

Latex Allergen Sensitization Reaction in Exposed and Un-Exposed Groups as well as Associated Factors

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ABSTRACT

General aim: this study aims to determine the prevalence of sensitization reaction on exposed and unexposed groups of workers at a latex factory. Specific aim: to determine the latex allergen sensitization reaction and factors such as atopy, age, sex, smoking, length of working, exposure concentration.

Sample and method: the sample population consists of workers at a sphygmomanometer and condom factory who were exposed and un-exposed to latex material at the factory. The number of sample was determined based on the two proportion formula.

This study was a cross-sectional study using the Chi square test, Fisher test, Mann Whitney test, and Kruskal Wallis test.

The results of the study and conclusion: The prevalence of latex allergen sensitization reaction in the exposed group was 2.38%, while in the un-exposed group 3.33%. The correlation between exposed and un-exposed group to the latex allergen sensitization reaction (overall) was not significant ($p=0.181$), but if the correlation of each factor was calculated, the most significant correlation was between the negative latex allergen sensitization reaction with a strength of +2 or above ($p=0.014$).

In this study, atopy ($p=0.000$), exposed concentration ($p=0.014$), and smoking ($p=0.018$) are factors that were associated with latex allergen sensitization reaction. Workers at the condom factory were at higher risk than those at the sphygmomanometer factory, with a prevalence of 7.14% and 2.31% respectively.

Key words: Latex, Allergen, Sensitization Reaction, Condom Factory.

INTRODUCTION

Natural latex is a top export commodity for Indonesia, the second largest latex-producing nation after Thailand. Latex is produced into various goods such as toys, dolls, balloons, household supplies such as gloves, shoes, sandals, infant nipple, sporting goods, and health supplies such as gloves, infusion pipes, stethoscope, catheter, injection drug bottle cap, tape, re-breathing bag, and contraceptive devices (condoms and diaphragm).¹⁻¹¹ However, lately, the use of latex as a raw material for medical equipments is starting to be a problem, since the allergenic protein component is now known to cause allergic reactions in its users.

Even though the protein level in latex has been greatly reduced during processing into latex, there is a remaining 12% that may still potentially cause an allergic reaction.¹²

Latex most commonly causes irritation (non-allergic) dermatitis. Second to that, latex may also cause contact allergy/type IV slow-reacting hypersensitivity reaction dermatitis. Aside from that, it may also cause type I hypersensitivity reaction, also known as rapid type or anaphylactic reaction. This last reaction is caused by the latex protein, and not by chemical substances (thiuram, carbamate, mercaptobenzothiazole). They occur immediately after the body is exposed to the allergens, and is mediated by IgE antibody, manifested through the skin prick test found in this study.

Type I reaction is initiated with the sensitization phase, which is a time needed from the formation of IgE to binding by specific receptors on the surface of mastocytes and basophils. The activation phase is the time during recurrent exposure with specific antigens, when mastocytes release its granular contents, causing a reaction. The effector phase is the time when a complex response (anaphylaxis) towards the substances released by the mastocytes by pharmacological activity.

Type 1 reaction (allergy) was first reported in Ger-

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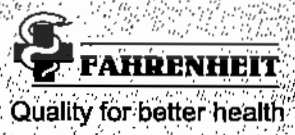
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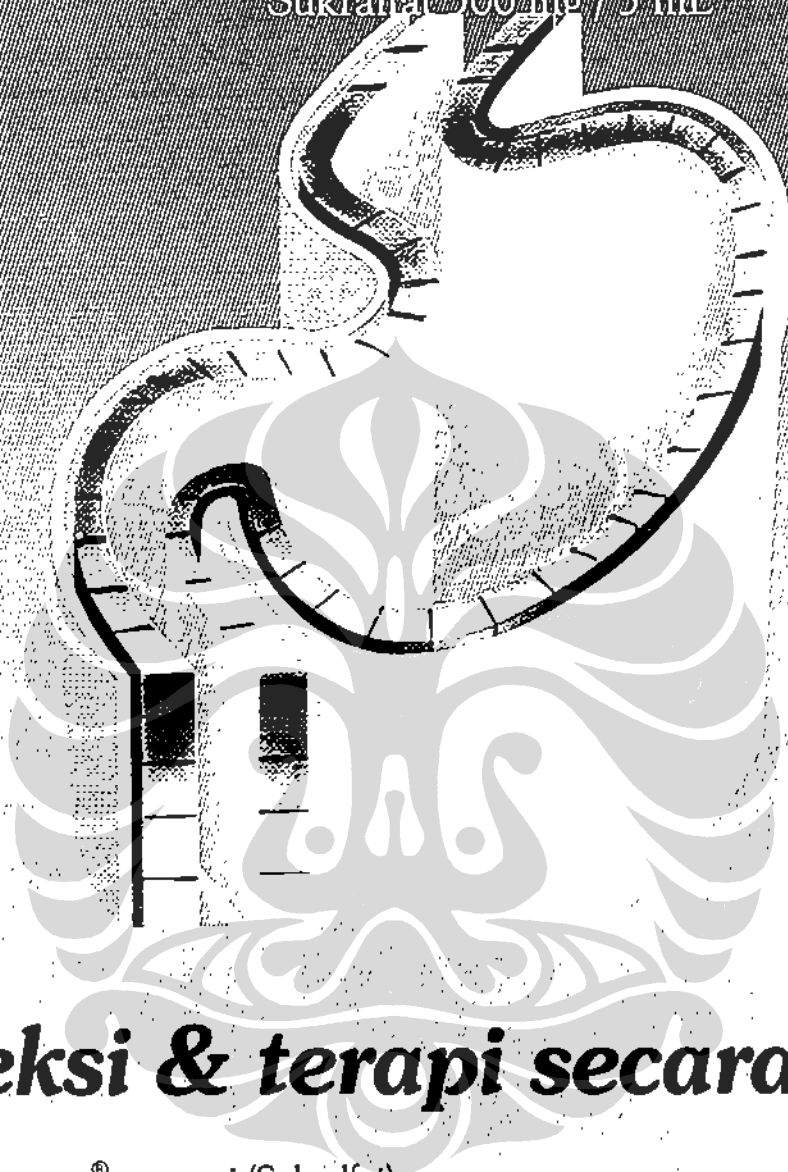


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many in the year 1927, when a person suffered from urticaria and oral edema after the use of latex dentures.¹³ In the year 1979 in England, a person suffered from urticaria after using latex gloves.¹¹ In 1984, there was a case of anaphylactic shock during surgery.¹¹ In the United States in 1989, there was a case of anaphylaxis in a child with spina bifida.¹⁴

During latex processing, rubber is obtained from the trees, then turned into sheets (pre-latex material), then processed by adding chemical substances, formed into condoms/sphygmomanometer (bladder/bulb/tubing). This last step is the one studied in this study.

The sensitivity to allergic reaction by latex proteins often occurs in latex users, 5-10% of which are medical workers and 4% dentists, while only 1% of the general public is sensitive. A high percentage (48%) of spina bifida patients are sensitive, possibly due to frequent use of catheters made of natural rubber.¹⁵

The Center for Disease Control (CDC)⁵ in 1987 suggest the use of rubber gloves by medical workers, known by the term of "universal precaution". Increased use of gloves has been associated with increased frequency of various allergic diseases.

Based on these findings, the author would like to determine the prevalence of sensitization in workers at the sphygmomanometer and condom factories, aside from glove users, as well as factors that may be related with latex allergen sensitization reaction, thus preventive measures may be taken.

SAMPLE AND METHODS

The sample consisted of exposed and un-exposed workers at the latex-based sphygmomanometer and condom factories, consisting of 126 exposed workers and 118 un-exposed workers. The sphygmomanometer factory is located in In the larang, while the condom factory is located in Bandung. The study took place from April to May 2001. Sample size was calculated based on statistical formulas, and the sample estimate was calculated based on the two proportion formula.

The data obtained from the condom and sphygmomanometer factory workers (exposed group) was compared to administrative workers at the factory (un-exposed group) after each worker signed a consent form and filled out a questionnaire, a skin prick test was performed.

The skin prick test was performed on the inside of the lower left arm with a 26 G needle using extract materials from house bugs, cockroach, latex (a standard natural latex made by Stallergens®, France), positive con-

trol (histamine), and negative control (tcmoin). Readings were conducted after 15 minutes. The subject should not have taken anti-histamines or steroids within 1 week. The interpretation of the skin prick test were classified as follows: the same as control (negative), positive 1: induration with a diameter of 1-2 mm, positive 2: an induration with a diameter of 3-5 mm, positive 3: an induration with a diameter of 6-9 mm, positive 4: an induration of 10 mm or more.

To see the correlation for a table that is larger than 2x2, we used the Chi square test, while the Fisher test was used for 2x2 tables. Mann Whitney test was used to determine the average difference in the groups, while the Kruskal Wallis test was used in more than 2 groups, performed under the assumption of free distribution (non-parametric statistics). Significance was achieved at 5%.

RESULTS

From the data obtained, we performed skin prick test on 126 latex-exposed factory workers and 118 un-exposed workers at sphygmomanometer and condom factories, where 117 of the exposed workers and 99 of the un-exposed workers were from the sphygmomanometer factory, and the remaining 9 and 19 from the exposed and unexposed groups respectively were from the condom factory.

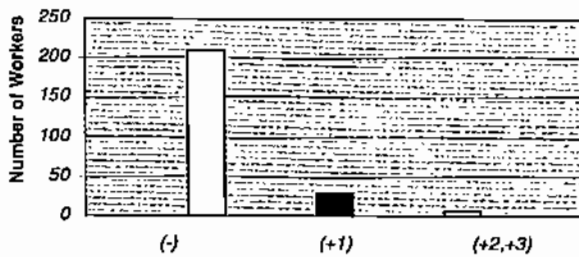
Overall, there were 244 study subjects, where 209 subjects (85.66%) demonstrated a negative sensitization reaction, while 28 subjects (11.48%) demonstrated a sensitization reaction of positive one and 7 subjects (2.86%) demonstrated a sensitization reaction of positive two and three. In the exposed group, a negative sensitization reaction to latex allergen was found in 104 subjects (82.54%), positive one in 19 subjects (15.08%) positive two in 2 subjects (1.59%), and positive three in 1 subject (0.85%). In the un-exposed group, there was a negative sensitization reaction in 105 subjects (88.99%), positive one in 9 subjects (7.63%), and positive two in 4 subjects (3.39%). The difference was not found to be statistically significant when tested using the Chi square test ($p=0.171$). When each factor was correlated, a correlation was found between the exposed and unexposed groups to latex allergen sensitization reaction (negative and positive 2 or above) with a p value of 0.014.

The factors that were suspected to play a role in the sensitization reaction of latex allergen that were found to be significant were exposure concentration, atopy, and smoking, with a p value of 0.014, 0.00 and 0.18 respectively.

DISCUSSION

A positive allergen sensitization reaction was found in 7 subjects, 3 of which belonged to the exposed group and 4 from the un-exposed group, where 2 subjects with a positive two reaction and 1 subject with a positive three reaction were from the un-exposed group, while the 4 subjects from the un-exposed group demonstrated a positive two reaction (Figure 1). All of these subjects were male smokers with atopy. The latex allergen sensitization reaction was classified as negative, positive one, and positive two or above. When we say "positive" we refer only to positive two or above. Allergen sensitization reaction is classified in such a manner since literature states that positive one does not have clinical value and is considered a weak positive, and should thus be separately

Figure 1. Latex Allergen Sensitization Reaction

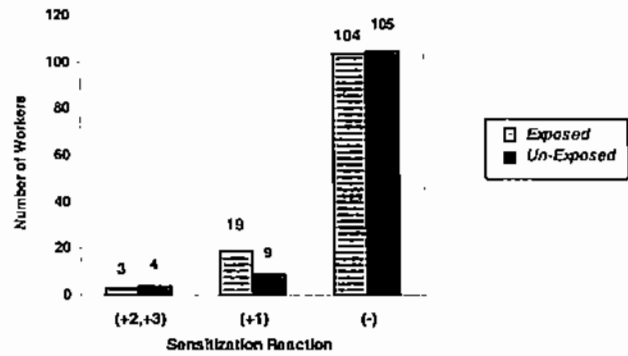


classified, so that increased sensitization reaction can be monitored, from positive one to positive four depending on the exposure. An allergen sensitization reaction is considered positive when comparable to the histamine positive results (positive two or more).¹⁶ The prevalence of positive latex allergen sensitization in the two groups was small and not significantly different. In the exposed group, there were 3 subjects with a positive reaction out of 126 subjects (2.38%), while in the un-exposed group, there were 4 subjects with a positive reaction out of 118 subjects (3.33%), as seen in Figure 2. There were more positive results from the un-exposed group, possibly due to a lack of samples. This finding differs from literature that a 1% positive reaction in the general public.^{8,11,15}

The correlation between the exposed and un-exposed groups and the latex allergen sensitization reaction (overall) was not significant ($p=0.171$) as seen in Table 1, while if each factor was correlated, there was a significant difference in the correlation between negative latex allergen sensitization reaction and positive two or more ($p=0.014$).

The possibility that subjects from the un-exposed group come in contact with latex goods out of the job turned out to be insignificant ($p=0.517$) based on the

Figure 2. Bar Graph of Latex Allergen Sensitization Reaction in Exposed and Un-Exposed Groups



questionnaire (Table 2). This data may not be very valid, since it is obtained from interview alone. Overall, we found 7 subjects to be positive out of 244 subjects (2.87%). This percentage is greatly different from (11%). Another possibility is that the number of samples was inadequate.

In Table 3, the correlation between atopy and latex allergen sensitization reaction demonstrated a significant p . This was in accordance with literature that states that atopy influences IgE production.^{11,15,17-19} When smoking was correlated to latex allergen sensitization reaction, there was a significant p , as stated in literature, even though smoking was not directly associated and the mechanism is still unclear, it is stated that smoking can influence IgE production.^{19,24} Table 4 demonstrates a significant p for the correlation between exposure concentration (the difference between latex concentration between the sphygmomanometer and condom factories) and latex allergen sensitization reaction, since there was a difference in the latex concentration at the two factories. If we see the prevalence rate for latex allergen sensitization reaction at the sphygmomanometer and condom factories of 7.14% and 2.31% respectively, we can conclude that workers at the condom factory are more at risk for sensitization. This may be due to the fact that at the condom factory, allergens are bound to talc can be inhaled through the nostril mucosa, while workers at the sphygmomanometer factory who come in contact with latex on the skin of their hands, even though the latex concentration is higher in the sphygmomanometer factory compared to the condom factory. Literature states that exposure through the mucosa is high, and thus the latex concentration is not as important as the means of entry into the body.

Ideally, the study should be performed at one factory, or the two factories should be analyzed separately. However, this was not possible due to a limitation of samples (the number of samples from the condom factory is very small).

Table 1. The Correlation Between Exposure and Non-Exposure to Latex Allergen Sensitization Reaction (Overall)

Variable (Group)	Negative (-) (%)	Positive 1(+1) (%)	Positive 2.3 (+2.+3) (%)	Test	p
Exposed	104(82.5)	19(15.08)	3(2.38)	χ^2	0.177
Un-Exposed	105(88.98)	9(7.63)	4(3.39)		

Table 2. The Correlation Between the Un-Exposed and Exposed Group and Contact with Other Latex Products

Group	Contact +	Contact -	p
Exposed	49	77	0.517
Un-Exposed	51	67	

Table 3. The Correlation Between Atopy, Smoking, and Latex Allergen Sensitization Reaction

Variable	Negative (-)	Positive 1 (+1)	Positive 2.3 (+2.+3)	Test	p
Atopy : +	123	25	7	χ^2	0.00
Atopy : -	86	3	0		
Smoking: Brinkman Index				χ^2	0.018
Non-Smoker	99	20	1		
Light Smoker	94	6	4		
Moderate Smoker	16	2	2		

Table 4. The Correlation Between the Variable of Exposure and Latex Allergen Sensitization Reaction

Variable	Negative (-) (%)	Positive 1 (+1) (%)	Positive 2.3 (+2.+3) (%)	Test	p
Exposure Concentration				χ^2	0.014
Sphygmomanometer	183(85.51)	28(13.08)	5(2.3)		
Condom	26(92.8)	0(0)	2(7.1)		

CONCLUSION

The prevalence of latex allergen sensitization in the exposed group was 2.38%, while for the un-exposed group it was 3.33%.

The correlation between exposure and non-exposure with latex allergen sensitization reaction (overall) was not significant ($p=0.171$). However, when each factor was correlated, there was a positive correlation between negative latex allergen sensitization reaction and that of

positive two or more ($p=0.014$).

Atopy ($p=0.000$), exposure concentration ($p=0.014$) and smoking ($p=0.018$) were factors associated with latex allergen sensitization reaction.

Workers at the condom factory were at a higher risk compared to those at the sphygmomanometer factory, with a prevalence rate of 7.14% and 2.31% respectively.

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