



Latex Content in Adult Vaccines

Maj Julie A. Davenport, MD, Robert Gomez, BS and Maj Derek M. Smith, MD
Wilford Hall Ambulatory Surgical Center, Joint Base San Antonio- Lackland AFB, TX

Introduction

Hypersensitivity reactions to natural rubber latex are well-characterized occupational concerns for health care personnel. The prevalence of latex allergy among health care providers is reported to be as high as 9.7%. The symptoms range from mild local cutaneous reactions to generalized urticaria, angioedema, allergic rhinitis, respiratory symptoms, and even life-threatening or fatal anaphylaxis. Health care providers are also at increased risk for exposure and possibly transmission of vaccine preventable diseases. Therefore, many health care facilities require providers to be vaccinated against these diseases to maintain employment. Specifically, hepatitis B and Tdap vaccinations are recommended by the Center for Disease Control for healthcare workers. Many of these vaccines come in single dose prefilled syringes whose packaged inserts have warning that state “the tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions.” The Advisory Committee on Immunization Practices and the Adverse reaction to vaccine practice parameter 2012 update, recommends that if a person has a history of a severe anaphylactic reaction to latex, then vaccines supplied in vials or syringes should be avoided.

Material and Methods

The goal of our pilot study was to quantify the natural rubber latex content in adult vaccines containing latex tip caps on their prefilled syringes, and paying particular attention to those recommended for health care professionals. Using a commercial Latex Allergen ELISA Assay kit for Hev b 1 (FITkit b1 manufactured by Icosagen AS), we evaluated the latex content of HAVRIX, ENGERIX-B, TWINRIX, and BOOSTRIX all manufactured by GlaxoSmithKline. Vaccines were tested undiluted and at 1:10 dilutions. These data were compared with the standard curve and kit positive control 169ng/ml (reference range 139-173 ng/ml). The limit of detection of the FITkit assay is <= 2.0 ng/ml.



Vaccine	Number of lots tested	Hev b 1 content (ng/ml)	Lot number
HAVRIX (GlaxoSmithKline)	2	<2.0 LIMITED OF DETECTION	4H37Y PZ353
ENGERIX-B (GlaxoSmithKline)	2	< 2.0 limit of detection	9X9ZT FT42N
TWINRIX (GlaxoSmithKline)	1	<2.0 limit of detection	53A15
BOOSTRIX (GlaxoSmithKline)	2	<2.0 limit of detection	XJ5L2 4P9CL



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Results

Results are presented in the table. These data demonstrate undetectable Hev b 1 content among all of the vaccines tested. This study provides the first known data quantifying natural rubber latex content in adult vaccines. There are two main limitations to our study that should be addressed. First, not all adult vaccines with natural rubber latex caps were tested due to vaccine access, supply, and financial limitations. However, results were consistent and reproducible among the individual vaccines and lots which were tested. Another limitation is that we did not test all of the known natural rubber latex allergens. A prior study in Europe found that Hev b1 was the most detectable single allergen found in different household products. We decided to evaluate Hev b 1 alone as an initial screen for natural rubber latex content. We plan to expand our study to test for Hev b 5, and Hev b 6.02 which are considered major allergens found in health care workers, keeping in mind that ultimately the only relevant “major allergen” is the one to which any one particular person is sensitized.

Conclusions

In conclusion, our study revealed undetectable levels of the natural rubber latex allergen Hev b 1 in the tested adult vaccines. It would be premature to claim that these vaccines are currently safe to use in latex allergic patients. We suspect that since Hev b 1 was undetectable, other known natural rubber latex allergens would also be undetectable. These data provide evidence for further laboratory research and prospective human trials into the safety of vaccinating latex allergic patients

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*The opinions or assertions herein are the private views of the authors and are not to be construed as reflecting the views of the Department of the Air Force or the Department of Defense.

Title: A Novel Activation-induced Cytidine Deaminase (AID) Mutation in an Adult with Hyper-IgM Syndrome (HIMS)

Introduction: Our objective was to confirm our patients Hyper-Immunoglobulin M Syndrome (HIMS) to direct therapeutic and prognostic discussion. The heterozygous mutation and affected parent and children support an autosomal dominant inheritance of a dominant-interfering mutation in the AICDA gene. We hope to show this biochemically with other collaborators.

Case Description: A 38-year old female with asthma, COPD, and an undiagnosed immunodeficiency was transferred to us for ECMO therapy. She initially presented to an outside ER with multi-lobar pneumonia requiring intubation, but developed refractory hypoxemia and hypercarbia resulting in her transfer. A medical review revealed a history of recurrent infections, hospitalizations, and intubations in recent years with intermittent intravenous immunoglobulin (IVIG) therapy. Additionally, her two sons had recurrent severe infections and were recently genetically diagnosed with HIMS at an outside hospital. She received 40 gm 10% IVIG, ECMO, and piperacillin/tazobactam. Her labs revealed IgG = <300 mg/dL, IgA <50 mg/dL, and an elevated IgM = 767 mg/dL. Her flow cytometry revealed a normal T-cell population, extended B-cell flow revealed normal numbers of CD19 cells but reduced CD27+, reduced CD38+IgM-, and elevated CD19+IgM+ cells.

Treatment Plan: The patient responded well to therapy. She was extubated after two weeks, and antibiotics and ECMO were discontinued. She is planned to restart routine IVIG with her immunologist.

Discussion: We report a novel familial AID mutation in HIMS not previously published. This mutation resulted in fewer opportunistic infections, autoimmune diseases, or malignancies, which can occur in XHIMS with need for bone marrow transplant.

References

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