

Latex allergen contents of rubber gloves packaged in sterile medical kits and trays

Richard T. Jones, BS,^a Terry W. Lobland, BA,^b Donald R. Scheppmann,^{b†} and John W. Yunginger, MD^{a,c} Rochester, Minn

Latex allergy is a leading cause of occupational rhinitis and asthma in health care workers.¹ Natural rubber gloves, particularly powdered gloves, are the major reservoir of latex aeroallergens.² To decrease exposure of

patients and employees to latex allergens, our medical center phased out the purchase and use of high-allergen brands of gloves in 1993.³ However, many sterile medical kits and trays come packaged with gloves already inside. This 2-year, prospective study was conducted to compare the latex allergen contents of these gloves with those of gloves supplied in stand-alone cartons, with a view to identifying and eliminating any additional sources of latex allergens in our medical center.

METHODS

A selection of sterile kits and trays was obtained from the Mayo Medical Center inventory on 3 occasions in January 1996, July

From ^athe Allergic Diseases Research Laboratory, ^bthe Division of Materials Management, and ^cthe Department of Pediatric and Adolescent Medicine, Mayo Medical Center, Rochester.

†Deceased.

Reprint requests: John W. Yunginger, MD, Allergic Diseases Research Laboratory, Mayo Medical Center, 200 First St SW, Rochester, MN 55905.

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TABLE I. Latex allergen levels in gloves packaged in sterile trays and kits at 3 time points during 1996 and 1997

Category	Item	January 1996	
		Supplier	AU/mL
Suction kits	Suction kit w/catheter, 14FR	Professional Med. Prod.	<100
	Suction kit w/catheter, 12FR	Professional Med. Prod.	<100
	Suction kit w/catheter, 10FR	Professional Med. Prod.	<100
	Suction kit w/catheter, 8FR	Professional Med. Prod.	<100
	Suction kit w/catheter, 6.5FR	Professional Med. Prod.	<100
	Suction catheter kit 14FR	Kendall Healthcare Prod.*	<100
Urethral catheterization kits	Catheter suction kit 14FR	Baxter Healthcare Corp	260
	Urethral catheter tray, vinyl 14FR	Medline Industries Inc	<100
	Argyle urethral catheter tray, 14FR	Sherwood Medical	<100
	Urethral catheter tray, plastic, 14FR	Baxter Healthcare Corp	5700
	Urethral catheter tray, rubber, 14FR	Baxter Healthcare Corp	330
	Foley tray, 18FR	C. R. Bard Inc	1800
	Foley tray w/o catheter	C. R. Bard Inc	<100
	Urethral catheter tray w/o catheter	C. R. Bard Inc	240
	Urine meter Foley tray, 16FR	C. R. Bard Inc	320
	Urotrack Plus Foley tray	C. R. Bard Inc	<100
	Foley tray w/sampling port, 16FR	C. R. Bard Inc	150
	Urethral catheter tray, 16FR	C. R. Bard Inc	<100
	Urine meter Foley tray w/sampling port, 16FR	C. R. Bard Inc	540
Vascular access kits	Mahurkar dual lumen catheter, 11.5FR × 19.5 cm	Quinton Instrument Co	720
	Flexxicon II PC dual lumen catheter, 20 cm	Not tested	
	Mahurkar dual lumen catheter, 11.5FR × 16 cm	Quinton Instrument Co	<100
	Mahurkar dual lumen catheter, 11.5FR × 13.5 cm	Quinton Instrument Co	280
Miscellaneous kits	Flexxicon II PC dual lumen catheter, 12.5 cm	Not tested	
	Catheter prep tray for peritoneal dialysis	Baxter Healthcare Corp	440
	Kit isolation PAR	Baxter Healthcare Corp	16,000
	Mortuary pack	Baxter Healthcare Corp	36,000
	Cytotoxic drug spill kit	Sherwood Medical	<100
	ChemoBLOC chemotherapy prep/admin kit	Not tested	
	Vaginal prep kit	Becton Dickinson AcuteCare	450
	Skin prep kit	Becton Dickinson AcuteCare	870
	Central catheter site care (PICC) kit	Sterile Concepts*	<100
	IV site care kit w/transparent dressing	Sterile Concepts	<100
	IV site care kit w/gauze	Sterile Concepts	<100

Suppliers are Professional Medical Products Inc, Greenwood, SC; Baxter Healthcare Corp, Deerfield, Ill; Becton Dickinson AcuteCare, Franklin Lakes, NJ; Clinipad Corp, Norwich, Conn; C. R. Bard Inc, Covington, Ga; Sterile Concepts, Richmond, Va; Maxxim Medical, Clearwater, Fla; Quinton Instrument Co, Bothell, Wash; Vas-Cath Inc, Mississauga, Ontario, Canada; Medline Industries Inc, Mundelein, Ill; Kendall Curity or Kendall Healthcare Products, Mansfield, Mass; U. S. Clinical Products, Plano, Tex; and Sherwood Medical, St. Louis, Mo.

*Label specifies synthetic or nonlatex gloves.

1996, and December 1997. These kits and trays were in routine use and had not been purchased on the basis of the allergen contents of the gloves contained therein.

PBS extracts (1:5 wt:vol) of these gloves were tested for their total extractable latex allergen contents by inhibition immunoassay⁴ with an in-house solid-phase allergen, pooled IgE-containing sera from several latex-sensitive health care workers, and a nonammoniated latex standard (assigned potency = 100,000 Allergy Units [AU]/mL) kindly provided by the Center for Biologics Evaluation and Research of the Food and Drug Administration.

RESULTS AND DISCUSSION

The allergen contents of the gloves in 87 sterile kits and trays are shown in Table I. Allergen levels ranged from nondetectable (<100 AU/mL) to 36,000 AU/mL, which was comparable to levels found in a previous study of disposable medical gloves.⁴ In many cases it was not possible to determine from the package labeling whether the glove was powdered, lightly powdered, or powder-free. Allergen levels in gloves from the same kit manufacturer were less variable than allergen levels in gloves in kits from different manufacturers. For example,

latex allergen levels in gloves from suction catheter kits from Professional Medical Products were consistently low throughout the study period. However, a change in the supplier of sterile suction kits from Professional Medical Products (1996) to Kendall Curity (1997) was accompanied by an 8-fold to 30-fold increase in the allergen levels in gloves from these kits.

Although the gloves supplied with sterile kits and trays were usually wrapped in their own packaging, a few kits contained unwrapped gloves. When these gloves were powdered and contained high levels of latex allergens, the allergen-coated powder could easily contaminate the other components of the kit, increasing the chances of triggering an allergic reaction in latex-sensitive individuals. An even more disturbing finding was that latex allergen-containing gloves (containing up to 500 AU/mL of extractable allergen) were occasionally found in central catheter site or intravenous site care kits from Sterile Concepts or Maxxim Medical, even though the kits were labeled as containing nonlatex or synthetic gloves. Gloves from 2 other lots of Maxxim Medical IV

July 1996		December 1997	
Supplier	AU/mL	Supplier	AU/mL
Professional Med. Prod.	<100	Kendall Curity	2000
Professional Med. Prod.	<100	Professional Med. Prod.	190
Professional Med. Prod.	<100	Professional Med. Prod.	<100
Professional Med. Prod.	140	Kendall Curity	1000
Professional Med. Prod.	<100	Kendall Curity	3100
Kendall Healthcare Prod.*	<100	Kendall Healthcare Prod.*	<100
Baxter Healthcare Corp	14,000	Baxter Healthcare Corp	1800
Medline Industries Inc	<100	Medline Industries Inc	1100
Sherwood Medical	<100	Not tested	
Baxter Healthcare Corp	8600	Baxter Healthcare Corp	9600
Baxter Healthcare Corp	540	Kendall Curity	2900
C. R. Bard Inc	1700	C. R. Bard Inc	<100
C. R. Bard Inc	360	C. R. Bard Inc	130
C. R. Bard Inc	260	C. R. Bard Inc	<100
C. R. Bard Inc	<100	C. R. Bard Inc	190
C. R. Bard Inc	140	C. R. Bard Inc	130
C. R. Bard Inc	<100	C. R. Bard Inc*	<100
C. R. Bard Inc	<100	C. R. Bard Inc	110
C. R. Bard Inc	580	C. R. Bard Inc	<100
Not tested		Not tested	
Vas-Cath Inc	350	Vas-Cath Inc	400
Not tested		Vas-Cath Inc	260
Not tested		Not tested	
Vas-Cath Inc	530	Not tested	
Baxter Healthcare Corp	110	Baxter Healthcare Corp	190
Baxter Healthcare Corp	8000	Not tested	
Baxter Healthcare Corp	12,000	Not tested	
Not tested		Not tested	
U. S. Clinical Products Co	<100	U. S. Clinical Products Co	<100
Becton Dickinson AcuteCare	1100	Clinipad Corp	980
Becton Dickinson AcuteCare	930	Clinipad Corp	830
Sterile Concepts*	500	Maxxim Medical*	450
Not tested		Maxxim Medical*	380
Sterile Concepts	140	Maxxim Medical*	350

site care kits were retested in March 1998 and contained undetectable latex allergen (<100 AU/mL), but gloves from a second and third lot of Maxxim Medical central catheter site care kits (PICC kit) also contained measurable allergen (307 AU/mL and 392 AU/mL). The manufacturer of these kits were notified of our findings and are conducting an investigation.

We conclude that all gloves packaged in sterile medical kits and trays should be powder-free (to avoid having allergen-coated powder distributed to other kit components), should be packaged in their own wrapper, and should be clearly labeled as being latex or nonlatex. As of September 30, 1998, the Food and Drug Administration will require that medical devices containing natural rubber latex be labeled as containing natural rubber. If the identity, allergen content, or the manufacturer of gloves in sterile kits or trays is unknown, the gloves

should be discarded unused, and positively identified gloves of known lower allergen content should be substituted. Kits containing "loose" gloves should not be manufactured, distributed, or used.

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