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Perioperative Anaphylaxis After Insertion of a Latex Drain in a Patient with Known Latex Allergy

August 31, 2022
Kelly KJ. Perioperative Anaphylaxis After Insertion of a Latex Drain in a Patient with Known Latex Allergy. PSNet [internet]. 2022.
https://psnet.ahrq.gov/web-mm/perioperative-anaphylaxis-after-insertion-latex-drain-patient-known-latex-allergy

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Patrick Romano, MD; MPH, Debra Bakerjian, PhD, APRN, RN; Kevin J. Kelly, MD; and Amy Nichols, EdD, RN for this Spotlight Case and Commentary have disclosed no relevant financial relationships with commercial interests related to this CME activity.

Learning Objectives

At the conclusion of this educational activity, participants should be able to:

- Understand the history, epidemiology, cause of latex allergy and the reason that some individuals continue to be at high risk of allergic reactions or sensitization.
- Describe the risk to patients with latex allergy from contact with latex products in the hospital and operating room.
- Discuss the process for assuring latex avoidance in patients with latex allergy.
- Reinforce the principles of identification and treatment of anaphylaxis in the hospital and perioperative setting.

- Appreciate the importance of patient's self-identification of latex allergy.
- Understand risk factors associated with allergic sensitization to latex proteins.
- Describe hospital safety practices that will eliminate or limit the risk of exposure to latex products that are most likely to cause problems in latex-allergic patients.

The Case

A 65-year-old female with a documented allergy to latex underwent cricopharyngeal (CP) myotomy and trans-cervical diverticulectomy for a right-sided Zenker's diverticulum. The patient was stable after rapid sequence intubation and maintenance of anesthesia with methohexital, fentanyl, and a neuromuscular blockade agent. No antibiotics were administered during the procedure. There were no adverse events and surgery to repair the diverticulum was uneventful. Near the conclusion of surgery, a latex Penrose drain was placed in the neck surgical incision. The patient developed generalized urticaria, bronchospasm requiring high airway pressures to achieve ventilation, and hypotension within 5 minutes of placement of the drain. The drain was removed and replaced with a silicone drain. Epinephrine 0.3 mg IM, IV saline, and vasopressors were administered post-operatively to the patient with resolution of symptoms. She was later extubated and was hemodynamically stable.

The Commentary

By Kevin J. Kelly, MD

This case represents a common event that frequently occurred in the hospital and especially the operating room in patients with allergy to natural rubber latex (referred to as "latex" throughout the manuscript) from 1990 through 2010,[1-9] a period during which latex-containing products were ubiquitous in health care facilities. Recognition of latex allergy as an important problem led to many practice improvements and a decreased incidence of anaphylaxis, but life-threatening anaphylactic responses can and do still occur.

Strict attention to the risk of latex products represents an opportunity to improve health system safety in two ways. The first is through prevention of latex allergy in workers and patients by reduced exposure to allergenic proteins contained in latex. The second is through elimination of the use of latex products and substitution with appropriate non-latex products in patients who are known to have latex allergy.[10-14]

Despite numerous advances in the reduction of patient sensitization by minimizing exposure, inadvertent exposure to latex products remains a problem in the healthcare setting.[15-17] Latex allergy continues to be among the top three causes of serious allergic reactions in the perioperative period. Neuromuscular blocking agents, antibiotics, quaternary ammoniated anesthetics, narcotics, and chlorhexidine constitute the other major causes of anaphylaxis in the perioperative period, with a combined incidence of 1 in 3,500 to 1 in 20,000 cases.[18-19] In the largest published series, with 1816 reports of perioperative anaphylactic reactions from France, the most commonly implicated drugs were neuromuscular blocking agents (n=1067), latex (n=361), and antibiotics (n=236).

The team in this case quickly recognized the inciting event (direct contact of mucosa and/or tissues with a latex product). They removed the offending agent and intervened with the standard medications and care

of a patient with anaphylaxis, resulting in an excellent patient outcome. However, the event must be considered preventable, given that the patient had a documented history of latex allergy. The marked reduction in the number of patients sensitized to retained proteins in latex-finished products over the past two decades may lead to relaxed attention when an individual identifies to the medical team as allergic to latex. Although medical history checklists may easily identify such individuals, inadvertent lapses in reviewing these checklists and lack of knowledge concerning latex-containing products in current use (e.g., Penrose drains) may lead to significant morbidity or mortality that should be avoidable. Positive responses to standard questions asked prior to anesthesia about a history of latex allergy should immediately trigger “latex avoidance” in these patients. A list of common products containing latex should be readily available for physicians, nurses, and technicians to review. Alternative non-latex products should be substituted for latex products during medical and surgical care in these patients.

Background

What is latex and why would a plant make such a product?[20]

Latex is an intracellular cytosol that is secreted and flows in the circulation system of lactifer plants, which make up 20% of all plants. Latex is essential to these plants to heal surface injuries and create immune responses against invading organisms that might otherwise kill the plants. It has been estimated that over 40,000 manufactured products may contain natural rubber latex derived from the rubber tree *Hevea Brasiliensis*. As much as 60% of all-natural latex is used to manufacture tires. However, multiple medical products still contain latex with allergenic proteins that may cause anaphylaxis upon contact.

Why is latex used in the medical field?

Circulating rubber particles in lactifer plants are made from polymers of cis-1,4 polyisoprene. Extensive cross-linking of the isoprene molecules leads to one of the best impermeable barriers created. Latex is harvested for its cis-1,4 polyisoprene which may be cross-linked by heating to form an impermeable barrier to water, bacteria, and viruses. In addition to its barrier properties, latex has high tensile strength when stretched, resists tearing, and returns to its original shape without significant alteration after stretching. These characteristics made latex an ideal product for use in many industries, including healthcare.

Access to latex products became critical in healthcare to prevent transmission of bloodborne pathogens such as hepatitis and HIV in the 1980s. Efforts to improve safety of patients and workers led to the introduction of Universal Precautions (now known as “Standard Precautions”) to prevent human-to-human transmission of disease. This led to an exponential increase (over 100-fold) in the manufacture and use of examination gloves by individuals in healthcare and other occupations. The temporal relationship between increased latex examination glove use and sensitization to latex, followed by reduction in sensitization and occupational latex allergy when the use of non-latex gloves became widespread, suggests that latex gloves were the major cause of this disease. However, the general population appears to be still at risk, and vigilance in their care is necessary.

About 90% of finished products made with latex, such as rubber tires, are heat vulcanized at high temperatures for prolonged periods of time. This results in many of the proteins being destroyed or

denatured such that the allergen content of these products is low and less likely to cause an allergic reaction in a sensitized individual. Conversely, many latex products made by a dipping process (e.g., condoms or gloves manufactured on a porcelain form) are heat vulcanized at lower temperature for a short duration of time. This results in a final product with intact proteins that may be highly allergenic to humans.[20]

Why do individuals develop latex allergy?

Humans do not become allergic to the polyisoprene component of latex. Rather, immunoglobulin E (IgE)-mediated hypersensitivity develops to a subset of the over 200 polypeptides found in extracts of latex. Fifteen of these polypeptides (Hev B 1-15) have been classified by the WHO/IUIS Allergen Nomenclature committee as allergenic to humans.[2, 20] Many of these proteins easily wash out of finished products when contacting fluids, leading to skin or mucosa exposure in patients and workers (especially healthcare workers). Irritant and/or contact hand dermatitis also increases exposure on the skin of glove users, resulting in sensitization to latex allergens. Additionally, secondary lubricants used for easy donning of wearable latex products (e.g., exam gloves), such as cornstarch powder, may lead to airborne exposure to proteins absorbed onto the powder, resulting in mucosal (eye, nose, and lung) reactions in sensitized subjects. Many advances in manufacturing, such as using alternative lubricants (e.g., halogenation) and extracting harmful allergens by washing or other mechanisms, have made these products safer.

Which individuals are susceptible to developing IgE mediated allergy to latex products and why?

This disease reached epidemic proportions in specific groups[5-8, 21-34] during the early identification of this disease, including up to or about 5% of patients who had multiple surgeries, 10-17% of health care workers, and 70% of patients with spina bifida. Table 1 summarizes the major occupations, patient diseases, and immunologic susceptibilities that put some individuals at high risk for developing this hypersensitivity. Condom use may also be a risk factor. Approximately 1% of the general population may develop latex allergy.

Table 1: Populations Susceptible to Latex Allergy

Occupations	Medical Diseases	Immune Susceptibility

Health care workers Hairdressers Painters Food handlers Security personnel Florists	Spina bifida Prematurity Urogenital anomalies Tracheoesophageal fistula Patients with multiple surgeries Ventriculoperitoneal shunt Type 1 diabetes (insulin injection)	Atopic individuals Food allergic individuals Contact dermatitis Irritant dermatitis

Approach to Improving Safety and Patient Safety Target

When the increasing incidence of latex allergy was initially identified, low temperature heat-vulcanized products had an extremely high content of allergenic proteins resulting in IgE sensitization and subsequent typical allergic reactions of urticaria, angioedema, pruritis, bronchospasm and associated chest tightness, rhinitis, conjunctivitis, and anaphylaxis. However, cutaneous and respiratory signs and symptoms may be difficult to recognize in the anesthetized patient, who may be covered by surgical drapes and unable to communicate with the healthcare team. Thus, unexplained hypotension, tachycardia, and high airway pressure for adequate ventilation (due to bronchospasm) are key findings that anesthesiologists must recognize for prompt treatment.

Changes in production processes and substitution of alternative non-latex products (e.g., nitrile examination gloves) have led to a steady reduction in allergic sensitization and allergic reactions in sensitized patients.[20] These public health actions to prevent latex allergy sensitization and allergic reactions in developed countries have been highly successful. However, economic challenges and limited medical infrastructure have resulted in less success in countries where resources are more constrained.[2]

The optimal care of latex-allergic patients may be best described as “latex-safe” care instead of “latex-free” care. For example, a latex-allergic patient may safely use a wheelchair with high-heat vulcanized tires. Although direct skin contact with the tires is discouraged, an allergic reaction from brief skin contact with the tires is likely to be a rare event for a latex-allergic patient. An institution may still use these wheelchairs, resulting in a “latex-safe” environment, but it is technically not a “latex-free” environment. Restrictions of cornstarch powdered latex products resulted in a marked reduction or elimination of allergic reactions in latex-allergic patients.[11,14,35] During the early years after latex allergy was first described, patients with latex allergy were prioritized to be the first surgical case of the day. Removal of powdered latex products

from the operating room the night before an operation allowed clearance of airborne allergen in the room. Ultimately, the switch to synthetic (neoprene or butadiene) examination gloves and exclusion of individually packaged latex surgical gloves have made operating room care safer throughout the day. Latex-safe care refers to the elimination of sources of airborne latex and prevention of patients' skin or mucosal contact with low heat vulcanized latex products (e.g., Penrose drains). If medical personnel are unclear about the allergen content of a latex product, exclusion from use is prudent.

Medical products that touch patients are required to contain a label denoting the presence of latex. Procedures to eliminate these products from direct contact with latex-allergic patients require policies and procedures in medical settings. It is often necessary to have the highest leadership in the healthcare setting convene a latex allergy committee to oversee policies and procedures that will promote the safe care of these patients. Standard intake questions about latex allergy, latex-safe protocols, and substitution of non-latex products have all contributed to a safer healthcare environment.

The belief that latex allergy has disappeared in developed countries is problematic, as many affected patients could be harmed if latex-safe precautions are relaxed. The Pennsylvania Patient Safety Authority (PPSA) undertook such research and published the results on their website and peer-reviewed journals.[15-17] Their findings are sobering and represent a wakeup call to all our institutions. From 2014-2016, the PPSA found 616 reports of inadvertent potential exposure to latex products across the state's hospital systems. Of those potential exposures, 72 exposures were avoided, but 544 exposures still occurred. Seven exposures resulted in temporary harm to patients. Extrapolating these statistics across the United States, we could expect >16,000 inadvertent exposures to latex with approximately 185 events with temporary harm or worse. These data demonstrate that not every exposure will result in an allergic reaction, thereby increasing the risk of complacency by the medical and nursing staff. The case described above illustrates how an inadvertent exposure to latex can cause substantial harm if appropriate recognition and intervention do not occur. Thankfully, the team in this case quickly intervened and avoided permanent harm.

Although allergic reactions to latex may occur in all medical settings, over half of the events and near-misses occurred in the perioperative setting. Whereas gloves were the most common source of inadvertent latex contact during the early days of latex allergy, indwelling latex bladder catheters were by far the most common source of exposure in the recent PPSA series (n=408, 75.0%), followed by gloves (n=53, 9.7%), Penrose drains (n=19, 3.5%), and red rubber catheters (n=17, 3.1%). Red rubber catheters were used as tourniquets during surgery, intermittent urinary catheters, and feeding tubes. Twenty additional items (e.g., tourniquets, rubber bands, condom catheters) were rarely implicated in these exposures. The majority of these items have adequate non-latex substitutes available.

Systems Change Needed/Quality Improvement Approach

When the incidence of latex allergy was first noted to be increasing, medical records were kept on paper. Physical paper charts had highly visible stickers identifying the patient with latex allergy. Signs were placed on the doors to denote that latex avoidance was in force and no latex products were to enter the patient room. Also during this time, the prevalence of latex allergy was likely to be higher, such that it was on the minds of all the healthcare professionals. Finding equivalent substitute non-latex products was challenging.

Labeling was not consistent. Verifying the material contained in each product from long lists in central supply was a substantial task.

Today, the electronic health record may no longer provide easily recognized verification of a patient's latex allergy. Since virtually all latex examination gloves have been replaced by alternative material, vigilance may not be as prevalent. Surgical checklists may address latex allergy but this information can be easily overlooked among myriad other details. Despite many validated safety actions in the healthcare system (e.g., use of the electronic health record, checklists, time out procedures, and alternative non-latex products), mistakes still occur.

Loop Closure

What should health care organizations and facilities do?[2,15-17]

1. Every institution must have a responsible committee (e.g., patient safety committee, allergy alert committee, or a standalone latex allergy committee) to ensure that latex-safe environments are available for all latex-allergic patients.
2. This committee must have authority to eliminate unsafe latex products from hospital use when an appropriate substitute is available. In order to avoid medical and nursing staff conflict over these decisions, appropriate leadership (nursing, surgery, anesthesia, medicine, and allergy/immunology) should be represented on these committees, including administrative leadership with decision-making authority.
3. Given the advances in product manufacturing, non-latex substitutes must be obtained when an equivalent or superior material exists. Because medical, surgical, and nursing personnel will know whether there is a functional disadvantage to a substitute latex-free product (e.g., reduced effectiveness, exorbitant cost), their input is critical in these decisions.
4. The purchasing process and the product choice process (on the patient care unit) should be engineered to encourage use of non-latex products through automation and system-wide improvement efforts. A simple comparative example is that it is virtually impossible to hook up the oxygen source tubing to the nitrogen source, so it should be impossible to inadvertently choose a latex material for use when an adequate alternative material is identified.
5. In the case of a patient with known latex allergy, latex products that contact mucosa, skin, or tissue should not be used in that patient's care. In our case, a substitute Penrose drain made of non-latex material was available. If this substitute is equally functional and not cost-prohibitive, then latex Penrose drains should be removed from purchase and use in the hospital. The fact that such materials are still being purchased may reflect historical practices rather than conscious evaluation of the products available in 2022.
6. System improvement of the electronic health record can be critical to this improvement as well. When latex allergy is documented in the medical record, an alert could be programmed to pop up for the healthcare team when a product containing latex is scanned for use in that patient. Individuals involved in patient safety should work on such automatic preventions to avert adverse events.
7. Tracking errors and potential errors (e.g., "near miss events") in such an automated system can identify avoided events of latex exposure (i.e., where a latex product was nearly used for a latex-allergic patient) and those that were not avoided. Each exposure, with or without an allergic reaction,

can be analyzed for the possibility of bringing in alternative products or system actions that will prevent these in the future.

8. Finally, not everyone who states that they have latex allergy will have confirmed IgE mediated latex allergy. Similar to drug allergy, a concerted effort to eliminate overdiagnosis of latex allergy through evaluation by a clinical expert should be encouraged. When a person states they have a diagnosis of latex allergy, it is prudent to perform their procedure in a latex-safe environment and then have an evaluation performed after the procedure. The challenges of confirming a diagnosis in latex allergy are substantial, as there is no FDA-cleared skin test available in the US, and serologic assays have low sensitivity. A medical history has turned out to be the most sensitive and specific diagnostic test.[36-40]

Take Home Points

- Latex allergy is a persistent problem in healthcare, with the potential for life-threatening allergic reactions to proteins retained in latex-finished products.
- Reduction in the prevalence of latex allergy and latex allergen content of finished products may have resulted in fewer allergic reactions to latex.
- However, this reduction of allergic reactions to latex and disease prevalence may lead to complacency in the care of individual patients.
- A systematic review of the need for products that contain latex in every healthcare setting is warranted. If an equivalent or better substitute product is identified, the latex-containing product should be eliminated from use.
- Electronic health record enhancement to encourage exclusive use of non-latex products in latex-allergic patients could be engineered with potential improved results.

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This project was funded under contract number 75Q80119C00004 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The authors are solely responsible for this report's contents, findings, and conclusions, which do not necessarily represent the views of AHRQ. Readers should not interpret any statement in this report as an official position of AHRQ or of the U.S. Department of Health and Human Services. None of the authors has any affiliation or financial involvement that conflicts with the material presented in this report. View AHRQ Disclaimers