinical reactivity to at least one food, 53% were positive to prick testing with avocado, and a smaller number were reactive to potato, banana, tomato, chestnut, and kiwi. Cross-reactive allergens in banana appear at several molecular weights between 23 and 47 kd[22,23] and in avocado between 27 and 91 kd.[24] Papain[7] and profilin[25] have also been implicated as cross-reacting or common proteins in latex. It is notable that none of these investigations has focused on any one of the many identified discrete *Hevea* latex allergens but rather on pooled allergen extracts. In one study that attempted to identify individual cross-reacting latex proteins, the investigators found a broad range of latex peptide bands inhibited by banana extract[23]; in another, only the 14-kD latex band was inhibited by a crude avocado preparation.[24]

Structural homologies between *Hevea* proteins and food proteins have been noted in several studies. Hevein shares multiple domains with wheat germ agglutinin.[26] Patatin contains a region with strong homology to Hev b 7.[21] However, cross-reactivity between Hev b 7 and patatin is uncertain.[27] Hev b 5 is strongly homologous to the complementary DNA sequence in kiwi, pKIWI501.[11] Lysozymes are present in *Hevea* latex and are ubiquitous; homologies among these may elicit some of the cross-reactions seen.[28]

Latex antigen exposure can occur by cutaneous, percutaneous, mucosal, and parenteral routes, and the antigen can be transferred by direct contact and aerosol. Aerosol transmission of antigen has been well documented.[29-31] In another study the amounts of latex antigen measured in air samples from different areas of the Mayo Clinic correlated well with the frequency of glove use and glove changes in those areas.[32] Tomazic et al[33] have shown convincingly that the cornstarch powder with which gloves are dusted is a potent carrier of latex proteins.

Although severe systemic reactions have occurred after cutaneous and respiratory exposure,[34-37] it is clear that direct mucosal and parenteral exposure poses the greatest risk of anaphylaxis. Several reports highlight the hazards of patients with previously mild (and easily manageable) cutaneous or respiratory reactions who experience more severe reactions with mucosal or parenteral exposure.[38-43]

Latex antigens appear to be readily bioavailable across the skin and mucosal surfaces; anaphylactic reactions have occurred after all types of exposure. However, it is not clear that all latex antigens are equally absorbed by all routes. Yeang et al[8] have suggested that Hev b 1 and Hev b 3, which are particle-bound proteins that appear to be less soluble than other latex antigens, elicit reactions predominantly in patients with spina bifida, who are more likely to have repeated mucosal contact with latex gloves than are health care workers who, in general, have daily cutaneous exposure to gloves and respiratory contact to airborne allergens. The bioavailability of each of the identified latex allergens has yet to be studied.

WHAT ARE THE FACTORS THAT ENHANCE A PERSON'S LIKELIHOOD OF BEING SENSITIZED TO LATEX ALLERGENS?

The prevalence of latex allergy in the general population appears to have remained at less than 1%.[44-47] Distinct groups at risk for latex allergy include rubber workers, children with spina bifida and other congenital anomalies, and health care workers. The prevalence of latex allergy in patients with spina bifida is from 24% to 60%[21,48,49]; among health care workers the prevalence of latex allergy is reported to be between 5% and 15%.[50-56]

Several studies suggest that the most important factor in latex sensitization is the degree of exposure. In well-controlled studies 3 groups of investigators[57-60] found that the number of surgical procedures was the dominant factor in the development of latex allergy among children with spina bifida. Conversely, there appeared to be no increased risk of latex allergy associated with age or sex. Among health care workers exposure to latex allergens is the dominant factor in sensitization as well. Health care workers at the beginning of their training have the same likelihood of latex allergy as the general population. Apprentices starting careers in animal health, pastry making, dental hygiene or veterinary medicine, before any significant exposure to latex allergens, had a 0.7% prevalence of skin reactivity to latex.[61] In a cross-sectional study of dental students in Ontario, Tarlo et al[62] found no evidence of latex allergy among 20 first- or second-year students. However, among the third-year students the prevalence was 6% (2/36); for fourth-year students it was 10% (4/36). In a small study of patients with spina bifida less than 2 years old, latex avoidance decreased the seroconversion rate from 43% (3/7) to 0% (0/12).[63] Among 1351 health care workers who took part in another study,

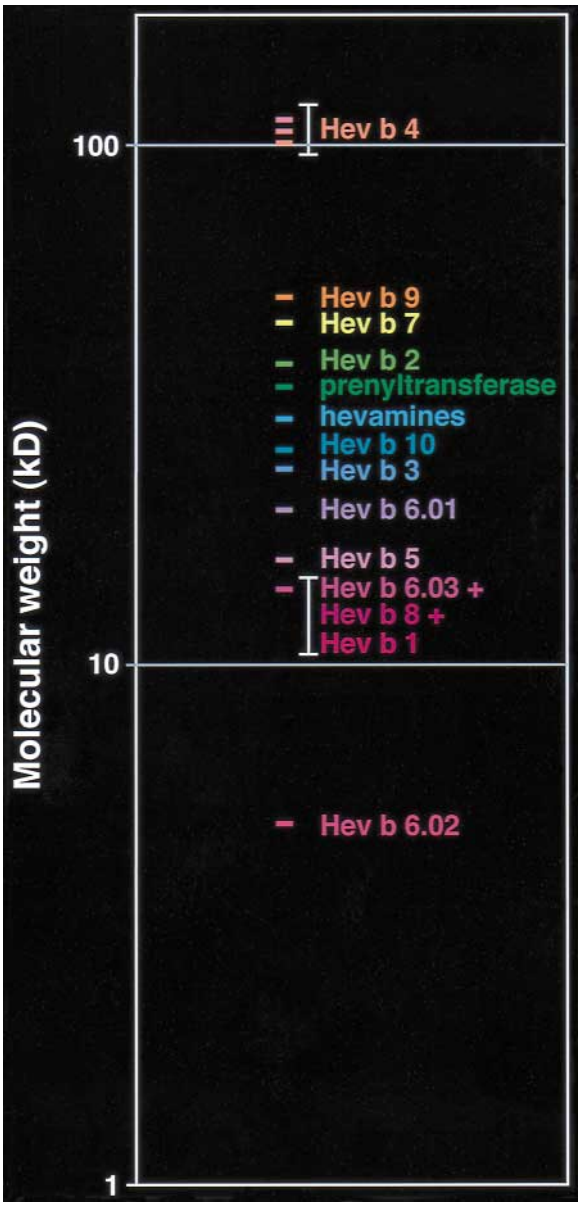

FIG 1. The molecular masses of identified *Hevea* latex proteins. In most cases these values are calculated from sequence information. The apparent molecular weights—based on the relative migrations of the proteins through separation media—are often different.

12.1% had positive skin test with the Bencard skin test reagent. When skin test reactivity rates were compared with latex surgical glove use per worker, hospital departments with greater surgical glove consumption rates had a higher prevalence of skin test reactivity.[64] Thus it seems that for these identified groups with frequent latex allergen exposure, a predictable minority will develop latex allergy unless latex avoidance is practiced. Exposure appears to be the most significant factor associated with risk of latex allergy. Other possible risk factors include atopy and the presence of a ventriculoperitoneal shunt.[65-68] Atopy was found to be a risk factor among health care workers in some studies; however, atopy was not an independent risk factor in a study of 59 children with spina bifida.[58] About 6% to 8% of these individuals will have serious generalized reactions with latex exposure.[69] The risk factors leading to anaphylaxis are not known.

THRESHOLD ALLERGEN EXPOSURE LEVELS

Threshold allergen exposure levels are *those levels that can be expected to elicit allergic reactions in exposed individuals.* Any discussion of such levels with respect to latex allergy must address several complicating factors.

TABLE I. *Hevea brasiliensis* proteins

Name	Trivial name/molecular mass	Reference
Hev b 1	Rubber elongation factor/C: 14590, A: 14600	102, 103, 104, GB: X56535
Hev b 2	β-1,3 Glucanase/C: 41305, A: 34-36000	10, 116, GB: U22147
Hev b 3	Small rubber particle protein/C: 22300, A: 24-27000	9, 108, EMBL: AJ223388
Hev b 4	Microhelix component/A: 100-115000	10
Hev b 5	Acidic latex protein/C: 17455, A:24-36000	11, 106, GB:U42640, U51631
Hev b 6.01	Preprotein/C: 21859, A: 20000	
Hev b 6.02	Mature hevein/C: 4719, A: 5000	95, 100, 110, GB: M36986/P02877
Hev b 6.03	C-domain: 14000	
Hev b 7	Patatin-like proteins/C: 42995, A: 46,000	111, 112, 113, GB: U80598
Hevamines (A/B)	C: 29550, A: 30000	101, SP: P23472
Prenyltransferase	A: 38000	98, 118, PIR: A34310
Hev b 8	Latex profilin/A: 14000, C: 14194	25, 114, 119, GB: Y15042
Hev b 9	Latex enolase/A: 51000	115, 120
Hev b 10	Manganese superoxide dismutase/A: 26000, C: 22915	115, 122, GB: AJ249148

Accession numbers for computerized databases: *GB,* GenBank; *SP,* Swiss Protein; *PIR,* NBRF PIR; *EMBL,* European Molecular Biology Laboratory. *C,* calculated; *A,* apparent.

First, latex is a complex mixture of potent allergens. Each of these allergens has different stability and bioavailability characteristics and is likely to be present in different levels in different environments, depending on the source of exposure. An aggregate threshold level may mask biologically significant specific allergen thresholds. No thresholds for specific latex allergens have been reported.

Second, unlike toxins, allergens elicit their adverse effects in 2 stages. In the first stage the immunologically naive individual is sensitized to the allergen. This is when the immune system develops the clonal responses necessary for subsequent immune reactivity. In the second stage repeated exposure to the allergen elicits the effector response. The threshold levels for these 2 stages are unlikely to be the same. Any discussion of threshold allergen exposure levels must address both the doses necessary to sensitize a naive individual and the doses necessary to elicit a response in a sensitized individual.

Third, the route of exposure may affect the minimum exposure level necessary to sensitize and elicit reactions. Sensitized individuals can react to latex allergens to which they have been exposed by different routes. It is likely that the sensitizing and eliciting doses of each allergen will vary by the route of exposure as well.

Only a few investigations have estimated threshold limits for IgE-mediated reactions to aeroallergens in the workplace (Table II). In examining these data, for which the denominator is the volume of filtered air, threshold allergen levels vary by a factor of nearly 10^7, from 0.25 ng/m^3 (fungal α-amylase) to 1.7 mg/m^3 (flour dust). This broad range may be due, in part, to intrinsic differences in the immunogenicity of the inhaled allergens. However, most of the differences are probably due to different measurement techniques. Predictably, investigators who determined allergen levels with immunoassays concluded that lower levels of the allergen were necessary to induce symptoms than did investigators who measured whole dust content.

The estimate of Baur et al[70] of sensitizing levels for latex allergens, measured by inhibition immunoassay, was 0.6 ng/m^3. This daunting figure is 100- to 1000-fold less than levels routinely measured in rooms where latex gloves are used,[71,72] suggesting that only thorough avoidance of aeroallergen exposure will prevent latex allergy in the workplace.

How likely is it that individuals are sensitized by aeroallergen exposure alone? Assuming a tidal volume of 500 mL, an ambient level of 1 ng/m^3 would result in exposure to only 18 ng in a normal 40-hour work week ($0.5\ L/breath \times 15\ breaths/min \times 60\ min/h \times 40\ h \times 10^{-3}\ m^3/L \times 1\ ng/m^3 = 18\ ng$). In contrast, latex gloves probably deposit far more allergen directly on the skin. In a survey of the allergen content of latex gloves, powdered examination gloves contained on average the equivalent of more than 600 μg of latex allergen per gram of glove.[73] Even if only a small fraction of this were bioavailable, the absorbed allergen dose would be significantly greater than the aeroallergen level near the threshold. However, as aeroallergen levels increase (up to 600 ng/m^3 in one study[71]), the relative contribution of the inhaled aeroallergen can become significant.

Threshold limits do not provide information on the incremental degree of sensitization that occurs with increasing exposure or, conversely, the reduction in sensitization and reaction rates associated with decreased exposure. Dose-response studies such as these are difficult to design and perform.

WHAT ARE THE STRENGTHS AND WEAKNESSES OF THE CURRENTLY AVAILABLE DIAGNOSTIC TECHNIQUES?

Although the physician can often make the diagnosis of latex allergy by taking a careful history of latex exposure and associated symptoms, confirmatory testing is often necessary. Patch tests[74] and flow cytometry[75] for the diagnosis of latex allergy remain investigational. The

TABLE II. Threshold aeroallergen levels

Allergen	Concentration (work area)	Reference
Fungal α-amylase	0.25 ng/m^3 (bakery)	125
Latex	0.6 ng/m^3 (different hospital rooms)	70, 127
Rat urinary aeroallergen	0.1-68 μg/m^3 (laboratory)	123
Western red cedar	0.2-0.4 mg/m^3 (sawmill)	126
Flour	1.7 mg/m^3 (bakery)	124

Modified from Baur X, Chen Z, Liebers V. Exposure-exposure relationships of occupational inhalative allergens. Clin Exp Allergy 1998;28:537-44.[70] Used with permission.

TABLE III. Commercial latex skin test reagents

Latex skin test reagent	Protein concentration	Reference
Bencard	No longer available from manufacturer	45, 64
Stallergènes	22 μg/mL	91
ALK-Abelló	1, 10, and 100 HEP units	91
Lofarma	12.5 μg/mL	58, 128, 129

HEP, Histamine equivalent potency.

TABLE IV. Latex provocational and challenge studies

Test	Reference
Modified glove provocational protocol	132
Two-stage latex provocation test	130
Glove use with laminar flow helmet and inhalation chamber	131
Hooded exposure chamber	121

Modified from Kurtz KM, Hamilton RG, Adkinson NFJ. Role and application of provocation in the diagnosis of occupational latex allergy. Ann Allergy Asthma Immunol 1999;83:634-9. Used with permission.

identification of latex-specific IgE may be made by 2 methods: skin testing and serum testing.

Worldwide, skin testing is commonly used to diagnose latex allergy. In Canada the Bencard skin test reagent was used in several published studies but is no longer available from the manufacturer. Stallergenes (France) and Lofarma (Italy) market commercially available ammoniated latex extracts. The Mayo Clinic reported a 5-year retrospective experience systemic reaction rate for latex skin testing of 152 to 200/10,000 skin tests.[76] In the United States a latex skin test reagent made from nonammoniated latex is currently under investigation.[77] As a result, US physicians predominantly use serologic tests to confirm the diagnosis of latex allergy.

One recent study compared 3 of the currently available tests for latex-specific IgE: CAP RAST FEIA (Pharmacia UpJohn), microplate AlaSTAT (Diagnostics Products), and HY-TEC-EIA (HYTEC). Intra-assay agreement was 96%. The AlaSTAT and CAP assays were equivalent in sensitivity and specificity. Each produced about 25% false-negative results. The HY-TEC produced 27% false-positive results.[78]

These 3 commercially available assays can be very useful in confirming latex allergy. However, none of the tests demonstrates complete diagnostic reliability; therefore caution should be exercised when patients have discordant latex IgE tests and histories. Patients with convincing histories of allergic reactions and a negative CAP or AlaSTAT test may be challenged with a confirmatory test (Table IV). Careful consideration of a patient with a negative history and positive HY-TEC result should also be given.[78] A negative challenge test in this case may allow a worker to return to the workplace.

HOW DO BARRIER PROPERTIES OF NONLATEX ALTERNATIVE GLOVES COMPARE WITH THOSE OF LATEX GLOVES?

For years, avoidance has been the only effective option for latex-allergic glove wearers. Health care workers and patients alike have been concerned that nonlatex gloves will compromise their health and safety. In static tests vinyl and latex gloves are comparable when taken from the manufacturer's box. However, dynamic testing has shown vinyl gloves to have significantly higher failure rates when they are compared directly with latex gloves under the same conditions. Double gloving offers little advantage during routine procedures.

Numerous authors have evaluated latex, vinyl, nitrile, and thermoplastic elastomer gloves for their ability to withstand tearing or rupture and to prevent the passage of fluid and microbial pathogens. Although stretch vinyl exhibits lower failure rates than standard vinyl does, the higher in-use leakage rates associated with vinyl gloves suggest decreased durability and potentially compromised barrier protection when this synthetic is used. The handling characteristics of nitrile examination gloves demonstrate that they could be an acceptable alternative to latex examination gloves. In general, nitrile gloves appear to be comparable to latex gloves in dynamic failure tests (Table V).

WHAT SPECIFIC AVOIDANCE MEASURES HAVE BEEN SHOWN TO WORK?

To date, avoidance of latex-containing products has been the only means to prevent serious allergic reactions. *Primary* latex exposure prevention for the nonsensitized is a more recent concept and involves minimizing or eliminating latex contact for individuals of known risk groups from the outset.[63] *Secondary* latex prevention for the latex-allergic subject involves screening to identify asymptomatic[79] individuals or known symptomatic patients.[6] Avoidance measures may include discussion of the Medi-Alert emblems and latex fruit allergy syndrome.[80]

For individuals with latex allergy, latex avoidance is a balance between disease prevention, lifestyle choices, and livelihood. A stepwise approach for latex-reactive patients, based on the severity of disease, may help these individuals achieve the balance that is best for them. Some authors have written of a latex-safe environment,

TABLE V. Barrier studies

Author	Material	Failure rate (%)	Conditions	Test
Newsom et al[135]	Vinyl Latex	10	Surgery	European Standard Test for Punctures
Rego et al[136]	Vinyl Latex Nitrile	12-61 0-4 1-3	Simulated use	ASTM D5151
Korniewicz et al[137]	Vinyl Latex	53 3	Full use	FDA watertight leak test
Dodds et al[138]	Surgical	12.5	Hand surgery	Bacterial contamination before and after
Korniewiscz et al[139]	Single/double latex and vinyl	53/19.7 vinyl, 4.1/3.8 latex	Single/double after clinical protocol to mimic stress	Dye and water leaks
Hamann et al[134]	Latex and thermoplastic elastomer	80-100 (latex), 30 (thermoplastic)	180 min exposure at 37°C with shaking	Bacteriophage ϕX174 plaque assay
Olsen et al[140]	Latex and vinyl	24 vinyl, 2 latex	Patient care	(1) Before and after quantitative hand culture with modified glove juice method, (2) quantitative external glove culture after patient contact, (3) ASTM watertight test

ASTM, American Society for Testing and Materials; *FDA,* US Food and Drug Administration.

suggesting that complete latex avoidance is impossible and, for the most part, unnecessary.[81,82] Substantial reductions in latex allergen exposure may be achieved by eliminating powdered latex gloves in the patient's immediate environment; this is a sensible minimal step for all individuals with latex allergy. Patients with immediate reactions to latex that result in serious morbidity or life-threatening anaphylaxis require the most stringent avoidance measures, including the complete avoidance of unnecessary exposure to latex-containing medical[83] and consumer devices. When exposure is unavoidable, choosing products that have a reduced latex content[84-86] may reduce the morbidity associated with exposure.

WHAT IS THE ROLE OF MEDICATION AND IMMUNOTHERAPY IN THE TREATMENT OF LATEX ALLERGY?

The role of premedication in the management of patients who are allergic to latex who require surgery is questionable. Case reports differ as to whether preoperative treatment with antihistamines and glucocorticosteroids prevents or modifies the severity of the allergic reaction.[87-89] No controlled studies have been performed.

Because avoidance can be difficult and premedication is of doubtful value, immunotherapy would appear to be an important option. Latex allergy is an IgE-mediated disease, and immunotherapy with well-characterized and potent mixtures of relevant allergens should be curative. Case reports of latex-specific immunotherapy have now appeared in the literature. Toci et al[90] reported oral latex desensitization with noncompounded ammoniated latex in 3 health care workers who had severe clinical latex allergy. Beginning at a 1:10,000 dilution of the lowest positive skin test concentration of latex, doubling doses were administered at 15-minute intervals until a final dose of 2 mg was reached. Thereafter, subjects received 1 mg of latex orally 2 to 3 times daily. After desensitization, latex skin test size diminished significantly in each of the 3 patients. All were able to return without undue symptoms to their jobs, which involved heavy latex exposure.

Pereira et al[91] treated an extremely reactive radiology technician with ammoniated latex. Latex sensitization was demonstrated by radioallergosorbent and positive skin prick tests to 2 different latex skin test reagents. Increasing weekly doses of latex vaccine (ALK-Abelló) were given by subcutaneous injection, beginning with 0.003 μg. At the patient's request the schedule was accelerated (by using a 1-μ/mL vaccine concentration) with injections 3 hours apart. A systemic reaction occurred at a dose of 0.5 μg. Ultimately, a weekly maintenance dose of 0.4 μg protein was achieved. The mean diameter of latex-specific skin tests declined steadily during the course of immunotherapy. Clinical symptoms improved steadily and the individual returned to work in an environment with significant latex exposure. Specific controlled provocation tests with use of latex gloves conducted in an airtight environment confirmed her lack of symptoms for up to 6 hours after exposure.

Alternative approaches to immunotherapy include allergen-specific immunotherapy, epitope-specific immunotherapy, and DNA vaccine immunotherapy. The availability of cloned and purified latex allergens (Table I) raises the possibility of specific immunodiagnosis and specific immunotherapy.[7,9] The T-cell and B-cell epitopes of several latex allergens have been identified in mice and humans.[92-95] A DNA vaccine for Hev b 5 elicited a specific antibody response in BALB/c mice.[96,97]

At this time, premedication and allergen immunotherapy remain investigational in the treatment of latex allergy, and avoidance remains the mainstay of therapy and prevention.

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