HPC Healthline

Latex Allergy Guidance Booklet

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INTRODUCTION

Throughout the world, gloves are used to protect people who are exposed to biological, chemical or physical hazards and they are used in huge numbers. For example, it is estimated that over 40 billion latex medical gloves are used each year to protect patients and medical staff from infection. Latex gloves have been important in medicine for a long time, but the numbers used increased rapidly after 1987 with the recognition of the need to protect against AIDS and viral hepatitis. Inevitably, as with many similar products in very large-scale use, a small proportion of users experience problems. In the case of latex gloves the problems are dermatitis and different types of allergic reactions. The purpose of this note is to provide important information to advisors, purchasers and wearers of gloves so that the risk of the problems is minimised and, where they are encountered, general information on the correct course of action is available.

WHY DO WE USE LATEX GLOVES?

The most important requirement for a glove material is that it should provide an effective barrier against pathogens. The best material for general health care use is considered to be natural rubber latex [1]. Latex gloves preserve the sensitivity and control required to perform delicate medical and dental tasks. Latex film moulds well to the variations in hand size and is a strong, easily donnable glove material.

Other non-latex, synthetic materials are in use, but generally do not have the barrier qualities or comfort of latex. Some synthetic gloves produce harmful toxins on incineration after use, whereas natural rubber latex produces water and carbon dioxide [2].

WHAT IS LATEX?

Latex is the natural sap of the rubber tree Hevea Brasiliensis. It is a milky substance which is extracted from the tree through a sloping cut in the back (the process is called tapping). Sap contains 30-40% of rubber hydrocarbon particles suspended in a serum together with a few percent of other non-rubber substances such as proteins, lipids, carbohydrates, sugars and some metal compounds. The remaining major component is water.

HOW IS LATEX MADE INTO PRODUCTS?

Latex is collected in the field is concentrated (generally by centrifuging, to remove part of the unwanted serum) to a dry rubber content of about 60%. It is then preserved with ammonia to stabilise it and combat bacterial growth. This becomes the starting material for all natural latex products, whether produced by dipping (gloves, balloons, condoms, catheters, baby soothers and dental dams) or foaming (latex foam or sponge) or extrusion (latex thread, more commonly known as ‘elastic’).

To make latex gloves, liquid latex concentrate is first mixed with various compounding chemicals, which are essential to produce a strong and stable film which hand-shaped formers are dipped into the latex ix to acquire a thin layer of the material. Dipping can be done either in the presence of absence of a destabilising chemical (coagulant dip or straight dip respectively). Leaching (washing) is carried out at various stages of the process and the product is cured at about 100° – 120°C to turn the liquid latex into a film. In recent years, more emphasis has been placed on improved leaching of gloves to remove as much as possible of the soluble proteins during processing. This has involved adding extra leaching facilities to production lines and increasing leaching times. Finally gloves are treated in order to make them easier to put on. This can be done by chlorination, applying a polymer coating or a coating of cornstarch powder.

HOW CAN LATEX GLOVES CAUSE REACTIONS?

Reaction risks vary greatly depending on the product quantity, but can occur through wearing gloves, coming into contact with gloves or being in an environment where powdered gloves are in use. Both latex proteins and processing chemical residues can cause irritations and allergies at the point of contact. Glove powder can carry the proteins in to the air from where it can be inhaled.

Reactions can also be caused by poor hand washing technique, washing agents or creams and may be incorrectly blamed on gloves. Thorough investigations are vital whenever reactions occur in order to identify correctly the true cause.

WHAT ARE LATEX REACTIONS?

Reactions to rubber were noted as early as 1927 and in 1979 the first immediate allergic reactions were identified {3,4}. An allergy is an acquired sensitised response to a specified agent. General allergic reactions are common in the population and can be many natural things including penicillin, nuts, insect stings etc. Latex is a natural product so it is not surprising that it can cause allergic responses in a small proportion of the population. Reactions have increased due to more extensive glove use since AIDS awareness in the 1980's.

Research has discovered that if someone is allergic to banana, avocado, kiwi, pineapple, peach, papaya, potatoes or chestnuts they will also have an increased propensity to be allergic to latex vice versa [5]. This fact can be used as a very simple guide to identifying those who may be at risk.

Not all reactions are allergies, some are irritations and irritations are more common than allergies.

- ***Irritant Contact Dermatitis***
  The commonest reaction, an irritation that is reversible by avoidance and presents on the hands as an itchy rash with cracks or sores.

- ***Type IV Allergic Contact Dermatitis***
  This is a **sensitisation** to the chemicals added to latex during glove manufacture and usually occurs 6 to 48 hours after glove contact. It is cell-based reactions usually confined to the contact area causing dry, itchy, leathery skin with papules, cracks and sores. Once sensitisation has occurred each subsequent exposure will cause a repeat of the symptoms.

Whenever the above symptoms appear latex gloves are often blamed, but consideration must be given to other causes such as hand washing technique, agents and creams.
Many of the causative chemicals in latex gloves are present in non-latex synthetic gloves too, so avoidance can be difficult.

- ***Type I Immediate Latex Protein Hypersensitivity***
  A serious allergic response to the extractable protein in the latex through contact with latex gloves or inhalation or airborne glove powder carrying the latex protein. Presenting as generalised rather than localised, symptoms may include rash, wheals, hives, facial swelling, respiratory distress, rhinitis, conjunctivitis, collapse and, rarely, anaphylaxis.

Type I and IV require prior exposure to sensitive the wearer.

HOW DO WE DIAGNOSE REACTIONS?

On developing a possible glove related reaction it is important to seek early advice from occupational health staff who may arrange testing to identify the cause. Several tests exist:

- ***Use Test***
  A moistened glove finger is applied for up to 30 minutes, a reaction will identify the source material but not the specific allergen.
- ***Patch Test***
  Used to identify specific antigens causing Type IV, delayed chemical hypersensitivity over a period of up to 2 days using a piece of test material beneath an occlusive patch. Responses are sought on removal at day 2 then day 4.
- ***Skin Prick Test***
  Seen as the 'gold standard' test to identify latex allergy [6]. Carried out by medical personnel with resuscitation facilities available in case anaphylaxis is induced by the test itself. A drop of test liquid is applied into the skin a prick site, a positive reactions of redness and swelling can be seen in minutes. The result is graded according to diameter compared to negative (saline) and positive (histamine) controls.
- ***In Vitro Testing***
  This test is carried out on blood serum in a laboratory rather than on the person to identify latex specific IgE. Such tests include RAST (RadioAllergoSorbent Text) and ELISA (EnzymeLinked ImmunoSorbent Assay)

WHO IS AT RISK?

Estimates show around 1% of the population may react to latex whilst higher risk groups will include health care workers, people who have had a lot of operations (e.g. Spina bifida sufferers 34-64% [7] and rubber industry workers. In Malaysia, 2-4% of rubber workers with constant exposure have latex protein allergy [8]

Atopic persons (i.e. those with dermatitis, asthma and food allergies including banana, kiwi, avocado, chestnut, pineapple, peach, papaya and potatoes) are known to be at increased potential risk of developing allergies in general including latex protein allergy [9].

Users of, and persons in contact with or in the environment of, heavily powdered latex gloves with high protein and chemical levels face a greater risk than if good quality low protein powder free latex gloves were used.

HOW CAN THE RISK BE MINIMISED?

By:

- Ensuring users and purchasers are aware of latex allergy and the risks
- Seeking informed opinions from occupational health professionals etc
- Enlisting the support of the glove company representative
- Using low protein powder free latex gloves. Gloves of a protein less than 100µg/g show little of no allergenicity [10].
- Producing and using a latex policy that includes risk assessment
- Ensuring that glove specifications meet current recommendations
- Covering any skin breaks before donning gloves
- Questioning whether gloves are needed? If so they should not be left on any longer than necessary and hands should be washed and dried on their removal
- Providing alternative materials to individuals sensitised to latex proteins (e.g nitrile)
- Carrying out pre-employment/admission assessments and recording the results clearly in personal notes.
- Always reporting and recording glove reactions to occupational health and as required the Adverse Incident Centre of the Medical Devices Agency.

HOW SHOULD WE MANAGE SENSITISED PERSONS?

By:

- Ensuring that they are fully understand their allergy, its risks and management.
- Ensuring that colleagues, occupational health, GPs, Dentists and purchasers of gloves are aware of a person's allergy and the implications.
- Providing them with latex free alternatives after an adequate assessment of their barrier properties has been performed.
- Requiring that gloves should only be worn when necessary and removed as soon as possible with hands being washed and dried after removing gloves to remove proteins and chemicals
- Eliminating the use of powdered latex gloves from the working environment (Latex proteins can be carried in to the air by glove powder and inhaled) [11].
- Ensuring latex allergy sufferers are first on the operating list if they need surgery, to reduce the risk of contact with airborne proteins.
- Ensuring persons with Type I reactions should be consider wearing a Medic-Alert type bracelet and carrying an anaphylaxis kit (e,g an EpiPen on MiniJet). Extreme reactions are rare.
- Reporting the allergy to the Adverse Incident Centre of the Medical Devices Agency. They can use this information monitor the incidence of latex allergy*
- Contacting the Latex Allergy Support Group for practical advice and support**

HOW TO QUANTIFY THE ALLERGIC POTENTIAL OF LATEX?

Despite intense research, the molecular properties and allergen quantities of latex proteins are not yet fully known [12]. It is acceptable that the incidence of latex sensitisation increases with exposure to latex protein allergens. Allergens are said to be structures recognised by IgE antibodies and being capable of inducing immediate hypersensitivity reactions in those previously sensitised. Removal of the allergens from the proteins would be the preferred solution, but presently insufficient is known regarding the molecular identities of the allergens so efforts continue to remove or reduce the protein content. The same allergens may not cause reactions in different people.

Different sources of latex will have different protein levels and different manufacturing processes can produce further variations in protein levels and allergen structures. Several test methods exist which can give us information on allergenicity, but not one has been universally accepted. For comparisons, only one test method can be used and this needs to be sensitive and accurate.

Presently tests fall into two main types:

1 measurement of total extractable proteins.
2 assessment of allergenicity or allergen content.

1 ***Total Extractable Protein Tests***

Modified Lowry (Draft European Standard Test – pr EN 455 – 3 and ASTM D5712)
Bradford Microassay
RRIM Size Exclusion HPLC
Amino Acid Analysis by HPLC
LEAP (Latex Elisa for Antigenic Proteins)

Different results are achieved by each test and cannot realistically be compared.
The Modified Lowry test referred to in pr EN 455-3 is that to which all manufacturers will have to report for sales in the EU. All values will have to be quoted in µg/g (micrograms per gram) [13] with a minimum allowed claim of '<50µg/g'.

2 Allergenicity/Allergen Content Tests

Skin Prick Test
IgE Latex Specific RAST Inhibition
IgE Latex Specific ELISA Inhibition

The tests are specific to latex allergens rather than extractable proteins.

Skin prick is the most appropriate as it is in vivo (in the body), however it is limited as a product test as persons with latex hypersensitivity are not widespread and are generally willing to allow themselves to be used for product testing.

Test requiring only blood serum containing the IgE latex specific antibodies are more frequently used for product testing. Serological tests are sophisticated and tedious to perform [14]

As there is no standard reference pool of IgE serum of latex allergens, even tests in different labs using the same glove can differ.

In practice the tests generally used are the simples extractable protein type, though to see a meaningful indication of allergic potential it is important that the extractable protein values correlate with the allergic response allergen contents of the sample, as with the RRIM Modified Lowry test [15]

Tests show that extractable protein levels rise after latex compounding, vulcanising and drying at 100° – 120°c and reduce the effective leaching, ageing and chlorination. This further shows that processing methods alter the allergic potential of products [16].

Work at the Rubber Research Institute of Malaysia (RRIM) strives to remove or reduce extractable proteins from Malaysia latex products and identify allergens, whilst research in Europe and the US concentrates on improving diagnostic tests and management strategies for those sensitised.

STUDY FINDINGS

By Dr E Yipp, Ng Kok Poon and Mok Kok Lang of the rubber Research Institute of Malaysia (RRIM) and Kristina Turjanmaa of University Hospital, Tempere, Finland.

39 commercially available latex medical gloves produced using different processes were analysed and clinically tested.

The extractable protein levels (EP) were determined and allergic responses assessed using the skin prick test performed on 59 latex hypersensitive subjects (5 groups) in Finland.

Allergenicity is measured as a % of negative allergic responses:

It can be seen from the study that in *already latex hypersensitive* persons:

- High protein levels = higher degress of allergic reaction
- Low protein levels = low or no allergic reaction
- Gloves of about 0.4 mg/g EP produced no allergic reaction in 60% of subjects
- **Most importantly it demonstrated that gloves with extractable protein levels of below 100 µg/g produce very low or negligible allergenicity.**

SHOULD WE USE VINYL OR OTHER NON LATEX GLOVES

Gloves are worn primarily as a barrier and as such are a significant safety device for health care workers. They are not impermeable, but do significantly reduce the risk of contact and harmful materials. Latex provides the most effective barrier protection so simply changing to, for example, vinyl is not the answer as the likelihood of that barrier breached is increased.

Vinyl glove barrier properties are rapidly reduced with use, compared to the effective barrier maintained by latex. Research has highlighted the deficiencies of vinyl as a barrier material compared to latex [17,18,19,20,21].

Incineration is the only safe method of disposal of gloves. Vinyl gives off harmful toxins, whereas natural rubber latex produces only water and carbon dioxide.

When considering other non latex gloves it is important to consider the quality of the barrier they provide and also factors such as ease of donning, smell and cost.

Non-latex gloves may elicit a Type IV hypersensitivity reaction in some users since the same compounding chemicals used with latex may be used in their processing. Therefore, unless one is latex sensitive, the glove of choice should clearly be that of latex.

WHAT CAN WE DO TO BE SURE THAT WE ARE USING SAFE GLOVES?

- Use a reputable supplier able to supply a full range of gloves, including non-latex alternatives, on a continuing basis.
- Ensure gloves meet all current recommendations
- Where possible, choose latex – it offers the best barrier protection
- Insist on low protein powder free gloves (less than 50 μg/g).
- Ask to see independent test results for protein and residual chemical levels of the gloves you are using.
- Keep abreast of findings and advice
- Set up a glove advisory group to pool all experts/interested persons.

FIRST AID TREATMENT FOR ALLERGIC REACTIONS

- Recognise the symptoms of an allergic reaction: itching, rash, swelling, wheezing, pallor/flushed skin, distress, shock (lowered blood pressure), collapse and unconsciousness.
- Promptly remove contact with the likely cause if possible.
- Sit of lie the victim down.
- Ensure a clear airway, loosen restrictive clothing.
- Seek urgent medical attention if the patient continues to be unwell/distressed.
- Make a note of previous medical history, including ANY other allergies.
- Assist the patient with any medication they would normally take in these circumstances.
- If the victim loses consciousness, place them in the recovery position and stay with them until the ambulance arrives.

If you know the patient has a history of severe allergic reactions and you recognise the symptoms, if they have an auto-injection device and are unable to use it themselves consider giving it yourself. Normally instructions are simple and you may save their life.

Be prepared to assist respiration in severe reactions.

First aid skills may save a life – make sure you would know what to do in an emergency. D Brown, RGN, 1998

Your HPC Healthline Account Manager will be happy to provide any further information or assistance you may require
Please call 020 8335 3636

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