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Critique of the multicenter latex skin testing efficacy study

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To the editor:

We read with great interest Hamilton et al's accounting of the clinical evaluation of the Greer latex antigen preparation (J Allergy Clin Immunol 1998;102:482-90). This much-awaited publication addresses the safety and diagnostic efficacy of a reagent, which if effective, could fill a serious clinical need. To their credit, the authors described a protocol that included such methodologic safeguards as double-blinded skin testing and proficiency standards for testers. Nevertheless, as reported, the study leaves a number of questions unanswered.

One concern is the ambiguous and sketchy manner in which the procedure for recruiting and classifying subjects was described. Exclusion criteria were clearly spelled out, whereas inclusion criteria were left to the reader's imagination. According to the authors, "...the primary investigator assigned each subject to 1 of 3 groups...on the basis of each subject's clinical history...." We did not find this to be a clearly reproducible methodology.

The authors explicitly state that the "gold standard" for the diagnosis of latex allergy was the glove provocation test. Under conventional usage of the term "gold standard," this would imply that all subjects had undergone provocation testing before being classified as having

latex allergy (LA) or no latex allergy (NLA).¹ However, as best we can determine this was not the case: the test appears to have been applied selectively and on a post hoc basis. On the basis of negative glove provocation test responses, 24 subjects whose clinical histories were suggestive of LA, but whose puncture skin test (PST) responses were negative, were reclassified from LA to NLA. This maneuver substantially reduced the number of “false-negative” PST results relative to the original historical classification, boosting the calculated sensitivity of the test. On the other hand, any effect that glove provocation testing would have had on the classification of subjects with concordant histories and PST results remains purely speculative.

Another problematic point was the elimination of subjects who reported only acute dermal symptoms during and after use of latex gloves (referred to in the article as the “contact dermatitis” or “CD” group). The authors even went so far as to classify these patients—who had reported skin symptoms on their questionnaires—as “sensitized but asymptomatic.” In our clinic (like many others), skin symptoms are a more frequent presenting complaint among latex-exposed health care workers than are respiratory symptoms. If, as some have suggested, coincident skin and respiratory tract allergy represent a more advanced stage of sensitization than dermal allergy alone, exclusion of the contact dermatitis group from this analysis alters the apparent sensitivity and specificity of the test reagent, neglecting persons with early, symptomatic sensitization for whom intervention may help salvage a working career.

On a final note, we are concerned that the use of the term “contact dermatitis” to describe acute, latex-related skin symptoms may be misleading. The term “contact dermatitis” implies either allergic contact dermatitis (Type IV allergy or delayed hypersensitivity) or irritant contact dermatitis. “Contact urticaria,” on the other hand, is used to describe the acute erythema, pruritus, and urtication characteristic of Type I allergy to natural rubber latex.

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Reference

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