

Risk factors for latex hypersensitivity in childhood

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As hypersensitivity to natural rubber latex (NRL) has become an increasingly recognized problem in children, identification of all groups at risk seems important. In this study hypersensitivity to NRL was evaluated in 337 children with potential risk factors. We identified by questionnaire children's underlying diseases, history of surgical procedures, evidence of atopy and patient's history of NRL-specific reactions. Hypersensitivity to NRL and other allergens relevant in the Düsseldorf area was evaluated by skin prick test and specific IgE. In 9.2% of all children hypersensitivity to NRL was observed. Significant risk factors for hypersensitivity to NRL were, among the underlying diseases, spina bifida (odds ratio 29.2), hydrocephalus internus (10.1), gastrointestinal malformation (5.2) and atopy (2.2). Surgical procedures with significant risk were the implantation of a ventriculo-peritoneal shunt (15.7) and surgery of the gastrointestinal tract (3.1). Frequency of surgical procedures correlated ($p < 0.001$) with risk of hypersensitivity. Frequent surgery and atopy were found to have an additional effect on the risk of hypersensitivity. Information about previous NRL-specific reactions obtained by questionnaire was of little predictive value when performing multivariate analysis. For children at high risk for hypersensitivity to NRL preoperative evaluation and, in case of hypersensitivity, preventive measures seem to be advised.

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Introduction

Hypersensitivity to natural rubber latex (NRL) was first mentioned in 1927 by Stern (1). Initial case-reports described immediate and delayed type hypersensitivity reactions in highly exposed health care workers (2, 3), children with spina bifida (4, 5), or congenital abnormalities of the genitourinary tract (6). Surveys from different countries calculated the prevalence of hypersensitivity to NRL for health care workers at 8% to 17% (7–10). In various studies of children with spina bifida the prevalence of hypersensitivity to NRL ranges from 10% to 72% (11–15). Atopic disease was found to increase the risk of hypersensitivity to NRL in patients with and without frequent exposure to NRL (16). However, recent reports of anaphylactic reactions in patients with no known risk factors (17, 18), indicate the presence of previously unidentified risk factors.

The clinical relevance of hypersensitivity to NRL emerges from the increasing prevalence of hypersensitivity reported among frequently exposed individuals. From 1988 to 1992 the FDA received reports of more than 1000 systemic allergic reactions to NRL, 15 of which were fatal (19). In their position statement of 1995, the American College of Allergy, Asthma & Immunology pointed out the need for further studies on the incidence, prevalence and risk factors of hypersensitivity to NRL (20). Children constitute a major group among patients with severe hypersensitivity to NRL and it is estimated that allergy to NRL may be the main cause of anaphylactic shock during surgery in the pediatric population (16, 21). To enable future preoperative screening strategies, identification of all potential risk factors that could lead to well-defined risk groups is important. Thus, we analyzed 337 children in order to evaluate the rate of hypersensitivity to NRL according to fac-

tors of risk previously described and to potential factors of risk not assessed before.

Methods

Patients

This study included 337 patients of the Pediatric and the ENT Department of the Heinrich-Heine University, Düsseldorf. The mean age was 10.6 years (standard deviation 5.9 years, range 4 months to 29 years of age, 199 boys, 138 girls). Patients included children from all inpatient and outpatient clinics between January and August 1995. The study was approved by the local ethics committee and all patients and parents gave their informed consent to participate in the study. Only patients with completed questionnaires and at least one of two diagnostic tests (skin prick test and specific IgE) were included in the analysis.

Questionnaire

Patients or parents answered a questionnaire about all previous and current diseases including atopic diseases. Atopy was defined by the presence of either atopic dermatitis or allergic asthma or allergic rhinitis. For definition of allergic asthma and allergic rhinitis in addition to clinical symptoms at least one positive skin prick test result or positive specific IgE for common environmental allergens was required. Previous surgical interventions were recorded by number, type of surgery and age at performance. Intraoperative or postoperative complications suggesting allergic reactions were registered and verified from hospital records. Patients and parents were asked for regular contact (> 3 times per week) to latex gloves or latex catheters. Reactions related to contact with rubber balloons were also documented.

Skin prick tests

Hypersensitivity to NRL was evaluated by skin prick test (SPT) with low ammoniated natural rubber latex milk (Ansell Medical, Munich, Germany) with a total solid content of 61.5–61.8%, a dry rubber content of 60.0–60.2% and a minimum of 0.2% of NH₃. SPT for definition of atopy were performed using 22 inhalant and food allergens (grass mixture, rye, early flowering tree pollen, beech, ash, poplar, mugwort, dandelion, dermatophagoides pteronyssinus, dermatophagoides farinae, cat, dog and guinea pig epithelia, alternaria, cladosporium, aspergillus, egg yolk, egg white, cow's milk, wheat flour, rye flour and hazelnut (ALK-Scherax, Hamburg, Germany)). All SPT including NRL were performed in accordance with the recommendations of the European Academy of Allergology and Clinical Immunology (22).

A positive SPT-result was given, if the diameter of the tested allergen was $> 50\%$ of the histamine diameter minus the sodium chloride control. We were able to perform SPT in 90.8% of the patients, in 9.2% parents did not give their consent.

Allergen-specific IgE

In vitro tests were offered to all patients and included latex-specific IgE (Pharmacia CAP RAST system, Freiburg, Germany) and IgE specific for inhalant and food allergens (Pharmacia SX-1 and FX-5). If a patient had a positive multiallergen test, hypersensitivity to 10 inhalant or food allergens was further analyzed by RAST (Pharmacia CAP RAST system). The cut-off point for positive results was set at 0.70 kU/l. *In vitro* tests could be performed in 93.1% of the patients.

Statistical methods

Study results were analyzed using SPSS for Windows 6.0.1. Each potential categorical risk factor was analyzed for association with hypersensitivity to NRL by comparing patients at risk with those patients not exposed to that risk. Significance levels for categorical risk factors were calculated with chi-square analysis using Pearson for cells > 5 patients and Fischer's exact test if at least one cell was < 5 patients. The significance level was set at $p < 0.05$. Odds ratios for each categorical risk factor were analyzed using confidence intervals of 95%. The association between frequency of surgical procedures and hypersensitivity to NRL was assessed by non-parametric Mann-Whitney U test as normal distribution was not given (Kolmogorov-Smirnov test). Multivariate analysis was performed by stepwise logistic regression with a significance level of $p < 0.05$ to identify potentially confounding factors.

Results

Thirty-one (9.2%) of 337 patients were sensitized to NRL as defined by a positive test result in either SPT (four patients), RAST (eight patients) or both methods (19 patients). For 287 patients (85%) with both test methods applied, concordance was at 97% for negative results and at 70% for positive results. Positive RAST was observed more frequently than positive SPT in non-atopic patients (13 vs. six patients), whereas in atopic patients positive SPT and RAST were equally distributed.

Table 1 shows the association of the underlying disease with hypersensitivity to NRL. The proportion of sensitized children ranged from 4.8% in children with CNS-tumors to 71.4% in children with spina bifida. Odds ratios for hypersensitivity to

Table 1. Risk factors for latex hypersensitivity in childhood: a) Diseases

Underlying disease	No. of children with latex-sensitization/total no. of children	Sensitization in %	p=	Odds ratio (with CI)
Spina bifida	5/7	71	<0.001	29.2 (5.4–158.1)
Hydrocephalus internus (not associated with spina bifida)	5/12	41.7	<0.001	10.1 (2.9–34.6)
Gastrointestinal malformation	5/16	31.3	0.013	5.15 (1.7–16.0)
Atopy	17/126	13.5	0.035	2.2 (1.1–4.6)
Urogenital malformation	2/16	12.5	n.s.	1.44 (0.31–6.6)
Congenital heart defect	1/9	11	n.s.	1.24 (0.15–10.3)
Leukemia/hematologic disease	4/62	6.5	n.s.	0.63 (0.21–1.9)
Solid tumors (excluding CNS)	4/74	5.4	n.s.	0.49 (0.17–1.5)
CNS-tumors	1/21	4.8	n.s.	0.48 (0.06–3.7)

NRL were significantly increased in children with spina bifida, hydrocephalus internus, atopy and gastrointestinal malformations (including children with esophageal atresia, megacolon congenitus, anal atresia and other congenital malformations of the gastrointestinal tract requiring surgical intervention). As spina bifida may be associated with hydrocephalus by Arnold-Chiari-malformation, for hydrocephalus due to other etiologies (e.g. intracranial bleeding) the risk of hypersensitivity was calculated separately and remained significant. In children with other diseases, such as urogenital malformation, hypersensitivity to NRL was common but there was no statistical evidence of an increased risk.

A previous history of regular contact to NRL or allergic reactions to materials containing NRL was associated with an increased risk of hypersensitivity to NRL, as shown in Table 2. In particular in children with previous allergic reaction to rubber balloons, the odds ratio for hypersensitivity to NRL was elevated. The sensitivity of anamnestic information, however, was rather poor. Parents of only six of the 31 children sensitized to NRL had reported a previous allergic reaction to rubber balloons (sensitivity=19%). Hypersensitivity was influenced by the child's age at time of surgical procedures: children with at least one operation within the first 6 months of life were at a significantly increased risk of subsequent hypersensitivity to NRL.

The association between surgical procedures and hypersensitivity to NRL was analyzed both qualita-

tively and quantitatively. The frequency of previous operations was higher in NRL-sensitized children (mean 4.1, median 4.0) than in children not sensitized to NRL (mean 2.0, median 2.0, $p<0.001$). As demonstrated in Fig. 1, with the frequency of operations the prevalence of hypersensitivity to NRL increases. Stratification for atopic and non-atopic children, as shown in Fig. 2, illustrates a constantly increasing risk of hypersensitivity for each of the two groups. Atopy as an additional factor further increases the risk attributable to surgery alone. The average risk of atopic patients with a history of at least one operation was 17.1% compared to 7.4% of non-atopic patients under the same condition. Atopy alone constitutes a sufficient risk factor for hypersensitivity even in children without previous surgery. Whereas in non-atopic children without surgical intervention no hypersensitivity was observed, 8.9% of atopic children never having experienced surgery were sensitive for NRL. This baseline hypersensitivity rate in atopic patients was exceeded in non-atopic patients only after 3–4 surgical procedures.

The type of surgical procedure was also found to influence the risk of hypersensitivity to NRL. Children having a surgical implantation of ventriculo-peritoneal shunt (V-P-shunt) had a prevalence of hypersensitivity to NRL of more than 50%. In accordance to the increased risk in children with gastrointestinal malformation, we also found the hypersensitivity rate in children with surgery involving

Table 2. Risk latex for latex hypersensitivity in childhood: b) Risk factors identified in patient's history

Information derived from questionnaire	No. of children with latex-sensitization/total no. of children	Sensitization in %	p=	Odds ratio (with CI)
Allergic reaction to rubber balloon	6/9	67	<0.001	24.3 (5.7–103.4)
Allergic reaction to latex materials	3/7	43	0.019	8.1 (1.7–38.0)
Operation in the first 6 months of life	15/60	25.0	<0.001	5.4 (2.5–11.8)
Allergic reaction related to operation	2/6	33	n.s.	5.2 (0.9–30.3)
Regular contact to latex materials	5/29	17.2	n.s.	2.2 (0.79–6.4)

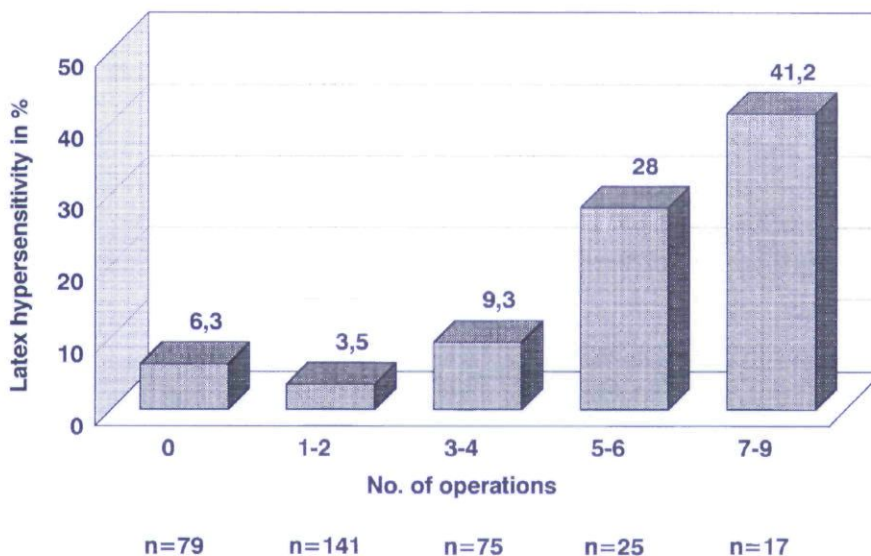


Fig. 1. Latex hypersensitivity in relation to the number of surgical procedures.

the gastrointestinal tract significantly elevated (21.7%). This group comprised children with correction of anal or esophageal atresia, intestinal resection or colostomy; operations characterized by intensive contact of gloves with serosal and mucosal membranes of the gastrointestinal tract. Abdominal surgery not including the gastrointestinal tract or V-P-shunt was not related to increased risk of hypersensitivity to NRL. Appendectomy and pylorotomy were considered as operations, where intensive contact to mucous membranes rarely occurs and were therefore entered into the latter group. Within this subgroup NRL hypersensitivity was not observed. The hypersensitivity rates in children with other types of operation varied from 4–13%. A statistical significance, however, was not reached (Table 3).

As risk factors may be dependent on other factors, a multivariate analysis using stepwise logistic regression was performed to identify confounding variables. A multivariate analysis including all underlying diseases confirmed high significance ($p < 0.001$) for spina bifida, hydrocephalus internus (not related to spina bifida), gastrointestinal malformation and atopy. Both significant risk factors among operations, shunt-implantation and surgery of the gastrointestinal tract, were significantly related to increased risk of hypersensitivity ($p < 0.005$) when performing multivariate analysis using all types of surgery. In a further multivariate model all factors in patients' past medical history identified by questionnaire were stepwise added to the underlying diseases and operations. In this model, no factor in patient's past medical history was longer pre-

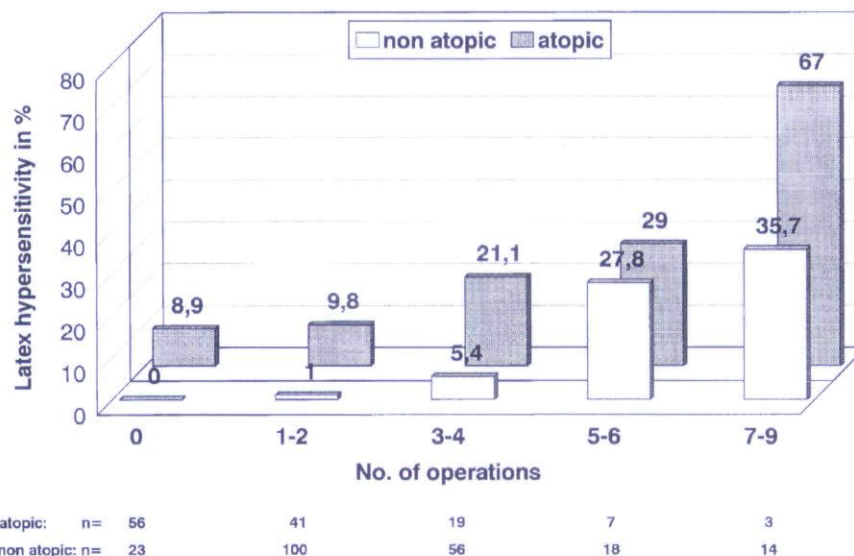


Fig. 2. Latex hypersensitivity in relation to the number of surgical procedures: role of atopy.

Table 3. Risk factors for latex hypersensitivity in childhood: c) Operations

Site of surgical intervention	No. of children with latex-sensitization/total no. of children	Sensitization in %	p=	Odds ratio (with CI)
Shunt-implantation	10/19	52.6	<0.001	15.7 (5.8–42.9)
Gastrointestinal tract	5/23	21.7	0.048	3.1 (1.1–9.0)
General surgery (incl. orthoped.)	13/98	13.3	n.s.	1.9 (0.9–4.0)
Genitourinary tract	2/17	11.8	n.s.	1.3 (0.3–6.1)
Thoracic and cardiac surgery	2/21	9.5	n.s.	1.0 (0.2–4.7)
Cranial surgery (other than shunt)	2/25	7.4	n.s.	0.84 (0.2–3.8)
ENT-surgery	6/77	7.8	n.s.	0.79 (0.3–2.0)
Implantation of central venous catheters	6/88	6.8	n.s.	0.66 (0.3–1.7)
Abdominal surgery (other than GI-tract or V-P-shunt)	2/41	4.9	n.s.	0.47 (0.1–2.1)

dictive of NRL-hypersensitivity. This was not surprising, as some anamnestic information such as time-point of surgery < 6 months are rough parameters compared to specific types of diseases or operations, which imply early surgical intervention within the first weeks of life (i.e. spina bifida, congenital gastrointestinal malformation).

Discussion

In the present study of 337 pediatric patients hypersensitivity to NRL was evaluated by SPT and latex-specific IgE (Pharmacia CAP RAST system). The sensitivity and specificity rates of >90% for SPT have been reported before in several studies (15, 23). For latex-specific IgE detected by CAP-RAST a specificity of 100% and a sensitivity between 63% (24) and 94% (25) are reported. Overall concordance between the two test-methods was satisfying, however, we observed differences within the target populations identified by both methods with a preference for RAST identifying non-atopic cases.

The study results show a high proportion of hypersensitivity to NRL (71%) among patients with spina bifida. As the main purpose of this study was to assess previously unidentified factors of risk for hypersensitivity to NRL, the number of children with spina bifida included in this study was low. However, the result confirms the findings of other surveys (11–13), where prevalence rates between 60% and 72% were found. One possible explanation might be the high number of surgical procedures that children with spina bifida undergo. In fact, the mean number of operations in this group was 4.7. However, the hypersensitivity rate in spina bifida patients exceeded the average hypersensitivity rate in other patients with five or more surgical interventions. This comparison may be of importance with respect to understanding the mechanism of allergic sensitization. Konz et al. (13) assume a relationship of the neurologic system and the immune response

in children with spina bifida, as interactions between mast cells and associated nerves have been demonstrated in animal models. The effect of congenital denervation of mast cells, as it may occur in children with spina bifida, has not yet been investigated.

Children with hydrocephalus not related to spina bifida have not been analyzed earlier. With a prevalence of 42.7% of hypersensitivity to NRL in our children this disease should be regarded as a risk factor for hypersensitivity to NRL. Of interest are similarities to children with spina bifida: a mean number of operations of 4.7 and a previous implantation of a V-P-shunt in all children later found to be sensitized to NRL. As for children with spina bifida, the reason for the increased prevalence of hypersensitivity to NRL remains to be completely understood.

As we suspected from a previous observation (18), children with gastrointestinal malformations (31.3%) and children undergoing surgery of the gastrointestinal tract (21.7%), represent another important, previously unidentified, group at risk for hypersensitivity to NRL. One might speculate that intensive contact of latex-containing gloves leads to sensitization via the mucosal or serosal membranes, but the underlying cause of this comparably high hypersensitivity rate needs to be further analyzed.

Our observation that hypersensitivity to NRL increases with the number of surgical procedures confirms the results made by Niggemann et al. (26) among 145 children with spina bifida. However, it seems advisable to stratify for atopy, when defining the impact of surgery on hypersensitivity to NRL. Atopy, as major risk factor should be considered as both additional and sufficient cause for hypersensitivity to NRL. Without a history of surgical intervention the degree of hypersensitivity was 8.9% in atopic children compared to 0% in non-atopic children. Thus atopic children should be regarded at risk even without a history of surgery. When exposing atopic children to surgery the risk of hypersensitivity

ity is constantly higher elevated than in non-atopic children. As demonstrated before, the two risk factors atopy and exposure to surgery seem to act additionally. Moneret-Vautrin et al. in their survey observed results with a comparable hypersensitivity rate of 9.4% in atopic adults not exposed to NRL, but 36.4% in atopic adults with frequent exposure to NRL (16). This increase is interpreted as synergistic effect, information about the frequency of exposure, however, was not provided.

The clinical relevance of hypersensitivity to NRL gains further importance because for some allergens, such as banana, chestnut and avocado, cross-reacting IgE-antibodies have been demonstrated by inhibition techniques (27–29), but probably more clinically relevant cross reactions exist. Our questionnaire comprised questions regarding hypersensitivity to food allergens with reported association to NRL in order to assess the predictive value of such information. No child, regardless whether hypersensitive to NRL or not, had a positive history for these allergens. A further analysis of the relationship between hypersensitivity to NRL and certain food allergens would be beyond the scope of this paper and will be presented in a forthcoming publication.

For practical use, identification of risk factors in patient's history by questionnaire is a tempting but not a predictive method, as either sensitivity of the information was poor or identified risk factors act as confounding variables and may be better characterized when specifying the type of disease or surgery. Though a given positive history of hypersensitivity on NRL certainly should alert each clinician, the absence of clinical symptoms when being in contact with latex does not necessarily exclude hypersensitivity to NRL.

The absence of statistical significance in other diseases and surgical procedures should be interpreted with caution, as hypersensitivity rates of 4–13% were observed. For urogenital malformations, suspected to be a risk factor for hypersensitivity to NRL (6), negative results may derive from the low number of children included in the analysis. For children at high risk with spina bifida, hydrocephalus, atopy and gastrointestinal malformation, however, preoperative analysis, as recommended by the American Academy of Allergy and Immunology (30) and preventive measures, e.g. a latex-free environment during surgery, seem to be advisable.

In summary, this study of 337 children demonstrates that hypersensitivity to NRL occurs in more groups at risk than previously suspected. In addition to established groups at risk, children with congenital malformation of the digestive tract and children with hydrocephalus not related to spina bifida should be offered preoperative screening methods. Atopy may act either as individual or as additional risk fac-

tor to surgical intervention. Thus preoperative assessment of atopic disease in children is mandatory.

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