

Natural rubber latex allergy in children who had not undergone surgery and children who had undergone multiple operations

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Background: Children with spina bifida and other children requiring multiple surgical procedures represent a well-known risk group for natural rubber latex allergy. Children not undergoing surgery can also be sensitized, but findings in this group of children with latex allergy have not been thoroughly examined.

Objectives: We sought to examine the frequency of latex allergy in a large group of children admitted for inhalant or food allergy testing for the purpose of collecting information on a series of children with latex allergy and comparing the symptoms and findings between those not undergoing surgery and those undergoing multiple operations.

Methods: Children admitted to the allergy laboratory of Tampere University Hospital were screened by skin prick tests (SPTs) with latex glove extract. All children with allergy as determined by the screening or admitted because of suspected latex allergy were reexamined from 1995 to 1996. For a definite diagnosis of latex allergy, positive SPT, latex RAST, and latex glove use test results were required.

Results: From 1992 to 1995, a total of 3269 children were skin prick tested with latex glove extract, and 55 (1.7%) had a positive response. On reexamination, 37 (1.1%) children had positive responses to SPTs, and 33 (1.0%) were confirmed to have latex allergy by means of RASTs and latex glove use tests. Since 1988, we have identified a total of 30 children with latex allergy who had not undergone surgery and 12 who underwent multiple operations. The clinical histories were similar in both groups; the mean ages at diagnosis were 5.7 and 8.1 years, and the frequency of atopy was 97% and 83%, respectively. Symptoms had occurred in 63% of the children who had not undergone surgery and in 75% of the children who underwent multiple operations. Contact urticaria was the most frequent symptom, and only one child had intraoperative anaphylaxis. Balloons, followed by gloves, were the most common latex products causing symptoms. The children with latex allergy who had not undergone surgery and those who underwent multiple operations showed no significant differences in SPT responses to commercial latex allergen extract or in specific IgE levels.

Conclusions: The prevalence of latex allergy among children admitted for inhalant or food allergy testing was 1%. Although multiple operations at an early age are a well-known risk factor for latex allergy, the majority of children with latex allergy identified at screening or admitted because of suspicion of latex allergy belonged to the group of children who had not undergone surgery. One third of all the children studied were free of symptoms, indicating that screening with SPTs can be a valuable tool for detecting occult latex allergy in children. (*J Allergy Clin Immunol* 1997;100:606-12.)

Key words: Latex allergy, prevalence, atopy, skin prick test, RAST, use test, children, surgery

Natural rubber latex (referred to as latex in this article) allergy is a well-recognized occupational problem among health care workers, housekeeping personnel, and other persons using gloves or other latex products in their work.¹ In physicians and operating room nurses the prevalence of latex allergy has been shown to be between 5% and 11%.¹⁻³ Children with spina bifida and other children requiring multiple surgical procedures represent a second well-known risk group, with a frequency of latex allergy as high as 50%.⁴⁻⁷ Many of these children with latex allergy experienced systemic reactions during surgery.⁸⁻¹⁰ There are also a few reports of children with latex allergy who had not undergone surgery who exhibited allergic reactions caused by balloons, rubber toys, and pacifiers.^{11, 12} This suggests that in addition to children who have undergone multiple operations, children without such histories may become sensitized from exposure to latex products.

In this study we screened a large group of children admitted for inhalant and food allergy testing by skin prick tests (SPTs) with latex glove extract and reexamined all children suspected of having latex allergy since 1988 in our hospital. For the purpose of this study, the diagnosis of latex allergy was made on the basis of positive responses to SPTs, RASTs, and use tests; and we paid special attention to comparison of symptoms and findings in the children who had not undergone surgery and those who underwent multiple operations.

METHODS

Patients

Since 1988, we have collected data on all children under the age of 16 years who had a positive response to skin prick testing with latex glove extract in the allergy laboratory at the Depart-

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Abbreviation used

SPT: Skin prick test

ment of Dermatology, Tampere University Hospital. These children were admitted because of suspicion of latex allergy, or they were discovered to be allergic at screening for latex allergy during routine allergy testing. In 1988 we included latex glove extract in the inhalant test series, and in 1992 we included the same extract in the basic food allergen SPT series. These series are used in our allergy laboratory to test children suspected of having inhalant or food allergies, various atopic disorders, or both. The children were admitted for allergy examinations by general practitioners, pediatricians, and dermatologists serving a general population of 440,000.

We invited all 64 children who had positive responses to SPTs with latex glove extract from 1988 to 1995 for more detailed examinations. Nine children were seen before 1992, 55 were seen from 1992 to 1995, and a total of 59 (92%) children attended. The study was approved by the Ethical Committee of Tampere University Hospital, and the children, their parents, or both gave informed consent to participate. Past or present atopic disorders (i.e., asthma, allergic rhinitis, atopic dermatitis) were registered. The number of surgical procedures and underlying disorders were recorded, and all unexpected intraoperative events were verified by the hospital records. Similarly, a detailed history was taken for allergy symptoms and their causes in the group of children with latex allergy who had not undergone surgery.

After reexamination, the final diagnosis of latex allergy was based on three criteria: (1) positive SPT response with at least one of the two latex allergens, (2) positive response to latex RAST, and (3) positive response to latex glove use test.

SPT

The screening of latex allergy was performed with a latex glove extract (1:5 wt/vol, Triflex; Baxter, Valencia, Calif.). A fresh extract was prepared every month as described previously,^{13,14} and the same lot of gloves (lot 06 92L12DPGN) was used since 1992. At reexamination, SPTs were performed also with a commercial latex allergen (Stallergènes, SA, Fresnes, France), which had been standardized by *in vivo* and *in vitro* methods.¹⁵ Measurement of the total allergen content of the latex glove extract was performed with an ELISA inhibition method by using freshly frozen, nonammoniated latex from Malaysia (latex reference preparation) and pooled sera from patients allergic to latex (including sera from health care workers and children with spina bifida). Allergen levels in latex glove extracts measured by this *in vitro* method have been shown to correlate highly significantly with their ability to induce positive SPT reactions in patients with latex allergy.¹⁶ The allergen content of the latex reference preparation (total protein concentration 10 mg/ml; modified Lowry method) was assigned a value of 100,000 allergen units/ml. The glove extract had a total protein concentration of 200 µg/ml and a mean allergen content of 1400 allergen units/ml. The commercial latex allergen extract had a total protein concentration of 22 µg/ml when standardized to produce a wheal with a mean diameter of 7 mm in subjects with latex allergy.¹⁵ In addition, SPTs were performed with seven common inhalant allergens (birch, timothy, and mugwort pollens; cat and dog danders; *Dermatophagoides pteronyssinus* and *D. farinae* [Allergologisk Laboratorium a/s, ALK, Hørsholm,

Denmark]). Banana, kiwi fruit, and avocado SPTs were performed with freshly peeled fruit by the prick-prick method. SPTs were performed on the forearm with a commercial one-peak lancet (ALK) as described previously.¹⁴ Histamine dihydrochloride (10 mg/ml, ALK) served as a positive control, and physiologic saline solution served as a negative control. The diameter was measured at 15 minutes, and a wheal half the size of that of histamine and 3 mm or larger was regarded as positive.

RAST

On reexamination, blood was drawn for determination of total and specific IgE. A commercial latex RAST was performed with the CAP method (Kabi Pharmacia, Uppsala, Sweden), and values greater than 0.4 kU/L were regarded as positive. A standard CAP method was used for determination of total IgE.

Use test

Each use test was started with a finger piece of latex glove (Triflex) applied on a wetted finger for 15 minutes.¹⁴ The test result was regarded as positive if two or more wheals were seen on the contact area. If the response was negative, the challenge was continued with a piece of glove around the wrist for 15 minutes. If still negative, the challenge was continued for 1 to 5 hours a day up to 1 week. A piece of vinyl glove was used as a negative control in every use test.

Statistics

The Mann-Whitney U test was used to compare the results of latex SPTs, latex RASTs, and total IgE measurements in the children who had not undergone surgery and those who underwent multiple operations. Probability (*p*) values below 0.05 were considered significant.

RESULTS

Prevalence of positive SPTs to latex

From 1992 to 1995, a total of 3269 children were skin prick tested with latex glove extract, and 55 (1.7%) of those children showed a positive result (Table I). Fifty (91%) of these children were reexamined, and 37 (1.1%) had a positive response to latex glove extract, commercial latex allergen, or both. Thirty-three (1.0%) children were confirmed to have latex allergy by latex RASTs and latex glove use tests.

Children reexamined for latex allergy

Data on a total of 64 children with positive responses to SPTs with latex glove extract have been collected since 1988. Fifty-nine (92%) of these children, 47 who had not undergone surgery and 12 who underwent multiple operations, were reexamined from 1995 to 1996. On the basis of three diagnostic criteria (positive responses to SPTs, latex RASTs, and latex glove use tests) and the history of surgical procedures, the children were divided into three groups for more detailed analysis. Group I included 30 children who had not undergone surgery (four seen from 1988 to 1991 and 26 seen from 1992 to 1995) who met all the diagnostic criteria. Group II included 12 children who underwent multiple operations (five seen from 1988 to 1991 and seven seen from 1992 to 1995) of whom nine met all three diagnostic

TABLE I. Number of positive skin prick test responses to latex glove extract* in 3269 children examined with inhalant or food skin prick test series from 1992 to 1995

Year	Inhalant series†	Food series‡	Total
	No. of positive results/No. tested	No. of positive results/No. tested	No. of positive results/No. tested
1992	4/375 (1.1%)	1/107 (0.9%)	5/482 (1.0%)
1993	5/579 (0.9%)	5/217 (2.3%)	10/796 (1.3%)
1994	11/623 (1.8%)	9/307 (2.9%)	20/930 (2.2%)
1995	10/688 (1.5%)	10/373 (2.7%)	20/1061 (1.9%)
TOTAL	30/2265 (1.3%)	25/1004 (2.5%)	55/3269 (1.7%)

*Triflex glove eluate (1:5 wt/vol).

†Includes seven pollens: birch, alder, meadow fescue, meadow grass, timothy, mugwort, and dandelion; four animal danders: dog, cat, horse, and cow; and *D. pteronyssinus*, *D. farinae* and *Cladosporium herbarum*.

‡Includes allergens of egg, fish, cow's milk, pea, and soybean.

TABLE II. Gender, mean age at time of diagnosis, and personal history of atopy in children in both groups

Group of children	Male (%)	Mean age (range)	Atopic disorder (%) (atopic dermatitis/ rhinitis/asthma)
I, No surgery (n = 30)	63	5.7 (0.6-13.7)	97 (90/67/33)
II, Multiple operations (n = 12)	50	8.1 (0.7-13.1)	83 (67/42/25)

tic criteria (Table II). Three children were not challenged by the latex glove use test because of a history of systemic allergic reactions. Group III included 11 children with probable latex allergy who had not undergone surgery. Eight children had two positive responses and three had one positive response to latex allergy tests (Table III). One reexamined child had negative results on all latex tests and was excluded from the study. In addition, five children had positive responses to latex glove use tests but negative responses to SPTs and latex RASTs. All five children were allergic to cow's milk, and because the gloves contained casein,¹⁷ the use test result was regarded as false-positive.

Demography and surgical history in children with latex allergy

The mean age at diagnosis was 5.7 years in the children who had not undergone surgery and 8.1 years in the children who underwent multiple operations. The two groups were matched for age and sex. Most children had present or past atopic disorders (83% and 97%, respectively), of which atopic dermatitis was the most frequent (Table II).

Seven of the 12 children with latex allergy who underwent multiple operations had spina bifida, two had other congenital anomalies, one had anal atresia, one had hydronephrosis, and one had been operated on for club-foot. The mean number of surgical operations was 9.1 (range, 5 to 15) in these children. Five

children in the group with latex allergy who had not undergone surgery had a history of one to two minor operations such as adenotomy, hernioplasty, or excision of a nevus.

Symptoms in children with latex allergy

Eight (27%) of the children with latex allergy who had not undergone surgery and four (33%) who underwent multiple operations were admitted because of symptoms indicative of latex allergy. A careful history from the parents, medical records, or both revealed symptoms compatible with latex allergy in another 11 children with latex allergy who had not undergone surgery and in five who had undergone multiple operations. After this, there were 19 (63%) children with symptoms in the group who had not undergone surgery and nine (75%) in the group who had undergone multiple operations.

Contact urticaria was the most common symptom, occurring in 14 (74%) children who had not undergone surgery and six (67%) who had undergone multiple operations (Table IV). The frequency of lip and facial swelling was 58% and 56% and eye symptoms 21% and 44%, respectively. Asthmatic attacks had occurred in one child who had not undergone surgery and two children who had undergone multiple operations. One child with multiple congenital abnormalities and a history of nine operations had experienced anaphylaxis during surgical treatment of scoliosis. Another child with latex allergy who had been operated on 10 times had once experienced contact urticaria, but none of the remaining seven children with symptoms had a history of allergic reactions during their 70 operations.

Balloons had caused symptoms in 14 (74%) children who had not undergone surgery and five (56%) who had undergone multiple operations (Table IV). Two children in the latter group also had a history of intraoperative symptoms. Four (44%) children who had undergone multiple operations had experienced symptoms caused by surgical gloves, and four (21%) children who had not undergone surgery had symp-

TABLE III. Allergy test results and occurrence of symptoms in 11 children reexamined for probable latex allergy

Patient no.	Sex	Age (yr)	Skin prick test to latex glove extract	Skin prick test to commercial latex allergen	Latex RAST (kU/L)	Total IgE (kU/L)	Use test	Symptoms from latex products
1	M	1.5	5/5*	6	5.0	1408	—	—
2	M	0.7	5/6	3	<0.4	24	+	+
3	M	5.4	3/5	3	<0.4	8	—	+
4	M	10.7	2/5	3	<0.4	4405	+	—
5	F	2.8	2/5	0	5.9	1359	+	+
6	M	0.6	0/5	0	18	5193	+	—
7	M	9.5	0/6	0	2.5	ND	+	—
8	M	4.3	0/5	0	0.9	ND	+	+
9	M	1.0	0/5	0	2.8	358	+	—
10	M	1.6	0/5	0	8.1	1485	ND	+
11	M	1.3	0/6	0	2.7	481	—	+

ND, Not done.

*Triflex extract/histamine dihydrochloride (10 mg/ml); mean diameter of wheal in millimeters.

toms caused by use of protective gloves at home. Elastic bandages and rubber toys had caused symptoms in a few children (Table IV).

Results of SPTs and RASTs in children with latex allergy

Twenty-nine (97%) children with latex allergy who had not undergone surgery had positive responses to SPTs with the latex glove extract, and 27 (90%) had positive responses to the commercial latex allergen extract. Twelve (100%) of the children who had undergone multiple operations had positive responses to SPTs with the latex glove extract, and 11 (92%) had positive responses to the commercial latex allergen extract. The diameters of wheal reactions to the latex glove extract and commercial latex allergen were similar in the group that had not undergone surgery and the group that had undergone multiple operations (Table V). Similarly, no significant differences were found in the levels of specific IgE or total IgE in the two groups (Table V).

The children with latex allergy who had not undergone surgery had higher frequencies of positive responses to SPTs with pollens (90% and 25%), animal danders (73% and 25%), and house dust mites (33% and 8%), respectively, than those who had undergone multiple operations. Positive responses to SPTs with fruits were also more common in the children who had not undergone surgery (87%) than in those who had undergone multiple operations (50%). The frequencies of positive responses to SPTs with banana were 63% and 25%, to kiwi fruit 67% and 42%, and to avocado 65% and 17%, respectively.

Findings in children with probable latex allergy

The mean age of the 11 children with probable latex allergy who had not undergone surgery was 3.6 years (Table III). All of these children were atopic, and six (55%) had a history of symptoms compatible with latex allergy. Responses to SPTs with latex allergens were

TABLE IV. Symptoms and latex products causing reactions in 28 children with latex allergy

	Group I* (n = 19)	Group II† (n = 9)
Symptoms		
Contact urticaria	14 (74%)	6 (67%)
Lip and facial swelling	11 (58%)	5 (56%)
Eye symptoms	4 (21%)	4 (44%)
Rhinitis	1	3 (33%)
Asthma	1	2 (22%)
Anaphylactic reaction	0	1
Latex products		
Balloons	14 (74%)	5 (56%)
Gloves	4 (21%)	4 (44%)
Toys	3 (16%)	2 (22%)
Elastic bands	4 (21%)	1

*Children with latex allergy who had not undergone surgery.

†Children with latex allergy who had undergone multiple surgeries.

positive in four (36%), responses to latex RASTs were positive in six (73%), and use test results were positive in seven (64%) children (Table III). Seven (64%) children had positive SPT responses to pollens, seven (64%) had positive responses to animal danders, and three (27%) had positive responses to house dust mites. Nine (82%) children had positive responses to SPTs with fruits: six (55%) to banana, seven (64%) to kiwi fruit, and six (55%) to avocado. One child with probable latex allergy had a history of adenotomy.

DISCUSSION

During 4 years, we skin prick tested 3269 children admitted for inhalant or food allergy testing with latex glove extract and found a positive result in 55 (1.7%) children. Later, 50 of these children were retested with the same latex glove extract and also with a commercial latex allergen extract, and a positive SPT result was recorded in 37 (1.1%) children. Previously, Shield and

TABLE V. Results of skin prick tests, latex RASTs, and total IgE measurements in children in Groups I and II

	Group I* (n = 30)	Group II† (n = 12)	p Value‡
Skin prick tests (in mm diameter)			
Latex glove extract	7 (1-11)§	5 (3-13)	0.47
Commercial latex allergen	6 (0-10)	6 (0-10)	0.97
Histamine (10 mg/ml)	5 (4-7)	5 (3-7)	0.44
Latex RASTs (kU/L)	5.0 (0.4-72.2)	2.9 (0.7-74.2)	0.50
Total IgE (kU/L)	350 (27-3940)	224 (24-2036)	0.15

*Children with latex allergy who had not undergone surgery.

†Children with latex allergy who had undergone multiple surgeries.

‡Mann-Whitney U test.

§Median (range).

Blaiss¹⁸ reported that three of 80 (3.8%) children, referred to their clinic for evaluation of inhalant allergies, had a positive SPT response to a latex glove extract. Liebke et al.¹⁹ screened 609 atopic and nonatopic children in Germany for latex allergy with commercial latex RASTs and found elevated IgE levels in as many as 61 (10%) children. Latex glove challenge tests confirmed latex allergy only in 12 of these children, which is a prevalence of 2%. In this large series from Finland, we used three diagnostic criteria (i.e., SPTs, latex RASTs, and latex glove use tests) and found that the prevalence of latex allergy was 1% among the children admitted for inhalant or food allergy testing.

When we reexamined the children on whom data was collected prospectively from 1992 to 1995 and used strict criteria for the diagnosis of latex allergy, we found three times more children with latex allergy who had not undergone surgery than children with latex allergy who had undergone multiple operations. This clearly shows that when active screening of latex allergy is performed among children admitted for routine allergy testing and all children referred for suspicion of latex allergy are sampled at the same time, most of the children with latex allergy thus identified had not undergone surgery. However, if screening is done separately in the groups of children who had not undergone surgery and those who had undergone multiple operations, which we did not do, the frequency of latex allergy could certainly be much higher in the children who had undergone multiple operations. The former group is a well-known risk group for latex allergy, and as many as 50% of the children with spina bifida examined in the United States or in Europe had positive responses to SPTs with latex.^{4, 6, 7} In contrast, the prevalence of latex allergy in the children who had not undergone surgery is at present not known.

A common denominator in the two groups of children with latex allergy in this study was atopy. The frequency of atopic disorders was 97% in the children who had not

undergone surgery and 83% in the children who had undergone multiple operations. The latter percentage is in good agreement with the 77% and 83% prevalences of atopy reported earlier in the children with latex allergy who had undergone multiple operations.^{10, 20} The two groups of children were also matched for sex and age at diagnosis. Moreover, we found no major differences between the two groups in regard to the size of SPT reactions to latex allergens or in the IgE levels in latex RASTs. All these data suggest that the two groups of children with latex allergy have similar in vivo and in vitro sensitivities to latex allergens. Immune responses to various latex allergens could, however, be different in the two groups. It will be of interest to find out whether the specific IgE in children without histories of multiple operations is directed primarily to prohevein and hevein (Hev b 6), the major allergens for adult health care workers,^{21, 22} and not to the hydrophobic rubber particle-associated latex allergens, the rubber elongation factor (Hev b 1), and the 23/27 kd latex protein (Hev b 3) characteristic of children who had undergone multiple operations.²³⁻²⁵ As many as 87% of the children who had not undergone surgery in this series had positive responses to SPTs with fruits known to cross-react with latex.²⁶⁻²⁷ Thus in view of the accumulated clinical observations on cross-reactions and, considering in particular recent reports showing that hevein has cross-reacting IgE-binding epitopes with a 33 kd banana protein²⁸ and wheat germ agglutinin,²⁹ it is tempting to speculate that some children may have been sensitized by banana or other foods that cross-react with latex.

The clinical symptoms were mild and similar among the groups of children with allergy in this study who had not undergone surgery and those who had undergone multiple operations. The most common symptom was contact urticaria, followed by lip swelling, facial swelling, or both caused most often by balloons. In contrast to the frequent occurrence of severe systemic reactions reported in many studies in patients with spina bifida,³⁰⁻³² only one of the 12 children with latex allergy in this study who had undergone multiple operations had a history of intraoperative anaphylaxis. In addition, no anaphylactic reactions were encountered among the children with latex allergy who had not undergone surgery. The reason for the mild symptoms and the single intraoperative anaphylaxis in our series could be that only low-allergen latex gloves have been used since 1990 in our hospital. The second reason seems to be patient sampling. Only one third of the children were referred because of symptoms, whereas most of the children were identified at routine SPT screening for latex allergy. An important finding was that even after taking a careful history from the parents at reexamination, 37% of the children who had not undergone surgery and 25% of those who had undergone multiple operations had been free of symptoms of latex allergy. Previously, Yassin et al.³³ and Nieto et al.⁷ reported that the clinical history was negative in 50% of their patients with spina bifida who are allergic to latex. We demonstrated with the latex

glove use test that the children with asymptomatic latex allergy reacted to the challenge with contact urticaria. This obviously indicates that these children with previously asymptomatic latex allergy could be at risk of exhibiting severe allergic reactions during surgery or when blowing balloons, for example. It is important therefore to find these children without symptoms and to provide them with information on protection from exposure to latex products both in medical care and at home.

In this study we identified 11 children who had not undergone surgery and had a positive SPT response to screening with latex glove extract, but who after reexamination did not meet all three diagnostic criteria for latex allergy. We therefore classified these children as probably allergic to latex. Six of these children had symptoms caused by balloons or other latex products, three of the six had a positive latex glove use test result, four had a positive latex RAST, but only two had positive SPT responses to latex allergens. At present, we do not know the reasons for the discrepant latex test results in the 11 children with probable allergy to latex. Previous studies have shown that patients with positive SPT responses and latex glove use tests can have negative latex RASTs^{13,34} and vice versa.¹⁹ It is, however, difficult to explain why SPTs yielded negative results at reexamination in so many children. False-negative SPT reactions may occur in latex allergy, but to diminish this possibility, we skin prick tested the children with two different latex allergens. Several children who initially had positive SPT responses but had negative responses at reexamination had avoided latex products for many months or even years, a factor that could have contributed to the discrepant SPT results. Another explanation could be that the size of the SPT reactions in screening in many of those children was small, less than that of histamine. It seems that clinicians cannot rely only on one test when diagnosing latex allergy and that special attention should be paid to those children who have shown marginal SPT reactions to latex allergens. The positive latex RASTs in the children with negative SPT responses could also have been false-positive reactions because of the cross-reactivity between banana and latex allergens.²⁶⁻²⁸ Finally, five children allergic to cow's milk had to be excluded from the study because of a false-positive latex glove use test result. These five children and the 11 children with probable allergy to latex clearly show that there is a need to improve the accuracy of the diagnostic tests for latex allergy.

In conclusion, this study showed that children who have not undergone surgery can also be frequently allergic to latex. The clinical history is often mild or even absent both in the children with latex allergy who had not undergone surgery and those who had undergone multiple operations, and therefore it seems worthwhile to extend the search of latex allergy to children admitted for routine inhalant or food allergy testing. This study also focuses on the need to improve the accuracy of diagnostic tests for latex allergy.

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