Allergology International (1999) 48: 31–36

Review Article

Summary of appropriate measures to prevent natural rubber latex allergy

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Abstract

This paper presents a short overview of the diagnostics and background of type I allergy to natural rubber latex proteins and makes recommendations for preventing corresponding allergic diseases in the future. These recommendations and prevention strategies are based on the current knowledge of latex allergy presented in the literature and are addressed to legislative bodies; manufacturers; directors of hospitals; those working at nursing facilities and physicians' and dentists' practices; as well as to other health service employees. Primary prevention is the focus but advice is also given on secondary prevention. The major preventive aim is the elimination of causative protein allergens in all latex devices and thus, the minimization of latex-related health problems.

Key words: allergological diagnostics, allergy, natural rubber latex, preventive measures.

Introduction

In recent years, the widespread use of medical gloves and other medical devices made of or containing latex, (i.e. natural rubber latex) has induced a strong increase in immediate-type (type I) hypersensitivity diseases, especially among healthcare workers. The prevalence of latex sensitization in this working group is in the range of 5–17%.[1–6]

Symptoms of latex allergy range from an itchy skin rash, urticaria, angiedema, rhinoconjunctivitis and asthma to anaphylactic shock. Fatal cases have also been reported[6–8] (Table 1).

To date, diagnostic criteria have often been quite different and have not enabled a comparison of the various groups of subjects and prevention measures. Also, job fitness evaluation criteria are often not homogeneous.

Although recent studies have indicated that latex sensitization is strongly associated with the intensity of exposure to latex allergens (including those that are airborne), necessary preventive measures have often not been taken.[9–13] Remarkably few healthcare employees are aware that hypersensitivity to latex is a serious health condition, while hospital and other health care managers also need to be informed of this problem. In order to standardize diagnostics and intensify primary and secondary preventive measures, we have summarized the current information and experiences on dealing with products containing latex and with latex-related allergies. The ultimate goal is a total or almost total elimination of allergens in latex medical devices.

The information is directed toward legislative bodies, manufacturers, hospital managers, those working at nursing facilities and physicians' practices, as well as other health service employees. In order to ensure safety in the use of latex articles, in particular the various medical devices, internationally accepted regulatory requirements for biocompatibility are urgently needed. Further, harmful substances in glove material should be at the lowest achievable level and should be listed in the user instructions. Finally, training programs must be focused not only on users, but also on purchasers who currently favor latex products for economic reasons.

The following recommendations take into consideration previous suggestions by different working groups (i.e. the German interdisciplinary group 'Natural rubber

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Received 14 April 1998. Accepted for publication 14 August 1998.

Table 1. Allergic and irritant glove-related diseases

Disease	Pathogenesis	Etiologic Agents
Allergic contact dermatitis	Cell-mediated allergy	Accelerators Vulcanizers Antioxidants Organic pigments
Irritant contact dermatitis	Mechanical effect Occlusion Associated use of disinfectants	Lubricant powder crystals Alkaline soaps Bacterial toxins Ethylene oxide
Irritant or pseudo-allergic urticaria	Non-immunological mechanism	Lubricant powder Heat Pressure
Contact urticaria, protein contact dermatitis	IgE-mediated allergy	Latex proteins
Rhinitis, asthma	IgE-mediated allergy	Latex proteins
Angiedema	IgE-mediated allergy	Latex proteins
Anaphylactic shock	IgE-mediated allergy	Latex proteins

latex allergens'[14] and the National Institute of Occupational Safety and Health (NIOSH)[15]) as well as our clinical and analytical experiences.

Regulations and background

In order to warn people who are allergic to latex, the Food and Drug Administration of America (FDA) has published a rule, effective from 30 September 1998, which requires certain labeling statements for all medical devices that contain or have packaging that contains natural rubber latex.[16] In Germany, natural rubber latex has been classified as a sensitizer of the skin and respiratory tract.[17] It has been stipulated that employers must provide low allergen, powder-free gloves to protect workers from exposure to allergy-causing latex proteins. However, there is no rule which requires that medical devices containing natural rubber latex be labeled as such. As far as we know, this is also true for other parts of Europe.

In an effort to reduce the residual chemical additives in latex products, which are known to be able to cause type IV allergy in exposed people, the label 'hypoallergenic' was in the past applied to distinguish such products containing reduced levels of chemical additives from other products in the market. However, such latex devices, although labeled hypoallergenic, may contain protein allergens and can cause type I-allergic reactions in individuals sensitized to latex. The term 'hypoallergenic' has been frequently misinterpreted as being related to protein allergy. Consequently, in the FDA final rule the use of the claim 'hypoallergenic' on the labels of latex-containing medical devices is prohibited.

Although all of the documents and regulations, published by bodies such as NIOSH[18] strongly recommend the use of latex gloves with reduced protein content in order to minimize the exposure to latex proteins and thus to reduce the risk of latex allergy, as yet no maximum allowable level has been set for proteins or protein allergens in latex medical devices. The lack of standardized methods established to determine water-soluble proteins and protein allergens in latex devices as well as the lack of information about the threshold limit values causing the allergic reactions has been thought to be the major reason. According to our recent studies, more than 95% of our examined cases had no allergic reactions when wearing gloves with a protein allergen level of < 2 μg/g.[19]

Currently, more than 70% of all latex gloves used are powdered, mostly with cornstarch. Experimental and clinical data have demonstrated that latex proteins (allergens) can bind to cornstarch and that aerosolized powder on latex gloves is allergenic and can cause severe respiratory allergic reactions.[9,13,20–22] Many studies have indicated that powder-rich latex gloves often have much higher protein levels (Fig. 1).[23,24] Such studies have also shown that airborne glove powder represents a threat to individuals allergic to latex and that it is an important agent for sensitizing individuals who were previously nonallergic.

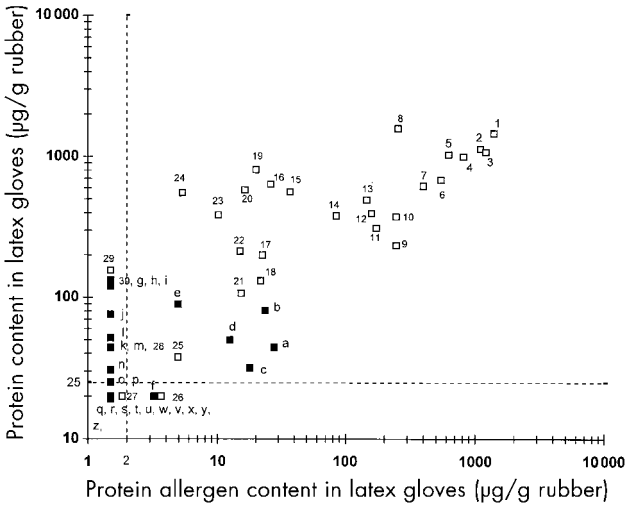

Fig. 1 Scatterplot of protein and protein allergen levels in 26 brands of powder-free latex gloves (■, lower case letters) and in 30 brands of powdered latex gloves (□, Arabic numerals). The methodology for measuring the levels of extractable proteins is based on a modified Lowry protein assay as recommended by the American Society for Testing and Materials (D 5712–95)[26] and the European Committee for Standardization (pr EN 455–3).[27] The levels of extractable latex allergens were analyzed by a competitive enzyme-linked immunosorbent assay with CAP-system (Pharmacia, Uppsala, Sweden). The detection limits for protein content and protein allergens were 25 µg/g rubber and 2 µg/g rubber, respectively.

DIAGNOSTICS

Latex allergy should be suspected in anyone with cutaneous and conjunctival nasal and/or bronchial symptoms during or after exposure to latex articles.

All healthcare workers and patients with the following traits in their history should undergo allergological diagnosis with regard to natural rubber latex allergy: (i) a history of incompatibility reactions to natural rubber latex products; (ii) intensive occupational contact with allergen-rich natural rubber latex products; (iii) frequent medical or surgical interventions; and (iv) a history of incompatibility reactions during surgical or medical treatment.

Evaluation of medical and occupational history

Factors predisposing individuals to latex allergy (e.g. atopy, food allergies, allergic contact dermatitis and other skin diseases) should be explored. Exposure to latex should also be evaluated by investigating the individual's type of job and department, the duration of employment, the glove type, and the average daily use (hours per day) and consumption of latex gloves.

Registration of latex-induced allergic symptoms should be undertaken, particularly regarding work-related skin and respiratory reactions. The date of onset should be recorded.

Allergy tests

Allergy tests are recommended as they are necessary for etiologic diagnosis. They include:

1. Specific IgE for latex: the use of a well standardized sensitive and specific test is necessary (e.g. CAP-System).
2. Prick tests with a standardized latex extract.
3. Patch tests in order to detect type IV sensitization to rubber additives.

Other tests useful for evaluating the relationship between occupational exposure to latex and symptoms include:

1. Wearing test in case of urticaria or protein contact dermatitis when the allergological tests are negative. It should be noted, however, that this test does not facilitate the identification of etiologic agents.
2. Peak expiratory flow monitoring in case of asthma symptoms.
3. Occupational exposure test according to Jäger et al.[25] or specific bronchial challenges in case of respiratory symptoms. These should be undertaken if other tests are negative and relevant diagnostic doubts and/or medical-legal reasons exist.

Differential diagnosis

Patch tests with rubber additives, powder additives and the most common antigens (e.g. European standard series) are necessary if an individual's history is suggestive of glove-induced contact eczema (Type IV allergy).

A positive patch test is the most important criterion for the diagnosis of allergic contact dermatitis and is needed to differentiate it from irritant contact dermatitis.

It should be noted that subjects demonstrating type IV allergy may have concomitant type I allergy.

RECOMMENDATIONS

Recommendations to legislative bodies and manufacturers of rubber products

For all medical products containing natural rubber latex, the label 'caution: contains natural rubber latex which may cause allergic reactions' should be regarded as obligatory. The term 'hypoallergenic' is not clearly defined

and thus should be deleted because it may mislead consumers by suggesting safety.

Extractable protein and allergen content as well as applied methods of extraction and determination should be included on packaging. For comparability, details of applied procedures should also be made available on request. Further, manufacturers should cease production of allergen-rich natural rubber latex products.

Recommendations on the use of natural rubber latex products in hospitals, health facilities, and physicians' and dentists' practices

A number of recommendations on the use of natural rubber latex products in hospitals, health facilities, and physicians' and dentists' practices have been made. First, non-latex gloves of high quality (accepted quality level-value ≤ 1.5) should be provided if contact with infectious material is likely. Second, in order to avoid allergic reactions in patients and employees who have already been sensitized to latex, as well as to prevent new sensitizations (in the above-mentioned risk groups), gloves poor in latex allergens (< 2 μg/g) or those which are allergen-free should be used in health facilities.

Third, conditions should be created in surgical facilities and hospitals which enable patients allergic to natural rubber latex to be examined and treated without risk. This especially applies to emergency units and operating theatres. For all patients with spina bifida, operations should be performed in an environment free of natural rubber latex allergens.

Fourth, training programs should be initiated for concerned personnel in order to provide information on the risk factors of latex gloves. Such programs could include information on possible glove-induced diseases, preventive measures, chosing gloves which are suitable for the job to be undertaken, and proper-use procedures. Fifth, high risk workers such as surgeons and nurses in operating theatres should undergo regular medical surveillance. Finally, medical practices, hospitals and health service institutions should elaborate upon recommendations stating the type of gloves to be used for each activity performed by staff.

Prevention measures

In order to protect medical staff from allergies to natural rubber latex, the following primary and secondary preventive measures are necessary.

Primary prevention

The aim of primary prevention is to prevent intensive skin contact and airway exposure to the latex allergens which to date exist in most health service areas. Allergen-rich, powdered natural rubber latex gloves should not be used, given that allergologically unobjectionable alternatives are available. Further, employees with known atopic disposition should avoid contact with natural rubber latex-containing products. Non-powdered gloves with reduced protein content are an alternative. This also applies to patients with hand eczema.

Secondary prevention for employees

In order to protect endangered workers and enable already sensitized ones to continue with their occupational activities, the following measures in workplaces are indispensable:

1. Allergen-free products, particularly gloves, must be made available to individuals suffering from allergies to natural rubber latex or who are at a high risk.
2. Due to the risk of inhalable allergens, powdered natural rubber latex products should not be used in the workplace by people allergic to natural rubber latex.
3. Appropriate work practices should be used in order to reduce reactions to latex. For example, when wearing latex gloves, individuals should not use oil-based hand creams or lotions unless they have been shown to reduce latex-related problems. Also, after removing latex gloves, hands should be washed with a mild soap and dried thoroughly. Good housekeeping practices should be used to remove latex-containing dust from the workplace (as in recommendation 3 for employers).
4. Employees should take advantage of all training courses in the use of latex products provided by their employer.
5. If an individual develops acute symptoms of latex allergy, he/she should immediately ensure that no further contact with latex gloves or other latex-containing products is made until a physician experienced in diagnosing latex allergy has been consulted.
6. For those individuals who suffer from latex allergies, a number of additional precautions could be helpful. These include avoiding areas where the powder of latex gloves worn by other workers might be inhaled; informing employers and health care providers of the latex allergy; and wearing a medical alert bracelet.
7. Physicians' instructions should be carefully followed when dealing with allergic reactions to latex.

Additional precautions for diagnostics, therapy and nursing of patients

During the treatment of patients allergic to natural rubber latex, only latex-free products should be used for diagnostics, therapy and nursing.

In order to avoid the sensitization to natural rubber latex of high-risk groups (e.g. patients with spina bifida or urogenital anomalies), diagnostics, therapy and nursing should be performed with devices free of natural rubber latex. These groups should avoid air-contaminated rooms.

Allergologists, dermatologists, general practitioners, surgeons, pediatricians, urologists, anesthetists, dentists, gynecologists, obstetricians and radiologists should routinely question their patients about allergies to natural rubber latex prior to examinations or interventions. Patients with an increased risk are health service staff, employees in the rubber processing industry, patients who have undergone several surgical interventions, spina bifida patients, individuals with urogenital anomalies and previous atopic disorders, as well as people frequently in contact with gloves made of natural rubber latex. High risk groups or individuals whose case history indicates allergy to natural rubber latex should be consulted by an allergologist, especially prior to surgical interventions.

Patients who have an immediate-type allergy to natural rubber latex should be provided with an allergy certification card containing the relevant information or, more preferably, with an emergency bracelet (e.g. 'Medic-Alert' bracelet). Sensitized patients hitherto without allergic reactions should undergo the same procedure, although investigation results on the course of such sensitizations do not yet exist.

Latex-allergic patients should be informed that allergy to natural rubber latex may be associated with a cross-allergy to food, particularly to avocado, banana, kiwifruit and/or sweet chestnut.

Allergen and protein contents in latex gloves

The level of extractable protein and allergen contents varies significantly in different devices made out of natural rubber latex. Because of the variation of production procedures, the extractable protein and allergen contents of the same glove brand can be different on different manufacturing dates. We have analyzed a great number of commercially available latex articles for their protein and allergen contents. The results listed in Fig. 1 indicate clearly that most powder-free gloves had remarkably low or even undetectable levels of extractable protein and protein allergens. In contrast, the majority of the powdered latex gloves, with few exceptions, showed a much higher protein and protein allergen content. These results also indicate that latex gloves of different manufacturers may vary considerably regarding the protein/allergen content. The provision of product information regarding the protein/allergen content of latex gloves may help hospital and other healthcare managers in their purchasing decisions.

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