

(a) *Results.* The comparative results, both medium- and long-term, are unquestionably better with the association of symptomatic and aetiopathogenic therapy than with symptomatic therapy alone. In the last few years, the results have been uniformly good in double-blind studies using adequately characterised and standardised antigens and with objective assessments (symptoms/medication and specific bronchial challenge tests).

(b) *Duration of immunotherapy.* According to the literature, and to more or less arbitrary criteria, immunotherapy should be maintained up to two to three years after the last asthmatic episode has occurred. In our own experience on long-term results (20 years), specific immunotherapy should be maintained until the respiratory symptoms have disappeared, or at least the bronchial ones (on the average, for 5.2 years after the last episode).

(c) *Age at which immunotherapy should be started.* It is usually recommended to initiate immunotherapy after the age of five years, because the systemic reactions tend to be more frequent and more difficult to control in the early years of life. However, this can be obviated to a great extent if the adequate precautions are taken. This attitude, however, should be revised. Our own experience, and also the opinion of the European Academy of Allergy and Clinical Immunology (expressed in its Position Paper in 1993) recommend starting immunotherapy at early ages, meaning already in one- to two-year-olds. This attitude is being endorsed by the results of the PTA project (Preventive Treatment of Allergy). Early immunotherapy would prevent the changes induced by iterative inflammation and repair and their consequences of "airway remodeling" and chronic asthma with bronchial hyperreactivity. Furthermore, specific immunotherapy reduces the acquisition of further sensitizations by one-half, a positive consequence not achieved in those patients not receiving immunotherapy.

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## Prevalence of latex allergy in the paediatric population

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Latex allergy might be termed an "European" disease. The first published case, described by Stern in Germany, dates back to 1927. It is in 1979, when Nutter<sup>1</sup> published one case of urticaria, that the "modern age" of this complaint can be said to have begun, and a highly variegated clinical symptomatology in association to latex has been reported since then: urticaria, angioedema, conjunctivitis, rhinitis, bronchospasm and even anaphylactic shock in the course of surgical interventions. In the U.S.A. the FDA has recorded, between 1988 and 1992, over one thousand systemic reactions induced by latex, with fatal results in fifteen of them<sup>2</sup>.

Latex is a substance obtained from the tree *Hevea brasiliensis*; after its collection, and after a number of curing processes, ammoniac, vulcanisation-accelerating additives and antioxidants are added to it, and all these may constitute the allergenic load it contains. The final product may have low (0.15 - 0.25% w/w) or high (ca. 1.6% w/w) ammoniac contents.

The protein content in latex may vary according to the production methods, and there may even be inter-batch variations. More than fifteen

distinct allergenic bands have been described, with molecular weights ranging between 2 and 100 kDa. In a joint U.S.-Finnish study, three antigenic bands were identified which predominate according to the population studied<sup>3</sup>. Among children with spina bifida, congenital urogenital malformations or a previous personal history of multiple surgical interventions the 27-kDa band predominates. This antigen has not been detected with sera from adults, suggesting that mucosal contact with the antigen is required for sensitization to occur. Among adults with skin symptoms the antigen corresponding to the 20-kDa-protein band (77% of the sera studied) has been identified as the one responsible for sensitization. A third antigen, with a molecular weight in the 14 kDa band, is detected in children with spina bifida; this suggests that the identified 27 kDa antigen may represent a dimeric form of the 14 kDa one; this hypothesis, however, has not been fully substantiated to this date.

### CLINICAL FEATURES

In the adult, sensitization to latex is fundamentally an occupational one. This sensitization may occur at ocular or nasal level, or by contact with the skin. Latex allergy represents a typical example of the contact urticaria syndrome described by Maibach and Johnson<sup>4</sup>, which is classed into four stages: (I) urticaria in the area of contact; (II) generalised urticaria and angioedema; (III) urticaria with asthma, rhinoconjunctivitis and oropharyngeal and gastrointestinal symptoms, and (IV) urticaria with anaphylactic reaction.

In the series reported by Turjanmaa et al<sup>5</sup>, comprising 42 adults with latex allergy, 2% of the cases had no symptoms in the contact area, and 10% evidenced eczematous exacerbations and pruritus. When these patients are stratified according to the Maibach and Johnson stages, 40% would be in stage I, 17% in stage II, 21% in stage III and 10% in stage IV.

In the paediatric population, latex allergy is influenced by the route of contact, the duration of the exposure and the early exposure to the antigen, which in children with myelomeningocele is associated to the immaturity of the mucosal defence mechanism.

Kwittken et al<sup>6</sup>, in their study, conclude that a direct correlation exists between latex sensitization and age at the time of the first surgical intervention: in 33 of the 35 children studied, the first surgical intervention had occurred at ages below one year. These authors class the severity of the clinical manifestations into four degrees; 31.4% of the reactions were considered to be severe (grades 3 - 4), and in 17 cases the symptoms occurred intraoperatorily.

### FREQUENCY

The actual incidence of latex allergy among the general population is unknown, but it would appear to be less than 1%. Turjanmaa et al<sup>5</sup> observed a frequency of 0.125% (1/800) among patients undergoing general surgery.

The "at risk" population is considered to comprise health care personnel (particularly the operating theatre personnel), workers in the rubber industry, and children with myelomeningocele or urogenital malformations.

Among health care personnel, Turjanmaa<sup>7</sup> found that 6.2% of the operating theatre personnel and 1.5% of the laboratory personnel evidenced positive tests to latex, while surgeons evidenced a 7.4% sensitization ratio.

Vanderpla et al<sup>8</sup>, in a population of 273 health care workers, found 13 (4.7%) with positive prick tests to latex; the allergological survey showed that all 13 had contact urticaria, 12 had rhinoconjunctivitis, and asthmatic symptoms were associated in 5, with positive bronchial challenge tests with latex in all these five.

In the study by Moneret-Vautrin et al<sup>9</sup>, 596 patients were stratified into four groups according to the presence or absence of atopic antecedents and to the presence or absence of latex exposure.

In the group of non-atopics, non-exposed, these authors found 0.37% latex-sensitized individuals; among the non-atopics who were exposed to latex, the sensitization ratio increased to 6.8%. When the two atopic groups were examined, the incidence of sensitization was 9.5% among those who did not report contact with the substance, but among those atopics who had direct contact with latex the number of positive skin prick tests was 36.4%. According to these data, the presence of

atopy increases the risk of sensitization among those not directly exposed by a factor of 25, and while both frequent contact with latex and the presence of atopy are risk factors, they seem to act synergically.

Tosi et al<sup>10</sup> found a positive RAST to latex in 38% of the children with spina bifida. In a similar population studied by Michael et al<sup>11</sup>, 49% (80/165) had a positive RAST; when the detection of sensitization was based on skin tests, 46% of the subjects (37/81) had a positive skin prick test.

## DIAGNOSTIC METHODS

The first step in the diagnostic work-up is a detailed anamnesis with particular emphasis on the apparition of urticaria or contact eczema, rhinitis, angioedema or asthma in relation with the use of balloons, gloves, or other latex-containing objects or medical or surgical material.

Although the allergens in latex have not yet been fully characterised, those available for skin prick testing are highly reliable. Moneret-Vautrin and Laxenaire<sup>12</sup> using a natural latex extract in tests on 907 health workers, obtained 100% sensitivity (18 positive tests in 18 patients with suggestive clinical features); the specificity of the test was 99%.

The assessment of specific IgE by RAST had 89% sensitivity in the study of Tosi et al<sup>10</sup>; also Michael et al<sup>11</sup> found good concordance between the skin prick tests and the CAP assessment.

Slater et al<sup>13</sup>, in a series of 93 patients with spina bifida, found a negative predictive value of 98% for RAST: only one of the 58 RAST-negative children in their series reported evident clinical manifestations upon contact with latex.

## CROSS REACTIVITY

From the '90s onward, the clinical evidence that latex-sensitized individuals also evidenced hypersensitivity reactions upon ingesting banana, avocado, chestnuts or kiwi began accumulating.

Makinenen-Kiljunen et al<sup>14</sup> found that 83% of their latex-allergic patients also had positive RAST to banana. Using immunoblotting, they identified eight allergens in the 14 to 75 kDa range in latex

which were inhibited by a banana antigen. They also identified 13 allergen bands in banana, with molecular weights ranging between 14 and 150 kDa, ten of which were inhibited by latex.

Blanco et al<sup>15</sup>, in 13 patients in a series of 25 cases of latex allergy, detected 42 episodes of fruit hypersensitivity (avocado, chestnut, banana, kiwi and papaya); 23 of these episodes were anaphylactic reactions. Using RAST inhibition they demonstrated the existence of cross reactivity between latex, avocado, chestnut and banana.

Lavaud et al<sup>16</sup> published in 1995 a study demonstrating the existence of a 30 kDa antigenic band which was shared by latex, avocado and banana.

## ATOPY AND LATEX ALLERGY

Most reports and studies on latex allergy document a predominance of atopics among the patients evidencing this particular form of hypersensitivity.

Liebke et al<sup>17</sup>, in 1996, published a study on latex sensitization in atopic and non-atopic children (which caused us to review our own experience on this subject). Using quantitation of the specific serum IgE by the CAP method, these authors found 1/303 (0.3%) latex-sensitized individuals among children with no personal antecedents of atopy; among the atopic children group, however, the incidence was 20.8% (60/306). A prick test with latex could only be performed in 48 children; 16 of them had positive tests when latex with a high ammoniac concentration was used; the use of latex with a low ammoniac concentration yielded positive prick tests in 17 of the 48 children. Twelve of the 48 children had a positive response in the bronchial challenge test with latex; 75% of these children had clinical manifestations of atopic dermatitis. The remaining 36 children, who were sensitized according to the prick tests, had never evidenced any symptoms in relation with latex, but they did have the antecedent of having undergone at least one surgical intervention.

According to these investigators, the most important risk factor for the development of latex sensitization would be the presence of atopy among the patient's antecedents, mainly if the actual atopic condition is atopic dermatitis. Fur-

ther factors considered to represent a risk situation would be a high specific IgE level, a positive history regarding latex exposure, the number of surgical interventions and the patients' age at the time of the first such intervention.

Reinheimer and Ownby<sup>18</sup> assessed the specific IgE levels in sera from 200 atopics (70.8% of them below 18 years in age), and found a 12% prevalence (24/200) of latex sensitization. All these sera evidenced a positive RAST inhibition test.

Among a population of 146 adult atopics, Hadjiliadis et al<sup>19</sup>, using skin prick tests, found a 7% incidence (10/146) of latex sensitization, while Fuchs<sup>20</sup>, in an allergological survey with skin prick tests on 1.288 individuals, observed latex sensitization in 54 subjects (4.2% incidence).

## PREVENTION

The American Academy of Allergy and Immunology has put forward a number of recommendations aimed at preventing latex hypersensitivity reactions; these recommendations include the following: anamnesis recording prior to any medical, surgical or dental procedures implying exposure to latex, avoiding latex in all individuals at risk, and ensuring that all health care institutions are able to care for latex-sensitized patients and have available latex-free material for all (sensitized) health care personnel.

Materials containing synthetic rubber (polychloroprene or nitrilocarboxylated rubber) or derived from other rubber-producing species, such as *Ficus elastica* or *Parthenium argentatum* have been recommended as substitutes for latex-containing materials.

Finally, in all those patients who are sensitized and/or have evidenced symptoms on previous occasions, premedication should be used prior to any risk-associated medical or surgical intervention.

## OWN SERIES

We have carried out a prospective study for the assessment of latex hypersensitivity in a random population attending our outpatient clinic for an allergological survey in order to establish or rule out an allergic mechanism in their condition.

Regardless of the actual complaint constituting the grounds for consultation and of the responsible aetiology, all these patients were included in a protocol for the detection of latex sensitization. The subjects were allocated to two groups: In Group A (185 children), skin prick tests were carried out with two different commercially available latex extracts, both of them with a low ammoniac content; 33 children who according to the allergological survey did not have any clinical manifestations suggesting an allergic process or clinical symptoms in relation to contact with latex-containing materials such as balloons, and who had not undergone surgical interventions, were included as a control group. In Group B (97 children of similar characteristics who had not been included in Group A) the serum levels of specific latex IgE were studied by CAP. Ten children were included as controls for the latter group, according to the same criteria as for the Group A controls.

As a complement to this study, 12 children were selected (and could be termed Group C) who had been referred to our Service specifically for investigation of a suspected latex hypersensitivity either because of suggestive clinical symptoms or because of being considered to constitute an "at risk" population. This group comprised two children who had evidenced reactions in relation with latex-containing material and ten children with myelomeningocele (one of whom had received a renal transplantation) and with a significant number of surgical interventions (between 5 and 11). In this specific group, the diagnosis of latex hypersensitivity was investigated both by skin prick tests and by specific IgE quantitation (CAP).

## RESULTS

According to universally accepted criteria which consider the presence of atopy to be the main risk factor, all the children in Groups A and B were subdivided, after completion of the allergological survey, according to the presence or absence of atopy. Considering this premise, the prevalence of latex hypersensitivity among our study population was as follows:

When the diagnosis was established exclusively through the skin prick tests, the study group com-

prised 118 children (63.7%) who were considered to be atopic at the completion of the studies, and 67 (36.3%) in whom no IgE-related mechanism was identified.

The prick test with latex extract was positive in two cases (2/185, or 1.08%); both these children were atopic: one of them had severe atopic dermatitis and was polysensitized to mites, egg and cereals, and the other one was a 10-year-old girl who consulted because of urticaria/angioedema and who was sensitized to fruit (peach, apple), nuts and fish.

When the study was completed *a posteriori*, the specific IgE assessment (CAP) was positive in both children; the CAP to avocado, banana, chestnut and kiwi was negative in the boy with atopic dermatitis, while in the girl with urticaria/angioedema it was positive for chestnut and banana (with no suggestive clinical manifestations in relation to these foodstuffs). Upon directed reinterrogation regarding a possible cause-effect relationship, both children reported having urticarial manifestations when manipulating balloons; this phenomenon had not been recorded in the anamneses, nor had it come to the attention of the parents until they were made aware of the problem.

In the group of 97 children in whom only a CAP assessment of latex-specific serum IgE had been performed, atopy was present in 65% of the cases (63/97); the immunologic study was negative in the remaining 35% (34/97 children).

Specific latex IgE was detected in seven children in this group (7.2% incidence). Six of these seven children were in the atopic subpopulation (6/63), increasing the incidence in this subgroup to 9.5%. Only in one non-atopic child (a case of vasomotor rhinitis) did we detect specific latex IgE (1/34, or 2.9%).

After completion of the study it was observed that only one among the children with positive CAP tests had a positive prick test result; this was a 12-year-old girl consulting because of atopic dermatitis and sensitization to house dust mites.

As concerns the presence of cross reactivity to fruits, positivity in various combinations to banana, chestnut, avocado and/or kiwi was detected both by skin prick tests and by CAP in four children, all of them atopic.

As in Group A (hypersensitivity detected by skin prick test), on directed reinterrogation aimed

at establishing a correlation between contact with latex and associated symptomatology two children reported slight urticaria upon contact with latex products, one of them after playing with balloons and the other one in the area of contact with diving goggles. The parents had not been aware of this particular problem in either of these two cases.

A further risk factor involved in latex hypersensitivity is the antecedent of surgical interventions. This represents an important consideration, as in Group B (CAP detection) four of the atopic children reported previous surgical interventions. These involved orthopaedic surgery in two cases, a laparotomy in one (appendectomy), and adenoidectomy in the last one. The one child who was not atopic but had had a positive CAP result had also undergone adenoidectomy and had an antecedent of meningococcal sepsis, suggesting close contact with latex-containing health care products. The two children with positive prick tests, who were both atopic, reported no surgical antecedents.

Twelve children formed the group specifically referred for investigation of a possible latex hypersensitivity (Group C). Nine of them had myelomeningocele, one had multiple malformations and had received a renal transplantation, and two had evidenced anaphylactic manifestations after contact with latex-containing products. Among the ten surgical cases (nine myelomeningoceles and one with multiple malformations), two were asymptomatic, two had had clinical manifestations after contact with balloons, and the other six had had various intraoperative incidences (the number of surgical interventions ranged between 5 and 11). The two children with anaphylactic reactions after contact with latex-containing materials had antecedents of minor surgery.

The immunoallergological study confirmed latex hypersensitivity (both by skin prick tests and by specific IgE assessment) in seven of the cases with myelomeningocele, in the one with multiple malformations and in the two with anaphylaxis. The study was negative precisely in the two children with myelomeningocele who were asymptomatic.

Regarding the existence of cross reactivity with fruits, four of the children with myelomeningocele had positive tests (both skin prick tests and CAP) to the various fruits usually involved.

## DISCUSSION

The prevalence of latex allergy differs widely according to the diagnostic methodology used. This observed disparity is common to all authors who have studied this diagnosis, either by skin prick testing or by specific IgE quantitation.

In all the studies published, the established risk factors are the personal antecedent of atopy and the personal antecedent of surgical interventions, together with the actual number of such interventions and the (early) age at which the patients underwent them.

In our own series of children attending our Allergy Outpatient Clinic and who were screened for latex hypersensitivity, divergent results were observed when using skin prick tests or specific IgE detection as the screening tool. When using exclusively the skin prick test method, the incidence of latex hypersensitivity was 1.08%, whereas, when the same criteria were applied but with specific IgE quantitation as the screening test, the observed incidence was 7.2%.

A remarkable difference was observed in both instances when the atopic and non-atopic populations were separated. While all the children who were positive by skin prick testing were atopics, yielding a 1.69% prevalence of latex hypersensitivity, we did not find any non-atopic child with a positive skin prick test with latex. In the population screened using the CAP method, the atopic children with latex sensitization represented 9.5%, as compared to 2.9% among the non-atopics.

The prevalence of latex allergy is noteworthy among the high-risk population: 80% (8/10) among the children with spina bifida, and 100% among the two children with suggestive latex-related anaphylactic manifestations. In this highly selective group no disparity was observed between the two screening tests used (skin prick tests and CAP for specific IgE assessment).

We can thus reconfirm the criterion that the risk factor of previous surgery plays a first-rank role in the mechanisms triggering this particular sensitization. This is quite evident in the high-risk group of children (myelomeningocele - anaphylaxis), as all of them (12/12) had undergone one or more surgical interventions.

Among the patients in whom latex sensitization was detected by CAP, surgical antecedents were

present in 71% (5/7). The disparity arises among the children with positive prick tests, as the "previous surgery" risk factor does not exist in them. However, the one child with atopic dermatitis had required several hospital admissions because of exacerbations of his dermatitis, in the course of which he had been manipulated with latex gloves in the administration of topical therapy.

Finally, the presence of cross reactivity reactions to various fruits should not be obviated, as its percentual significance is considerable: while among the CAP-positive patients concomitant sensitization existed in 67% of the cases (4/6), in the case of the high-risk patients the prevalence of fruit sensitization was 57% (4/7). None of the cases with prick test positivity had cross reactivity to these fruits, although there were positive tests with other fruits.

Our data are in agreement with those previously reported in the literature, both as to the actual incidence and as to the incidence when the populations studied are grouped according to the atopic "load". Furthermore, it should be stressed that all authors strongly insist in the antecedent of intensive contact with latex (as in the case of surgical interventions) as a risk factor of the first magnitude, together with the intensifying factors of surgery at early ages and number of surgical interventions.

Similar results were published by Porri et al<sup>21</sup> in 1997. These investigators, in a population of 286 individuals, found 17 cases of latex hypersensitivity (including in this sum those who evidenced serum and cutaneous hypersensitivity): nine of these cases were diagnosed of latex hypersensitivity because of a positive RAST and eight because of a positive skin prick test; however, none of them had simultaneously positive results in the two tests (thus, the positive concordance between skin prick test and RAST was zero).

There are a number of hypotheses attempting to explain these discrepancies between the diagnostic tests. Although no differences seem to exist in relation to the ammoniac contents in the various batches of testing materials, a differential factor would appear to exist in the type of extract used (commercially acquired vs. natural ones). The discrepancy might also be the consequence of the presence of a prophyllin, so that it cannot be ruled out that at least a fraction of the IgE detected

might actually be an anti-prophyllin one. The presence of different epitopes might also lead to each of them being able to induce the generation of its own specific IgE; as the RAST/CAP might not be able to differentiate them, they would be identified as a single comprehensive antibody.

Which should then be our attitude regarding this complex problem? We suggest incorporating the skin prick tests with latex into the routine studies in the following cases: children with atopic dermatitis, urticaria and angioedema; children at high risk (myelomeningocele, urogenital malformations, transplantation surgery, haemodialysis), and in all atopic children undergoing a second surgical intervention.

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## New perspectives in the treatment of allergic sensitization

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The best therapy for allergic disease is its prevention: a good prophylaxis begins with allergen avoidance, and for this purpose measures should be taken which help in changing the Th2 environment towards a Th1 one<sup>1-3</sup>, particularly in the case of the newborn and in children prone to this type of disease.