

ACCURATE DIAGNOSIS OF LATEX ALLERGY IN HOSPITAL EMPLOYEES IS COST-EFFECTIVE

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ABSTRACT

Aim: High exposure to latex gloves and glove powder makes healthcare workers particularly susceptible to developing latex allergy. Early diagnosis is essential. Both clinical and laboratory diagnostic methods can be used to diagnose latex allergy. The aim of this study was to assess the effectiveness of patient suspicion as a diagnostic tool and to determine a cost-effective diagnostic method.

Method: Latex allergy at Tygerberg Hospital has been investigated since 1998. High-risk individuals were identified by completion of questionnaires. These questionnaires captured demographic data, present and past latex exposure and 'patients' suspicion of having latex allergy'. Additionally, patients were asked to score seven latex-related symptoms for severity and work-related deterioration. Where specific criteria on the questionnaire were met, patients were followed up for determination of latex-specific IgE levels (n=250). Latex skin-prick tests were done where serum results were negative.

The study group was divided into patients who suspected latex allergy and those who did not suspect it, or were unsure about the possibility of latex allergy. Diagnostic results were then compared with patients' suspicion.

Results and conclusion: Treating and accommodating latex allergic workers would have a detrimental impact on the annual health budget. The results of this study showed patient suspicion to have a high false-positive rate and low predictive value. This confirms that testing patients for latex allergy would be far more cost-effective than to simply institute latex avoidance measures on patient suspicion alone.

INTRODUCTION

Latex allergy has become one of the major occupational diseases worldwide.¹ High exposure to latex gloves and glove powder makes healthcare workers (HCWs) particularly susceptible to developing latex allergy.^{2,3} Early diagnosis is essential. Sensitisation may lead to drastic lifestyle changes and may necessitate a change in, or even termination of, employment.^{4,5}

Proper diagnosis is the first step in managing a patient with latex allergy.⁶ This is followed by the institution of latex avoidance measures.⁵ Latex allergy is a notifiable occupational disease in South Africa. The Commissioner of Occupational Health must be notified of all affected HCWs.^{7,8,9} Re-evaluation of patients

needs to be done after a period of active avoidance of latex and latex-containing devices.

Usually, patients are aware of symptoms possibly related to the use of latex gloves or other latex devices and often seek medical advice themselves.¹⁰ Different clinical or laboratory diagnostic methods (questionnaires, skin-prick tests (SPT) or *in vitro* latex-specific IgE concentration determination) can be used to confirm latex allergy.⁷

Individuals with confirmed latex allergy need to continue to perform their daily working routine in a safe (i.e. latex-free) environment.² Only latex-free gloves should be used by these workers. Co-workers should only use powder-free gloves to limit airborne glove powder. These measures should be implemented by the employer.

The cost of gloves is an important factor in the choice of purchase by all hospitals. Accommodating latex-allergic workers could increase the cost of running a hospital. It is therefore of utmost importance to avoid unnecessary expenses by utilising extreme latex-avoidance measures in non-allergic employees.

MATERIALS AND METHODS

Since 1998 continuous testing for latex allergy has been done at Tygerberg Hospital (TBH). Questionnaires have been circulated for completion by staff members working in areas with high latex exposure (e.g. theatres and laboratories). The study population comprised 400 personnel from TBH (e.g. doctors, nurses, medical technologists, etc).

The questionnaire included a consent clause that all subjects signed on completion. The research team thereby committed to confidential management of all information. Subjects consented to voluntarily providing the information for research purposes.

Data captured by the questionnaire included demographic data (name, age, gender, occupation), atopy (personal or family history), allergies (drugs, food or other), present or past latex exposure (wearing of gloves and all surgical procedures), as well as any adverse effects after surgery (e.g. anaphylaxis). Subjects also had to indicate if they suspected or knew that they were allergic to latex. Positive 'patient suspicion of latex allergy' (hereafter referred to as 'patient suspicion') was defined if any confirmatory test (RAST, SPT) had been done previously or if the patients could positively link their symptoms with exposure to latex (e.g. dental or gynaecological examinations, gloves, condoms, balloons, kitchen gloves, etc).

The selection of latex-related symptoms included in the questionnaire was made according to symptoms most often reported in the literature.⁷ Patients were asked to score the following symptoms as absent, mild, moderate or severe and whether they were work-related:

- Anaphylactic shock
- Angioedema
- Bronchospasm
- Conjunctivitis
- Hand eczema
- Nasal congestion

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- Pruritus
- Rhinitis
- Shortness of breath
- Skin rash
- Urticaria

The study group (n = 277) was compiled by evaluating the questionnaires and selecting individuals from the study population for further investigation according to the following inclusion criteria:⁷

- Confirmed or suspicion of latex allergy (yes/maybe)
- Anaphylaxis / severe bronchospasm after latex exposure
- Food allergies known to cross-react with latex (e.g. avocado, banana, carrot, kiwi fruit, stone-fruit or other tropical fruit)
- Any listed symptom with work-related deterioration
- 2 or more severe symptoms listed on the questionnaire
- 4 or more moderate symptoms listed on questionnaire

Patients signed a second informed consent before venepuncture, detailing all procedures and the patient's rights with regard to refusal to participate. Two 7 ml SST vacuum tubes of blood were collected, allowed to clot for 10-15 minutes at room temperature and then centrifuged at 6 000 rpm for 10 minutes. Immediately after centrifugation, the serum was placed in two separate cryotubes and stored at -4°C until the day of analysis. Although the SPT is regarded as the gold standard for diagnosing latex allergy worldwide, the latex-specific IgE determination was preferred to the SPT to obtain quantitative results for statistical comparison. Because of the possibility of anaphylaxis, it is also not advisable to perform SPT on patients with a history of anaphylaxis or bronchospasm after latex exposure.

Total serum IgE and latex-specific IgE were determined according to the manufacturer's specifications (Pharmacia ImmunoCAP system).³ For latex-specific IgE a cut-off value of 0.35 IU was used. As far as possible, where latex-specific IgE was <0.35 IU/l, patients were followed up with latex SPT. Saline was used as negative control and histamine (10 mg/ml) as positive control. All SPT extracts were obtained from Soluprick (ALK Abello). The actual length of the two perpendicular axes of the wheal were measured (in mm), added together and divided by 2. The SPT reaction was regarded as positive when the mean diameter of the wheal of the latex extract was more than 2 mm greater than that of the negative control.^{3,11}

The following diagnostic criteria have been evaluated and the positive predictive value (PPV) for each calculated:

1. **Patient suspicion.** The study group was divided into patients with a positive or negative suspicion of latex allergy. For statistical purposes, patients unsure about their latex allergy status were included in the negative group.
2. **Number and severity of symptoms.** Patients who indicated more than three moderate or severe symptoms on their questionnaires were included in this group.
3. **Suspicion OR symptoms.** Patients who complied with the criteria for either Group 1 or 2.
4. **Suspicion AND symptoms.** Patients who complied with both criteria.
5. **Anaphylaxis.** Patients who had latex-related anaphylaxis previously.
6. **Bronchospasm.** Patients who reported moderate or severe bronchospasm as a consequence of contact with latex.
7. **Anaphylaxis OR bronchospasm.** Patients who reported either of the two symptoms on the questionnaires.
8. **Anaphylaxis AND bronchospasm.** Patients who reported both symptoms on the questionnaires.

State glove tender prices for 2000-2002 were used to calculate the total cost generated by latex allergy.

RESULTS

A total of 400 questionnaires were completed by staff members. According to the predefined inclusion criteria, a study group was compiled consisting of 277 HCWs. Total serum IgE and latex-specific IgE analyses were done on all 277 subjects, while a further 83 subjects with negative latex-specific IgE values underwent latex SPT. The remaining 157 subjects were not followed up because of lack of consent or termination of employment at TBH. Demographic data, latex exposure and laboratory results are summarised in Table I.

Of the 83 patients with confirmed latex allergy, only 36 (18 in the serum-positive group and 18 in the SPT-positive group) reported a positive patient suspicion on the questionnaire, while 6 subjects in the group with negative serum and SPT results also reported a positive patient suspicion.

Table I. Demographic data, latex exposure and laboratory results

	Study group	Serum (+)	SPT (+)	SPT (-)
n	277	37	46	37
Age (years)	35.0 ± 8.2	34.7 ± 7.3	36.0 ± 7.6	34.8 ± 8.0
M : F	46 : 231	8 : 29	4 : 42	5 : 32
Exposure				
Years	8.3 ± 7.3	9.5 ± 6.9	10.7 ± 7.1	10.4 ± 8.0
Hours / week	20.8 ± 15.9	19.3 ± 15.2	26.5 ± 14.2	27.8 ± 12.8
Pairs / week	18.5 ± 20.4	25.1 ± 36.0	19.3 ± 11.9	22.9 ± 16.6
Patient suspicion of latex allergy				
Yes	73	18	18	6
No	94	5	3	7
Don't know	109	14	25	24
Serum values (IU/l)				
Total IgE	138.3 ± 242.8	275.4 ± 342.2	108.1 ± 232.2	138.6 ± 225.9
Latex-specific IgE	4.2 ± 5.6	4.2 ± 5.6	< 0.35	< 0.35

Table II. Prevalences and PPV for different groups

	n (%)	(+) Serum / (+) SPT	(-) Serum & (-) SPT	(-) Serum, withdrew	PPV (+/n)
Positive patient suspicion	73 (26.4%)	36	6	31	49.3%
> 3 symptoms	142 (51.3%)	59	20	62	41.6%
Suspicion or symptoms	166 (59.9%)	66	23	77	39.8%
Suspicion & symptoms	47 (17.0%)	27	3	17	57.5%
Anaphylaxis	9 (3.3%)	6	0	3	66.7%
Bronchospasm	62 (22.4%)	28	9	25	45.2%
Anaphylaxis or bronchospasm	64 (23.1%)	27	9	28	42.2%
Anaphylaxis and bronchospasm	7 (2.5%)	6	0	1	85.7%

Negative patient suspicion was reported by 47 subjects in the confirmed latex allergy group and 31 in the negative group.

Owing to the high incidence of negative latex-specific IgE results and positive SPT (46/83, 55.4%), only patients with negative latex-specific IgE and negative SPT were included in the negative group for statistical analysis. Prevalences and PPVs for the different criteria groups are shown in Table II.

For the purposes of calculating the cost of latex allergy, the combination of positive suspicion and more than three moderate or severe symptoms (PPV = 57.5%) were used to predict the possible number of latex allergy cases. The cost of sterile gloves was used, because theatre personnel have the highest levels of latex exposure and are more likely to develop latex allergy.

State glove tender prices for 2002:

Latex pre-powdered gloves:

Sterile: R1.37 – R2.39

Non-sterile: R0.36 – R1.14

Latex powder-free gloves:

Sterile: R0.89 – R2.39

Latex-free gloves:

Sterile: R20.01

Non-sterile: R1.10

Cost per diagnostic test for latex allergy:

RAST (k82) = R60.00

SPT = R14.00

According to the questionnaires, 1 HCW at TBH uses an average of 22 pairs of gloves per week and 8-10 people work together as a staff unit. The cost for gloves per staff unit can be calculated as shown in Table III.

Table III. Glove costing

	Powdered latex	Powder-free	Latex-free
Routine issue – cost per week per staff unit			
22 pairs x R2.39 x 9 people	R 473.22	R0.00	R0.00
Cost per annum per staff unit	R 24 607.44	R0.00	R0.00
TOTAL R 24 607.44			
Accommodating 1 HCW with latex allergy			
– cost per week per staff unit			
22 pairs x R20.01 x 1 person			R 440.22
22 pairs x R0.95 x 8 people		R 167.20	
Cost per annum per staff unit	R0.00	R8 694.40	R22 891.44
TOTAL: R 31 585.84			
The annual cost of accommodating a single HCW with latex allergy will therefore be			
R 31 585.84 – R 24 607.44 = R 6 784.00			

A previous study done at TBH (1998-2000) generated the following data:⁷

Study population (all employees at TBH) – 5 000

HCWs working in areas with high latex exposure – 2 750

Patients with a history of latex-related bronchospasm or anaphylaxis – 23%

If the prevalence (17%) and PPV (57.5%) of a combination of positive suspicion and > 3 symptoms from the current study are extrapolated to these figures, the projected number of patients suffering from latex allergy can be represented as:

Patients likely to have positive suspicion and > 3 symptoms (2 750 x 17%) – 468

Without diagnostic testing, accommodating these patients would cost:

468 patients x R 6 978.40 = R 3 265 891.20

Testing this group would entail:

RAST in 23% (history of anaphylaxis or bronchospasm) – R60.00 x 108 = R 6 480.00

SPT in remaining 77% – R14.00 x 360 = R 5 040.00

TOTAL FOR DIAGNOSTIC TESTS R 11 520.00

According to the PPV of the chosen criteria, only 57.5% of these patients will be confirmed with latex allergy (468 x 57.5%) – 269

The total cost of testing the high-risk group and accommodating only confirmed cases, can be calculated as follows:

R 11 520.00 + (269 x R 6 978.40) = R 1 888 709.60

If intervention by means of testing had not been done and the entire group had been converted to latex-free gloves, the unnecessary expenditure would have been:

R 3 265 891.20 – R 1 888 709.60 = R 1 377 181.60

DISCUSSION

Self-administered questionnaires have previously been shown to be a useful tool in the identification of individuals at risk for latex allergy.⁷ However, because of low specificity, simultaneous clinical or laboratory verification is essential to confirm the diagnosis.¹²

Only 49.3% of persons with suspected latex allergy could be confirmed by a diagnostic test. The high false-positive rate found in this study implies volunteer bias. This could play a major role in prevalence studies. Additionally, the low PPV suggests that it is not an accurate predictive indicator of latex allergy, with less than 50% accuracy in this study. Similar low PPVs were found for most other criteria evaluated as indicators of latex allergy.

Although anaphylaxis and a combination of anaphylaxis and bronchospasm demonstrated the highest PPVs in this study, the small number of positive cases in both instances (9 and 7 respectively) might question the validity of these figures. Unfortunately, there is no infallible method of predicting and identifying all persons with latex allergy; regular follow-up and retesting should be done to monitor progression of symptoms.

The high percentage of patients with negative latex-specific IgE values and positive SPT results proves that a single diagnostic method might not be sufficient to verify all questionnaire results.¹³ Patient history and a critical clinical evaluation of symptoms should lead the clinician in deciding which test to perform. Usually, where symptoms are limited to the skin, an SPT should be sufficient, whereas respiratory or systemic symptoms might warrant an *in vitro* test. Any anaphylaxis or severe bronchospasm should immediately eliminate the possibility of SPT and a RAST should be performed in these cases.

Accommodating a single HCW with latex allergy places an additional burden of R 6 978.40 per annum on the health budget. In the current scenario, if latex avoidance measures are instituted on all HCWs with combination of positive patient suspicion and moderate to severe symptoms without testing, expenditure of more than R3 million per annum could be reached. However, if these patients are tested for latex allergy and avoidance measures are only instituted in confirmed cases, the combined cost of testing and accommodating affected personnel could be limited to only R1.8 million per annum.

CONCLUSION

Employers are compelled by law to provide a latex-safe working environment for affected employees.¹⁴ Most latex equipment is available in latex-free alternatives, but it is extremely expensive. Careful management is therefore essential to prevent unnecessary expense.

In more than 50% of cases, converting a unit to latex- or powder-free based on questionnaire evaluation alone, would be unnecessary. The calculated cost of this conversion necessitates a scientifically sound basis on which these decisions are made.

The results of this study confirm that there is currently no foolproof method of accurately predicting all patients with latex allergy. A combination of positive patient suspicion and moderate to severe symptoms is the criterion most likely to identify the highest percentage of these patients. It is imperative, however, that patients are followed up at regular intervals, re-evaluated for progression of symptoms and re-tested. At the same time, other possible contributing factors should also be investigated, e.g irritant or allergic contact dermatitis to soap or other detergents, etc. This approach would be far more cost-effective than to institute latex-avoidance measures based on one or two criteria alone.

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