

A prospective, controlled study showing that rubber gloves are the major contributor to latex aeroallergen levels in the operating room

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Background: Although protocols have been published for reducing natural rubber latex exposure in medical environments, there are no objective data documenting their effectiveness.

Objective: We prospectively studied the impact of a single intervention, substitution of low-allergen-containing latex gloves for high-allergen-containing latex gloves, on latex aeroallergen levels in a single operating room (OR).

Methods: We sampled OR air on 52 consecutive days, including 33 surgery days and 19 nonsurgery days. On each surgery day all personnel wore either high-allergen gloves ($n = 18$ days) or low-allergen gloves ($n = 15$ days). Latex aeroallergen levels (in nanograms per cubic meter) and extractable latex glove allergen contents (in allergen units per milliliter) were measured by inhibition immunoassays. An on-site study monitor recorded the number of gloves used, the total time spent by all patients in the OR each day (OR time), and the total time of all procedures for each day (operating procedure time).

Results: Latex aeroallergen levels during low-allergen glove use days (mean, 1.1 ng/m³; median, 0.9 ng/m³; range, 0.1 to 3.5 ng/m³) were significantly lower than on high-allergen glove use days (mean, 13.7 ng/m³; median, 7.7 ng/m³; range, 2.2 to 56.4 ng/m³) ($p < 0.001$) but not significantly different from that on nonsurgery days (mean, 0.6 ng/m³; median, 0.3 ng/m³; range, 0.1 to 3.6 ng/m³). Latex aeroallergen levels were strongly correlated with the total number of gloves used on designated high-allergen glove days ($r = 0.66$, $p = 0.003$). There was no appreciable day-to-day carryover of latex aeroallergen.

Conclusions: The substitution of low-allergen-containing latex gloves for high-allergen-containing latex gloves can reduce levels of latex aeroallergen by more than 10-fold in an OR environment. (*J Allergy Clin Immunol* 1996;98:325-30.)

Key words: Natural rubber latex allergy, aeroallergens, latex gloves, operating room

Allergy to natural rubber latex is being recognized with increasing frequency among health care workers,¹ rubber glove manufacturing workers,² and certain patient groups (e.g., patients with myelodysplasia or congenital urologic anomalies).³ Preliminary work from our own medical center⁴ and others⁵ indicates that latex aeroallergens can

Abbreviations used

HA:	High-allergen
LA:	Low-allergen
OP:	Operating procedure
OR:	Operating room

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be quantitated immunochemically and that the highest levels occur in medical settings where powdered rubber gloves are frequently donned and discarded during the workday.⁴ The allergen content of rubber gloves varies widely (>3000-fold).^{6,7} In one short-term study, the substitution of synthetic gloves for rubber gloves produced a decrease in the measurable latex aeroallergen level.⁵ We report a longer-term, prospective study of the effect of a single intervention (substitution of low-allergen [LA] latex gloves for high-allergen

TABLE I. Type, brand, number, and allergen content of latex gloves used in the study

	Powdered	No. lots		Total no. of gloves used	Allergen range (AU/ml)
		Used	Tested		
HA					
Sterile surgeon's gloves					
• Baxter Triflex*	+	8	7	500	2,075-10,713
Nonsterile exam gloves					
• Bodyguard†	+	3	3	1207	2,856-31,673
LA					
Sterile surgeon's gloves					
• Biogel‡	—	9	5	98	<75
• HPI Sensi-Grip§	+	6	6	46	<75
• Ansell Orthopedic	+	1	1	44	<75
• Ansell Powder-Free	—	2	2	2	<75
• Sensi-Derm	+	9	5	102	<75
• Maxxus¶	+	7	5	41	368-953
• Medi-Grip	+	1	0	2	NT
Nonsterile exam gloves					
• Safeskin#	—	12	7	482	<75-120

NT, Not tested.

*Baxter Healthcare Corp., Pharmaseal Div. (McGaw Park, Ill.).

†Jason Marketing (Huntington Beach, Calif.).

‡Regent Hospital Products Ltd. (Greenville, S.C.).

§Tillotson Healthcare Corp. (Bedford, N.H.).

||Ansell Inc. (Dothan, Ala.).

¶Johnson & Johnson Medical, Inc. (Arlington, Texas).

#Safeskin Corp. (Boca Raton, Fla.).

[HA] latex gloves) to minimize latex aeroallergen exposure in a hospital operating room (OR).

METHODS

Study setting

With the cooperation of personnel in the Departments of Anesthesia and Urology, we selected for prospective study one OR (24.5 × 20 × 10 feet, 131 m³) in Rochester Methodist Hospital. We installed a high-volume air sampler (3 L/sec), which was programmed to operate continually from 7:30 AM to 7:30 PM. The 52-day study period extended from May to June 1994. A study assistant assigned specifically to this project was stationed in the OR each day that surgery was being conducted; her job was to ensure that all gloves being used were of the proper type and to record the number of gloves used during the workday. For safety reasons, no latex-sensitive patients underwent surgery in this OR, and no latex-sensitive health care workers were assigned to this OR for the duration of the study.

Interventions

All sterile latex surgical and nonsterile latex examination gloves used in the OR were one of two types, LA or HA (Table I), on the basis of previous testing of these brands of gloves.⁶ Only four synthetic (vinyl) gloves were used during the entire study period. The gloves comprising the LA group were gloves that have been in routine

use at Mayo Medical Center since December 1993, when HA gloves were completely phased out of Mayo Medical Center inventory. However, to give personnel a choice of glove types, Mayo Medical Center has attempted to stock several brands of latex examination and surgical gloves. Maxxus gloves (Johnson & Johnson Medical, Inc., Arlington, Texas), despite containing moderate levels of latex allergen, were stocked to preserve this choice of glove type. During the course of this study, on designated LA days, OR personnel wore their usual brand of glove; but on designated HA days, they were encouraged to wear either of the two HA glove brands purchased specifically for this study. One or more lots of all latex gloves used in the study (except Medi-Grip [Ansell Inc., Dothan, Ala.]) were re-assayed to verify the previous findings. Medi-Grip gloves were assigned to the LA group on the basis of testing of previous lots of these gloves (<75 AU/ml).

During the 52-day study period, during which the air sampler was operated daily, there were 33 days during which surgery was being done and 19 days during which no surgery was performed. Each of the 33 surgery days was designated as either an HA or LA glove use day, and all gloved personnel in the study room were asked to use only the assigned glove type. During 5 surgical days when the study assistant was unavailable, the usual and customary gloves (all in the LA group) were used by OR personnel. During the 52-day study period, there were

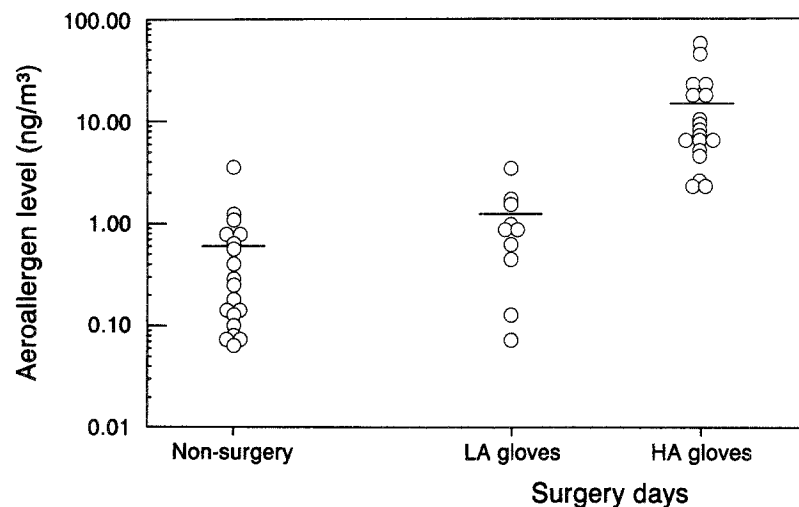


FIG. 1. Mean latex aeroallergen levels during a 12-hour sampling period in an OR during 19 nonsurgery days and during 28 surgery days when either LA ($n = 10$) or HA ($n = 18$) latex gloves were in use.

12 total crossovers from LA to HA gloves or vice versa. Additionally, the total time spent by patients in the room (OR time) and total operating procedure (OP) time were obtained from daily log sheets to estimate activity in the room as other variables for analysis. The OR times and OP times are routinely recorded and were not collected specifically for this study. On each surgery day there were no more than two procedures of varying durations.

Quantitation of latex aeroallergens

The air sampler collected air particles onto polytetrafluoroethylene (Teflon) filters, from which allergens were extracted by using 100 mmol/L phosphate buffer containing 0.2% bovine serum albumin and 0.01% sodium azide. The filter extracts were tested for latex allergen content by a previously described inhibition immunoassay.⁴ Briefly, a solid-phase allergen was prepared by adsorbing a concentrated extract of highly allergenic powdered examination gloves to the wells of microtiter plates. The assay was performed by adding several threefold dilutions of reference standard or filter extract with fixed quantities of a latex-specific IgE antibody pool and the solid-phase allergen. Results were expressed as mass protein per cubic meter of air, on the basis of the protein content of the assay standard (7 mg/ml). The sensitivity of the assay is 2 ng, allowing the detection of 0.1 ng/m³ in 20 m³ of air.

Statistical analysis

Pairwise comparisons of HA glove days versus LA glove days versus nonsurgery days, with respect to the average number of gloves worn and the mean latex aeroallergen level, were performed by using the rank

TABLE II. Glove use, OR time, and OP time during surgical days

	HA glove use days ($n = 18$)	LA glove use days ($n = 10$)	Probability
No. of HA gloves			
Mean	94.8		
Median	74.5	None	
Range	29-238		
No. of LA gloves			
Mean	5.3	72.1	
Median	4	67.5	
Range	0-19	22-160	
Total no. of gloves used			No significant difference $p = 0.24$
Mean	100.2	72.1	
Median	78.5	67.5	
Range	29-254	22-160	
OR time (hr)			No significant difference $p = 0.26$
Mean	4.7	3.7	
Median	4.5	3.6	
Range	0.8-8.8	0.7-6.6	
OP time (hr)			No significant difference $p = 0.28$
Mean	3.4	2.7	
Median	3.2	2.7	
Range	1.1-7.6	0.2-5.7	

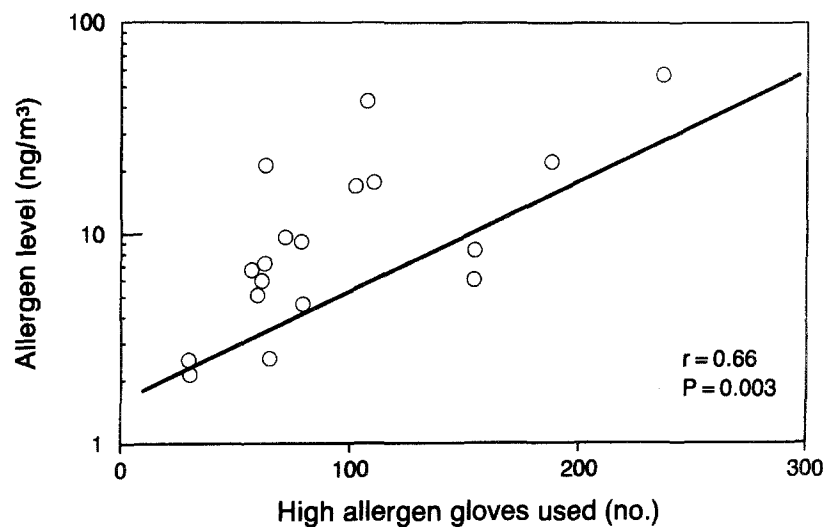


FIG. 2. Correlation between number of latex gloves used and mean latex aeroallergen levels during a 12-hour sampling period in an OR during 18 days when HA latex gloves were in use.

sum test. Spearman's rank correlation was used to assess the association of latex aeroallergen level with the total number of gloves used, the number of HA gloves used, the number of LA gloves used, OR time, and OP time. This analysis was limited to those days on which the OR was used for surgery and the study assistant was present. Multivariate stepwise linear regression was used, with a log transformation of the aeroallergen level, to identify a subset of independent predictors of aeroallergen level. Factors considered as potential predictors included the total number of gloves used, glove type (HA vs LA), OR time, and OP time. A stepwise backward algorithm was used to eliminate nonsignificant variables. In all cases two-sided tests were used, and *p* values less than or equal to 0.05 were used to denote statistical significance.

RESULTS

Compliance

There were no instances in which OR personnel used HA gloves during the 10 days designated for LA glove use (Table II). During the 18 days designated for HA glove use, only 5.3% of 1803 total gloves used were LA gloves. The number of gloves used on LA glove days was not statistically different than on HA glove days. Neither OR time nor OP time was significantly different for HA glove days versus LA glove days.

Latex aeroallergen levels

Latex aeroallergen levels on HA glove days (mean, 13.7 ng/m³; median, 7.7 ng/m³; range, 2.2 to 56.4 ng/m³) were significantly higher than on LA glove days (mean, 1.1 ng/m³; median, 0.9 ng/m³;

range, 0.1 to 3.5 ng/m³) (*p* < 0.001) (Fig. 1). Aeroallergen levels on HA glove days were also significantly higher than on nonsurgical days (mean, 0.6 ng/m³; median, 0.3 ng/m³; range, 0.1 to 3.6 ng/m³) (*p* < 0.001). Although aeroallergen levels on LA glove days were slightly higher than on nonsurgical days, this difference did not achieve statistical significance (*p* = 0.07). Moreover, aeroallergen levels on HA glove days were strongly associated with the number of HA gloves used (*r* = 0.66, *p* = 0.003) (Fig. 2) but not with the total number of gloves used on LA glove days (*r* = 0.18, *p* = 0.62) (data not shown). When HA and LA glove use days were considered together, aeroallergen level was found to be associated with the total number of gloves used (*r* = 0.47, *p* = 0.012), OR time (*r* = 0.52, *p* = 0.004), and OP time (*r* = 0.48, *p* = 0.010). Finally, when the four variables (glove type, total number of gloves used, OR time, and OP time) were considered multivariately, glove type and OR time emerged as independent factors associated with latex aeroallergen level.

To explore whether there was any carryover of latex aeroallergen after consecutive days of HA glove use, we plotted latex aeroallergen levels on each of the 52 study days (Fig. 3). There was no discernable tendency for aeroallergen levels to rise during consecutive days of HA glove use, and aeroallergen levels consistently declined on nonsurgical or LA glove use days that immediately followed an HA glove use day.

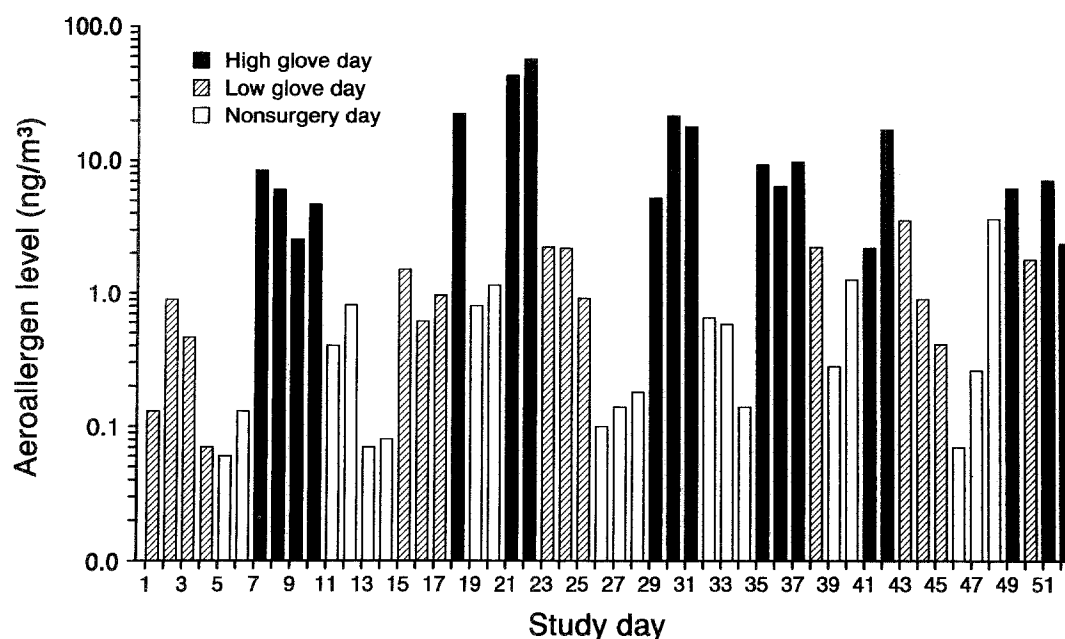


FIG. 3. Mean latex aeroallergen levels during a 12-hour sampling period for each of the 52 study days and types of gloves used on surgical days.

DISCUSSION

In this study, through multivariate analysis, we were able to show that the use of gloves containing low levels of latex allergen is associated with significant reductions in latex aeroallergen levels in a typical OR setting. We also showed that there was a strong correlation between latex aeroallergen levels and the number of HA gloves used; this correlation could not be demonstrated when LA gloves were used. As one would expect, there was also a strong correlation between aeroallergen levels and the total time that the OR was occupied by a patient (OR time), a reflection of room activity, especially on HA glove use days.

The threshold of latex allergen required for sensitization and symptom provocation is currently unknown. In a recent unblinded but controlled study by Vandenplas et al.,⁸ eight latex-sensitive nurses or physicians underwent graded inhalation challenge testing with various powdered or powder-free surgical gloves. All subjects exhibited a fall in FEV₁ of greater than 20% after exposure to high protein content gloves, whereas only two subjects reacted to this degree after challenge with "hypoallergenic" lower protein content gloves. Because our data show a reduction in latex aeroallergen to near-background levels on LA glove use days, mere substitution of LA gloves for HA ones should minimize latex-induced asthma and allergic

rhinoconjunctivitis in many latex-sensitized health care workers.

The study does not address the issues of contact urticaria and contact dermatitis in sensitized health care workers or the issue of intraoperative anaphylaxis in latex-sensitized patients undergoing surgery. Strict latex-free precautions should continue to be taken to prevent cutaneous, mucosal, and serosal contact with rubber in latex-sensitive persons.

We believe that rubber glove allergen content is the most important determinant of latex aeroallergen levels in the surgical setting. That other factors are present is suggested by the positive correlation of aeroallergen level with both the total number of gloves used, regardless of type, and the independent variable of OR time and by the finding of 4 ng/m³ latex aeroallergen on day 48, a nonsurgical day. Our data indicate that changing to LA gloves alone would not be sufficient to create a truly latex aeroallergen-free environment and that there are other sources of latex, such as importation of allergen from less restricted sites, either on clothing (e.g., scrub suits) or on equipment and supplies brought into the OR during surgical procedures. Perhaps switching to powder-free latex gloves would further reduce latex aeroallergen levels,^{5,6} although this intervention was not addressed in this study. Our findings suggest that there is little

carryover of latex aeroallergen from one day to the next in this study setting. Latex aeroallergen levels in various work areas of the medical center are presently being measured as a follow-up to a previous study.⁴

We conclude that substantial reductions in latex aeroallergen levels (>10-fold) can be achieved by a single intervention, the substitution of LA rubber gloves for HA rubber gloves. Similar studies should be performed to document the efficiency and cost-effectiveness of published latex reduction protocols that emphasize wholesale removal of all rubber-containing items in ORs.^{9, 10}

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