

Decreasing incidence of occupational contact urticaria caused by natural rubber latex allergy in German health care workers

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Background: The development of allergy to natural rubber latex (NRL) is a risk for health care workers. A regulation banning powdered NRL gloves was implemented in Germany in 1998.

Objective: This study assesses the effects of this regulation on the development of occupational skin disease caused by NRL in health care personnel working in facilities insured by the German statutory accident insurance company, covering some 1.8 million insured health care workers.

Methods: We reviewed the annual numbers of reported suspected cases of NRL-induced occupational allergies (mainly contact urticaria) from 1996 through 2002, as well as the number and type of gloves purchased in acute-care hospitals from 1986 through 2002.

Results: The number of purchased nonsterile examination gloves increased by 1387% between 1986 and 2002. The purchase of powder-free NRL examination gloves exceeded that of powdered gloves in 1998. The incidence of suspected cases increased until 1998 and has since decreased by 79.9%. Most suspected cases (67.9%) were identified as occupationally caused.

Conclusions: Reducing the purchase of powdered NRL gloves is associated with a decrease in suspected and proved cases of occupational contact urticaria caused by NRL. Development of occupationally caused contact urticaria by NRL can be reduced by banning the use of powdered NRL gloves. (*J Allergy Clin Immunol* 2004;114:347-51.)

Key words: Contact urticaria, natural rubber latex allergy, powder-free latex gloves, latex allergens, primary prevention

Allergic reactions to natural rubber latex (NRL) have increased since the mid-1980s, especially in health care workers (HCWs) exposed to NRL allergens. Up to 17% of HCWs are sensitized to NRL.¹ The proteins present in gloves and other products made of NRL and the inhalation and skin contact with this material have been identified to cause sensitization.²⁻⁴ Because of skin contact with the allergen, contact urticaria as a result of latex-induced

Abbreviations used

BGW: Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege

HCW: Health care worker

NRL: Natural rubber latex

type I hypersensitivity might develop. Local and severe systemic reactions (anaphylaxis) might occur and are particularly important in the health care sector.⁵ In addition to immediate-type hypersensitivity, in rare cases protein contact dermatitis resulting from type IV hypersensitivity has been described as a cause of cutaneous latex allergy.⁶

There have been recommendations to use powder-free and low-allergen gloves as preventive measures.^{7,8} Turjanmaa et al⁹ in Finland reported cessation or decreases in sensitization after changes in powder levels, allergen levels, or both in gloves in hospitals. In a cross-sectional study Levy et al¹⁰ found that no cases of sensitization occurred among dental students using powder-free gloves, whereas 5% to 15% of those using powdered gloves became sensitized.

In a previous study we were able to show that by switching to powder-free NRL gloves, detectable NRL aeroallergens were completely removed in a health care facility. Sensitized HCWs were able to remain at work after provision of NRL-free gloves, thus showing that these simple and practical measures led to a successful secondary prevention of NRL allergy in HCWs.¹¹ The following report describes how the regulation banning powdered NRL gloves in the workplace has changed the glove-purchasing policies in acute-care hospitals and the incidence of cutaneous NRL allergies among HCWs in Germany.

METHODS

Regulations

The education and information campaigns have been described previously.¹² In the regulatory field a revised version of the compulsory technical regulations for dangerous substances (TRGS 540) was published in December 1997 and has been enforced since 1998. It explicitly states that only low-allergen, powder-free NRL gloves can be used and that the use of powdered NRL gloves is not permissible in the workplace.

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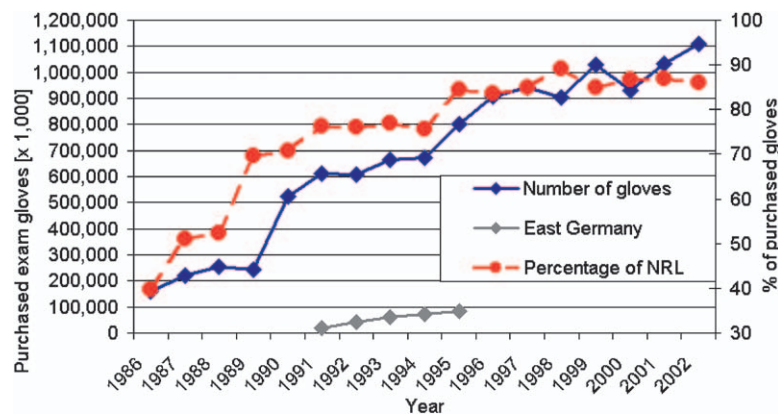


FIG 1. Purchase of nonsterile examination gloves in all German acute-care hospitals and percentage of NRL gloves from 1986 until 2002. Separate data for East Germany were available from 1991 through 1995.

TABLE I. Number of HCWs insured by the BGW, total incidence of suspected cases of occupational skin diseases, and incidence of NRL-induced contact urticaria from 1996 through 2002

Year	No. of insured persons	Suspected occupational skin disease	
		Incidence of all skin disease cases per 1000 insured workers	Incidence of NRL-induced contact urticaria cases per 1000 insured workers (% of all skin disease cases)
1996	1,727,766	1.48	0.30 (20.5)
1997	1,912,033	1.25	0.32 (25.4)
1998	1,857,491	1.43	0.35 (24.3)
1999	1,871,595	1.15	0.20 (17.1)
2000	1,779,963	1.10	0.17 (15.2)
2001	1,794,960	0.98	0.10 (10.2)
2002	1,816,727	0.91	0.07 (7.9)

Glove use data

The glove data were provided by the Gesellschaft für Pharma-Informationssysteme mbH (Frankfurt am Main, Germany) from 1986 until 2002 (including East Germany since 1991). The numbers represent purchases by all acute-care hospitals by projecting the sample of 280 hospitals. Data for powder-free NRL gloves became available in 1992.

Epidemiologic data regarding cases of suspected NRL allergy

The Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege (BGW) is the statutory accident insurance company for health care that is responsible for accident insurance, worker's compensation, and preventive measures. For example, all physicians' and dentists' offices, as well as all private and church-run hospitals (nearly 60% of all German hospitals with almost half of all hospital staff), are insured by the BGW. The number of insured persons and incidence rates are outlined in Table I. Every physician and dentist is required by law to report a suspected occupational disease to the appropriate statutory accident insurance company. The reported cases of occupational disease have to undergo a thorough medicolegal evaluation procedure that includes standard procedures

of type I hypersensitivity diagnostics, including skin prick testing, wearing tests, and specific IgE analysis, and, for differential diagnosis, type IV hypersensitivity screening. Diagnosis of NRL hypersensitivity was confirmed if the history and clinical picture were consistent and skin prick tests and NRL-specific IgE analysis both showed positive results. In rare cases diagnosis was verified if skin prick test and glove use test results were positive and NRL-specific IgE antibodies were not detectable. This process takes 1.8 years on average, which is mainly attributable to the legal confirmation procedure required by the insurance administration. The number of reported cases of suspected NRL allergies (both skin and respiratory) were available from 1996 through 2002 for all HCWs insured by the BGW. Detailed analysis of the insurance data made it possible to differentiate between all BGW-insured parts of the German health care system, and in this study we subanalyzed the number of insured personnel and the number of suspected cases in acute-care hospitals.

Statistics

Statistical evaluation was performed with the SPSS for Windows software package (German version 11.0 for Windows; SPSS, Chicago, Ill). The correlation between purchase of powdered NRL examination gloves and the number of suspected cases of NRL-induced contact urticaria was calculated by using the Pearson correlation coefficient.

RESULTS

The number of purchased nonsterile examination gloves increased 1387% between 1986 and 2002, reaching almost 1 billion per annum. In 1986, only 37% of all nonsterile examination gloves were made of NRL, 38% were made of vinyl, 18% were made of polyethylene, and the remaining 6% were copolymer gloves. In 2002, 86% of nonsterile examination gloves were made from NRL (Fig 1).

In 1992, only 1% of the purchased NRL gloves were powder free, but by 1998, sales of powder-free nonsterile NRL examination gloves had surpassed the purchase of powdered NRL examination gloves, and by 2002, their market share had reached 88% of all nonsterile NRL examination gloves bought by acute-care hospitals.

The number of sterile surgical gloves increased by 43% between 1986 and 2002. A decrease in the use of

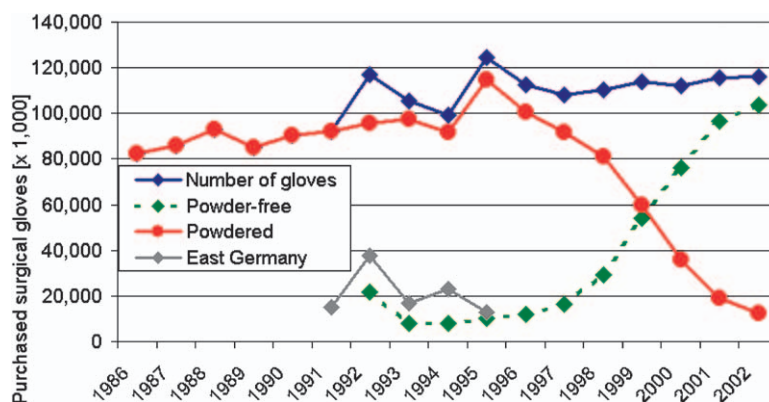


FIG 2. Purchase of sterile surgical NRL gloves in all German acute-care hospitals from 1986 until 2002 split into powdered and powder-free NRL gloves beginning in 1992. Separate data for East Germany were available from 1991 through 1995.

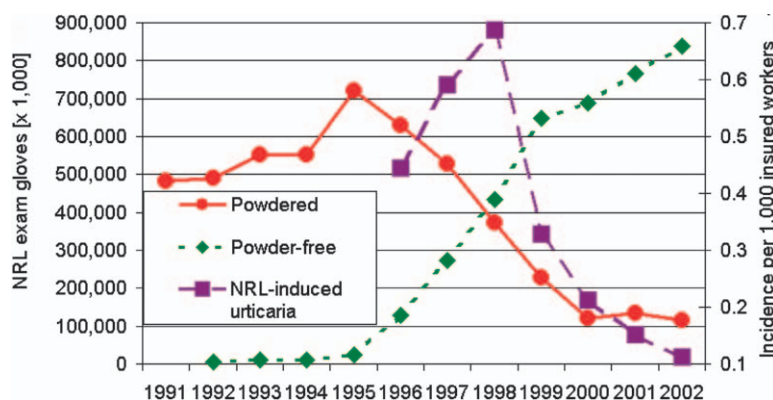


FIG 3. Purchase of nonsterile NRL examination gloves in all German acute-care hospitals plus incidence of suspected cases of NRL-induced contact urticaria per 1000 insured HCWs in private and church-run acute-care hospitals from 1996 through 2002.

powdered gloves began in 1997, and by 2000, the sale of powder-free sterile surgical NRL gloves had overtaken that of powdered gloves for the first time (Fig 2). In 2002, the market share for powder-free sterile surgical NRL gloves had increased to 89.4%. The market share of NRL-free surgical gloves increased from 0.4% in 1986 to 1.42% in 2002.

The incidence of suspected occupational NRL contact urticaria increased from 1996 through 1998 and has since decreased by 79.9% among all insured HCWs (Table I) and 83.6% among workers in acute-care hospitals (Figs 3 and 4). The records for acute-care hospitals show a significant positive linear correlation (Pearson correlation coefficient, $r = 0.983$; $P = .003$) between the purchase of powdered NRL examination gloves and the incidence of suspected contact urticaria cases caused by NRL allergy. The highest incidence of suspected occupational asthma cases among all HCWs caused by NRL was recorded in 1998 (0.15 per 1000 insured HCWs) and had decreased by 82.5% in 2002; among acute-care hospital staff, the incidence peak was reached in 1997 (0.3 per

1000 insured HCWs) and decreased by 87.8% in 2002. Separate data for suspected anaphylaxis were not recorded in the BGW database.

In the study period the number of occupational NRL-induced allergy cases confirmed by means of standardized expert medical evaluations varied between 63.5% and 70.0% (median, 68.5%) of reported cases and decreased by approximately 70% in the period from 1998 through 2002 (Fig 5).

DISCUSSION

The number of powdered NRL gloves purchased in acute-care hospitals in Germany for use in operating theaters and for examination purposes has dramatically decreased since 1996 after a massive increase commencing in 1986. Historically, there were 2 main reasons for the increased use of powdered NRL examination gloves in Germany. First was the increasing environmental pressure to reduce use of polyvinyl chloride gloves because they do

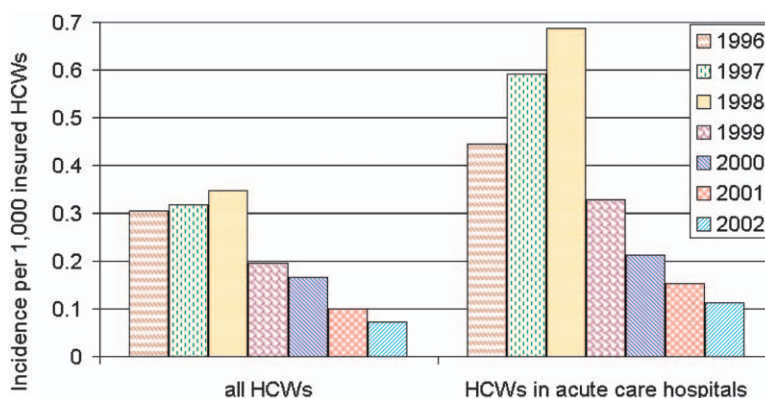


FIG 4. Incidence of suspected NRL-induced contact urticaria cases in BGW-insured HCWs and a subset of HCWs employed in acute-care hospitals.

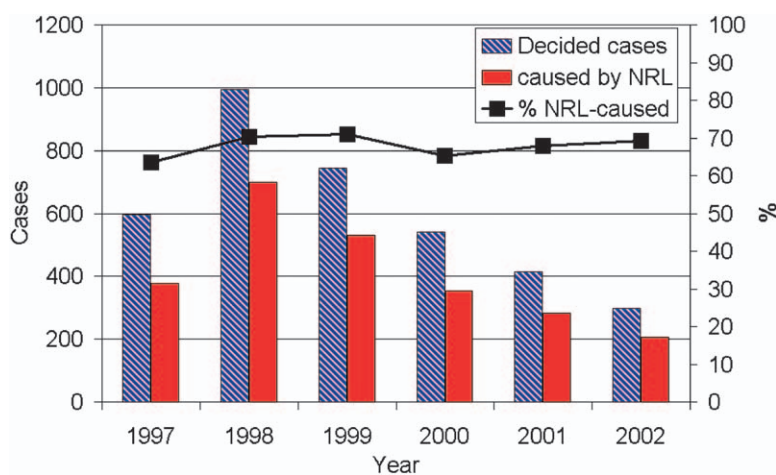


FIG 5. Decided cases of suspected NRL contact urticaria after medicolegal evaluation and number and percentage of confirmed cases of NRL-induced contact urticaria.

not rot well (biodegradability) in landfills and might pose a hazard when burned in incinerators. Second, the need to protect HCWs against HIV and hepatitis infections led to an increased use of powdered NRL examination gloves that reached a peak in the mid-1990s.

Before that time, NRL gloves were used mostly in operating rooms and for sterile procedures. Powder containing high levels of glove protein is suspected to trigger a sensitization to NRL. The accepted secondary prevention in NRL-sensitized individuals, especially HCWs, is to avoid exposure to NRL products because further personal use of latex products or bystander exposure from coworkers might maintain or worsen sensitivity and adverse health effects. It was our hypothesis that the use of powder-free, low-protein NRL gloves would reduce the development of allergic symptoms.

A significant positive correlation between the purchase of powdered NRL gloves and the reported suspected cases of NRL-induced contact urticaria is confirmed by means of statistical analysis and complements our data for NRL-induced occupational asthma previously reported.¹²

The first indication that reduction of powdered NRL glove use in a hospital environment led to a decrease in NRL allergy incidence was published in 1998, when no new cases of sensitization among HCWs in a powder-free environment were found, whereas 2 new cases of positive skin prick test responses could be documented in which use of powdered NRL gloves had been maintained.^{2,3}

The increase in reported cases from 1996 through 1998 is probably caused not only by an increase in the incidence of NRL allergies but also by the information campaign that reached every physician's office in 1997 and 1998. Before that period, knowledge about NRL allergies had been mainly limited to dermatologists who provide most allergy specialists (allergy is only a subspecialty in Germany). With increasing knowledge, general practitioners, as well as surgeons and other physicians, were more likely to identify and report work-related NRL allergies. Therefore we assume that the steady decrease in reported cases from 1998 until 2002 corresponds to a real reduction in the incidence of NRL allergy among HCWs insured by the BGW.

Tarlo and Liss^{13,14} also reported that despite the effect of increasing recognition and reporting, the introduction of gloves with reduced powder, protein, or both, as well as other interventions, has been associated with a decreasing number of cases of NRL-induced occupational asthma in Ontario, Canada.

Recommendations to use powder-free, low-protein NRL gloves or non-NRL gloves have been available (eg, by the Occupational Safety and Health Administration in the United States and other organizations in many other countries).^{8,15}

Reports to date at the level of the individual patient or hospital have shown that these recommendations are successful.^{2,11,16}

Our data for the German health care system show that the incidence of reported suspected cases of NRL-induced contact urticaria has decreased dramatically since 1998; medical evaluations confirmed a high level of accuracy in the reported diagnoses of NRL allergy among HCWs. Thus the decrease in suspected cases reflects a reduction of verified NRL-induced occupational skin disease in HCWs. The regulatory measures calling for complete replacement of powdered NRL gloves with low-protein, powder-free gloves were successful in reaching the intended goal of reducing the development of NRL-induced allergies. Finally, these measures not only lead to long-term benefits for HCWs but also reduce the likelihood of iatrogenically induced severe allergic reactions in NRL-sensitized patients.

We dedicate this paper to the memory of Hans Joachim Schwanitz (August 5, 1952—June 20, 2004), who was the Director of the Department of Dermatology, Environmental Medicine and Health Sciences of the University of Osnabrueck.

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