

Original article

Asthma, skin symptoms, and allergy in a condom factory

Background: Cases of occupational asthma have been reported in condom factories in the UK and France, but there has been no epidemiologic study of groups of workers in such factories. This investigation aimed to study the prevalence of symptoms in a Swedish condom factory, to determine groups at special risk, and to suggest preventive measures.

Methods: A questionnaire was mailed to 35 employees, 29 women and six men with mean ages of 37 and 32 years, respectively. All subjects were interviewed by a physician and underwent skin prick test with latex and epicutaneous testing with 39 substances, and blood samples were taken for allergy testing.

Results: Phadiatop® was positive in 23%, RAST against *Lycopodium* in 31%, and RAST against latex in one of these 11. Ten subjects (29%) had work-related nose/eye symptoms; of these, eight had positive RAST to *Lycopodium*; three also had symptoms of occupational asthma and contact urticaria. Only one had positive RAST to latex. Five of the nine subjects with positive Phadiatop also had positive RAST to *Lycopodium*. All those with RAST positive to *Lycopodium* had worked in packaging, the area of the factory with the greatest exposure. The results of the patch tests did not correlate with the work-related symptoms.

Conclusions: In a Swedish condom factory, there were a high prevalence of rhinoconjunctivitis and a small number of cases of asthma and contact urticaria caused by allergy to *Lycopodium*.

A. Rask-Andersen, J. Boman

Department of Occupational and Environmental Medicine, University Hospital, Uppsala

A. Grängsjö, M. Silverdal, M. Lindberg

Department of Dermatology, University Hospital, Uppsala

M. Lundberg

MIAB, Uppsala

L. Svensson

Department of Dermatology, Gävle, Gävle-Sandviken Hospital, Sweden

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Anna Rask-Andersen, MD, PhD
Department of Occupational and Environmental Medicine
University Hospital
SE-75185 Uppsala
Sweden

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Both latex and *Lycopodium* are allergens, and cases of occupational asthma caused by them have been reported in condom factories in the UK and France (1, 2). However, there has been no published study of groups of workers in such factories, and the present study appears to be the first of its kind.

The factory used for the study started manufacturing latex products such as urinary drip collectors, prostheses, and condoms in the 1950s. In 1992, the manufacture of latex products ceased; instead, the factory began only to package latex condoms imported from Japan. In Japan, the condoms were powdered with lycopodium to prevent the rolled condoms from sticking together, and additional lycopodium was added during packaging. Lycopodium is a plant product and consists of spores of the staghorn club moss, *Lycopodium clavatum*, common in central and northern Europe, Asia, and North America (Figs. 1 and 2).

At first, the packaging was semiautomatic. Operators loaded each condom by hand onto a conveyor belt before it entered the packaging machine. Since 1.5 million condoms were packed every week, the operators

had extensive skin contact with both latex and lycopodium powder and with materials such as flavorings and oil, which were also added to the condoms. Nowadays, with changes in the process, the condoms are placed in a funnel and transported automatically to the packing machine. However, the amount of lycopodium handled has increased, as the condoms are now tumbled in the material to prevent them from sticking together. This is now a very dusty operation, although the packing machines are enclosed, and the operators spend a limited time close to the machines compared with the whole workday in earlier times. The purposes of this study were to assess the prevalence of symptoms in the condom factory, to determine whether any groups were at particular risk of developing allergic symptoms, and to suggest preventive measures.

Material and methods

Questionnaire and interviews

A questionnaire was mailed to 33 current and two

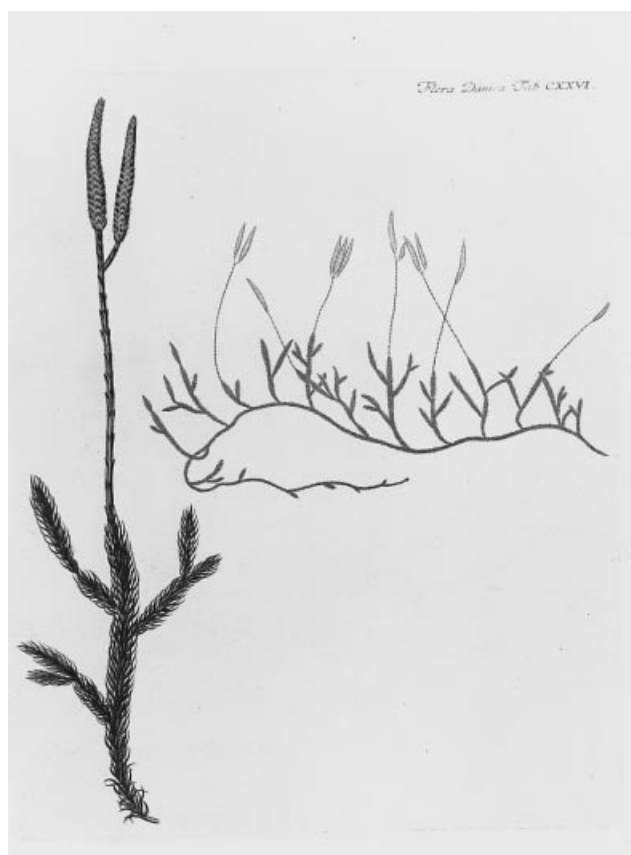


Figure 1. First published picture of club moss, *Lycopodium clavatum*, from *Flora Danica* (1764).

former employees of the factory. The two former employees had left because of work-related symptoms. The questionnaire sought to obtain information about work history, work conditions, and respiratory and skin symptoms. Physicians also interviewed all the subjects. Each subject underwent skin prick test with latex and epicutaneous testing with 39 substances, and blood was taken for allergy testing, including total IgE, and Phadiatop® and RAST against latex and *Lycopodium*.

Allergy tests

Serum total IgE concentrations and Phadiatop were determined with the Pharmacia CAP System test (Pharmacia and Upjohn Diagnostics, Uppsala, Sweden), and the results are given in kU/l. Serum samples with IgE concentrations of 0.35 kU/l or more were regarded as positive, as recommended by the manufacturer. Specific IgE reactivity was measured against latex with Pharmacia CAP System RAST® FEIA under standardized conditions, as recommended by the manufacturer. Specific IgE measurements were also performed against *Lycopodium*; the results are given in kU/l with the same Pharmacia Cap System as in the report from the French condom factory (2). A commercial skin prick test using a standardized extract from *Hevea brasiliensis* (Stallergènes-Pasteur, France) was performed with a

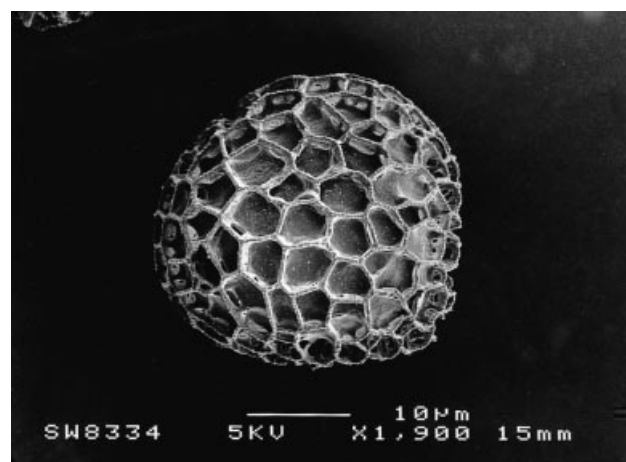


Figure 2. Spore of club moss, *Lycopodium clavatum*. Photograph by Sivert Nilsson, Palynologic Laboratory, Museum of the History of Nature, Stockholm, Sweden.

disposable blood lancet. A positive skin prick test was defined as the presence of a positive reaction with a diameter larger than 2 mm and an area at least 25% that of a reference histamine reaction (1 mg/ml histamine chloride). The RAST were carried out before the skin prick tests.

Patch test procedure

Patch testing was performed according to the internationally accepted method with the TRUE test standard series (24 substances) in Finn Chambers with the addition of 11 substances included in our own standard series (5). In addition to these, we also tested four substances that occurred in the factory – silicone oil, Edward oil, and strawberry and licorice flavorings (Table 1).

Measurements of allergen on the condoms

The level of latex allergen on the surface of the condoms was measured by RAST inhibition. This method measures the latex allergen in an extract prepared from the latex products. The Pharmacia CAP System was used to measure the amount of specific IgE antibodies from latex-allergic patients that had been inhibited by allergen in the latex extracts (6).

Statistical analysis

Proportions were tested with the chi-square test, and parametric variables were tested with Student's *t*-test. The distribution of total IgE levels was tested with Kolmogorov-Smirnov's test of normality, and after logarithmic transformation, it was tested with Student's *t*-test.

Table 1. Substances included in our own standard series for patch testing

1. Nickel sulfate	15. Carba mix	29. Germall II
2. Wool wax alcohols	16. Black rubber mix	30. Amerchel L 101
3. Neomycine sulfate	17. Cl + Me-isothiazolinone (Kathon CG)	31. Tixoclonolpivalate
4. Potassium dichromate	18. Quaternium	32. Toluenesulfonamide formaldehyde resin
5. Caine mix	19. Mercaptobenzothiazole	33. Euxyl K 400
6. Fragrance mix	20. <i>p</i> -Phenylene diamine	34. Budesonide
7. Colophony	21. Formaldehyde	35. Lichen acid mix
8. Epoxy resin	22. Mercapto mix	36. Silicone oil
9. Quinoline mix	23. Thiomersal	37. Edward oil
10. Balsam of Peru	24. Thiuram mix	38. Strawberry flavoring
11. Ethylenediamine dihydrochloride	25. Sesquiterpene lactone mix	39. Licorice flavoring
12. Cobalt chloride	26. Lidocaine hydrochloride mix	
13. <i>p</i> -ter-butylphenol formaldehyde	27. Phenol formaldehyde resin	
14. Paraben mix	28. Primine	

Table 2. Age and smoking habits of 35 workers in condom factory

	Number	Age (years)	Smokers	Ex-smokers	Nonsmokers
Women	29	37 (23–62)	8	4	17
Men	6	32 (24–44)	1	0	5

Results

Of the 29 women and six men, 23 were nonsmokers, nine were smokers, and four ex-smokers (Table 2). They had worked an average of 11 (4–21) years in the factory, 23 subjects working on the packing machines, and the rest working in distribution, administration, and the laboratory. However, the majority of the subjects, 32/35, had worked on the packing machines at some time.

Airways symptoms

Twenty-two subjects reported symptoms of rhinoconjunctivitis, nine of whom were atopic; that is, they had a positive Phadiatop. Three of the subjects with rhinoconjunctivitis had been diagnosed as having asthma, and two of these were atopic. Five had symptoms suggestive of obstructive lung disease.

Work-related symptoms and allergy test results

Ten workers had work-related nose/eye symptoms; of these, eight had positive RAST to *Lycopodium* ($P < 0.001$) (Table 3). Three of the 10 also had symptoms of work-related contact urticaria and suspected occupational asthma suggested by a history of asthmatic symptoms improving on days away from work. All three had positive RAST to *Lycopodium*.

The first patient with suspected occupational asthma and contact urticaria, a 24-year-old woman who had left the factory because of her symptoms, had severe work-related rhinitis and itching in the nose and eyes when working with packaging in the factory. When retiring at night after a day at work, she had experienced wheezing in the chest. She was symptom-free at the time of the

study. The second patient, a 32-year-old woman, had also stopped working at the factory and currently worked at home. She had worked in the factory for 10 years, and during the final 6 years had work-related rhinoconjunctivitis, which began upon her return to work in the packaging area after a pregnancy leave. After some time, she suffered work-related symptoms suggestive of obstructive lung disease. On exertion, she had wheezing in the chest, breathlessness, and intense cough. After she left the factory, all her respiratory symptoms disappeared. The third patient, a 31-year-old man, had worked in the factory for 11 years. After 9 years, he was diagnosed as having asthma and was transferred from the packaging to the distribution area, thus decreasing exposure to lycopodium powder. Once he had moved, his symptoms disappeared.

The more severe the symptoms, the higher the total IgE levels and the specific IgE levels against *Lycopodium* (Fig. 3). Thus, the highest specific IgE levels against *Lycopodium* were found in the three subjects with the combination of work-related asthma, rhinoconjunctivitis, and contact urticaria. Lower levels were found in the

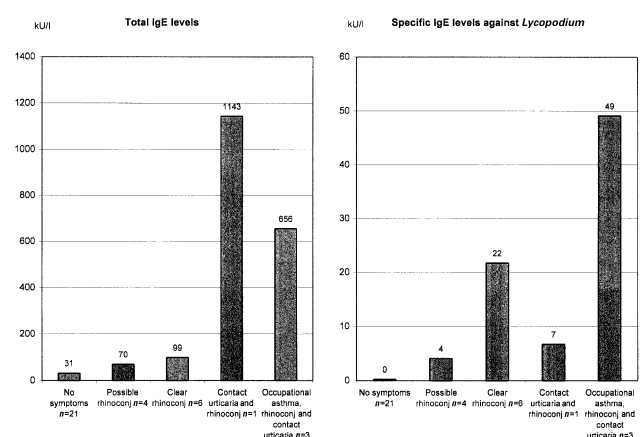


Figure 3. The more severe the symptoms, the higher the total IgE levels (left graph) and specific IgE levels against *Lycopodium* (right graph). Highest total IgE level was found in 47-year-old woman with positive RAST against latex; she had quite low level of specific IgE level against *Lycopodium* although it was positive.

Table 3. Work-related symptoms and results of allergy tests

	Men/women	Phadiatop positive	RAST latex positive	RAST <i>Lycopodium</i> positive	
All	6/29	9/35	1/35	11/35	
Work-related rhinoconjunctivitis	2/8	4/10	1/10	8/10	$P < 0.001$
Occupational asthma	1/2	1/3	0/3	3/3	
Work-related contact urticaria	1/3	2/4	1/4	4/4	
No airway symptoms	4/17	3/21	0/21	2/21	
					$P = 0.007$
					$P = 0.002$

subjects that had only work-related rhinoconjunctivitis, and very low levels were found in the subjects with no work-related symptoms. The total IgE levels were also high in the three subjects with the combination of work-related asthma, rhinoconjunctivitis, and contact urticaria.

RAST against latex

Only one subject, a 47-year-old woman with rhinoconjunctivitis and contact urticaria, had positive RAST against latex, and she also had positive RAST against *Lycopodium*. She had had a history of contact urticaria for over 10 years, starting after contact with latex during the period that latex products were manufactured in the factory. It seems that she became sensitized to latex at that time. At the time of the study, she was working in the laboratory testing the quality of the condoms and had only minor work-related upper airway symptoms such as sneezing. The highest total IgE level was found in this subject; she had a quite low level of specific IgE against *Lycopodium* although it was positive (Fig. 3). For safety reasons, the skin prick test with latex was not performed in this woman, and it was negative in all the other 34 tested. None of the subjects had any history of food allergy.

Risk groups for sensitization

All subjects with RAST positive to *Lycopodium* had worked in the packaging area, the area of the factory with the greatest exposure to lycopodium powder. The risk of sensitization had no correlation with years of

employment. The risk of sensitization to *Lycopodium* was higher in atopic subjects; five of the nine with positive Phadiatop also had positive RAST to *Lycopodium* ($P = 0.008$) (Fig. 4). The risk of sensitization to *Lycopodium* was similar in smokers and nonsmokers (Fig. 4). Interestingly, of the six atopic subjects with positive RAST to *Lycopodium*, five had positive RAST to pollen allergen (Table 4). The sixth atopic subject with a negative RAST to *Lycopodium* was a borderline atopic according to the Phadiatop level, which was 0.36 kU/l; the limit for atopy is >0.35 kU/l.

Skin symptoms and patch test results

The results of the patch testing were not correlated with the work-related airways symptoms or with work-related contact urticaria. Twelve of the subjects were diagnosed as having contact dermatitis, 11 women and one man. Two women had atopic dermatitis. Four subjects had acne, two folliculitis, two psoriasis, one vesiculosis, and one eczema of the legs. Fourteen had a positive patch test; of these, 11 were positive to nickel and two to fragrance mix. One woman was positive to rubber chemicals (Thiuram mix), thiomersal, and cobalt. Seven subjects with a positive patch test were also diagnosed as having contact eczema. Of these, six were positive to nickel and the seventh was the one positive to rubber chemicals, thiomersal, and cobalt. Eight of the 28 subjects with pierced ears had a positive patch test to nickel.

Measurement of latex on the surface of the condoms

No detectable level of latex allergens was found on the surface of the condoms.

Discussion

Allergic symptoms were common in the condom factory. Ten of the 35 current workers (29%) and two former workers had work-related rhinoconjunctivitis. Three of the 35 (9%) (among them, the two former workers) also had signs of occupational asthma in addition to work-related rhinoconjunctivitis. During periods of high demand for condoms associated with alarm about AIDS, the staff of the factory had been larger than at the time of our study, and the occupational health service told us that a number of workers had left the factory with symptoms. It is

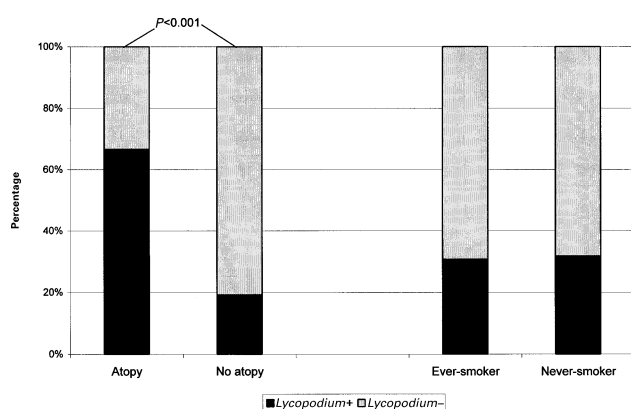


Figure 4. Positive RAST to *Lycopodium* in relation to atopy and smoking habits.

Table 4. Atopy, specific IgE to *Lycopodium* in relation to positive specific IgE to common allergen

Sex	Age (years)	Phadiatop	Phadiatop level kU/l	<i>Lycopodium</i> RAST	<i>Lycopodium</i> RAST level kU/l	RAST pollen	RAST house-dust mites	RAST animal dander	Work-related symptoms
Woman	48	+	14.00	+	6.70	Mugwort	DPT	Cat, dog	Rhinoconjunctivitis
Man	37	+	2.71	–	–	–	–	Cat, dog	–
Man	27	+	3.15	–	–	Birch	–	–	–
Woman	32	+	13.20	+	28.60	Birch	–	–	Rhinoconjunctivitis
Woman	29	+	4.60	+	10.00	Birch	DPT	–	Rhinoconjunctivitis
Woman	57	+	0.36	+	16.30	–	–	–	Suspected rhinoconjunctivitis
Woman	24	+	1.03	–	–	–	DPT	–	Suspected rhinoconjunctivitis
Woman	24	+	9.58	+	94.00	Timothy	DPT	Cat, dog	Occupational asthma
Man	28	+	18.70	+	3.80	Timothy	–	Cat, dog	–

DPT: *Dermatophagoides pteronyssinus*.

possible, therefore, that our results underestimate the true risk of sensitization, as we do not know how many workers left because of work-related symptoms. It was possible to include only two workers that had left the factory during the last few years.

The symptoms were significantly correlated with positive RAST against *Lycopodium*. Atopic subjects, especially those sensitized to pollen, had a significantly higher risk of sensitization than nonatopic subjects, but the risk was not related to smoking habits. The more severe the symptoms, the higher the total IgE levels and the specific IgE levels against *Lycopodium*. All three cases of occupational asthma also had work-related rhinitis and contact urticaria, as well as the highest specific IgE values against *Lycopodium*. There have been reports of skin rashes developing in those coming into contact with club moss in the woods, but it is unknown how common sensitization to *Lycopodium* is in the general population (7).

There was only one case of latex allergy among the 35 workers in the factory, and this was probably the result of high exposure during the period when the company manufactured latex products. Before automation, workers had extensive skin contact with the condoms, as well as inevitable exposure to latex, since 1.5 million condoms were loaded into the machines every week. The reason for the low prevalence of latex allergy is probably that low levels of latex allergen are found on the surface of the condoms, a fact which probably also results in low airborne levels, and it seems likely that the condoms are properly rinsed during their manufacture in Japan; we have not been able to discover whether workers in the Japanese factory have allergic symptoms.

Contact allergy to rubber chemicals was not the cause of symptoms; the one patient who did have a positive reaction to rubber chemicals on patch testing had no work-related skin symptoms. Thirty-one percent of the subjects (11/35) were allergic to nickel, and this high proportion is probably explained by the fact that 28 had pierced ears. However, allergy to nickel was not correlated with work-related symptoms.

To reduce the risk of occupational allergies, there are several options such as replacement, better ventilation, and encapsulation of the most dusty parts of the process. Several actions of this kind have already been taken in the factory. When the manufacturing of latex products ceased in 1992, considerable modernization of the plant was undertaken, and the work environment has been improved by, for example, improved general ventilation and local ventilation devices at the packaging machines. The loading of the machines was also automated, and the packaging machines were enclosed, thus minimizing the time the workers spend close to the machines; these changes have resulted in minimizing skin contact with the condoms.

The spores of *Lycopodium* have evolved to become airborne; thus, they are a substance troublesome to work with. Since the best cure for an occupational allergy is to replace the causative agent, it is likely that lycopodium powder will be replaced by cornstarch. However, cornstarch may actually carry the latex allergen. Therefore, there is a risk that this may potentiate the development of latex allergies, but, as the levels of allergen on the surface of the condoms are very low, this risk may not materialize. Allergy to latex is worse than allergy to *Lycopodium*, since latex allergy may cause symptoms by contact with latex in daily life, and there is also a well-recognized cross-reaction with allergens in some foods such as banana, avocado, kiwi fruit, and some nuts, as well as with *Ficus benjamina* allergens (8, 9). There are no reports of cross-reactivity between *Lycopodium* and food allergens, and none of the subjects in this study had a history of food allergy.

Since lycopodium has been used for such a long time in the factory, it is probably widespread there – in the ventilation ducts, for example. We were therefore concerned that those sensitized to *Lycopodium* would continue to have symptoms even after lycopodium powder is replaced. The symptoms of one of the occupational asthma patients improved after he was moved to the distribution area, an observation which suggests that substantial exposure

is needed to induce symptoms, and that the symptoms of other allergic individuals will improve once the lycopodium is replaced.

Atopic subjects had a significantly higher risk of sensitization to *Lycopodium*, as was to be expected, because it is well known that patients with atopy have a higher risk of sensitization to high-molecular-weight occupational allergens than nonatopics (10). Since as many as two-thirds of the atopic subjects in the study had become sensitized to *Lycopodium*, such persons would be well advised not to work close to the packaging machines until the lycopodium is replaced. Other studies have shown that the risk of occupational allergies increases with increasing exposure, but the numbers in this study were too small to demonstrate any significant difference between different exposure groups (11, 12). In particular, there were very few subjects who could be categorized as having a low exposure, since almost all the staff had worked at some time with the packaging machines, where the exposure to lycopodium was highest.

In this study, the risk of sensitization to *Lycopodium* was similar in smokers and nonsmokers. Earlier, there have been reports of a higher risk of

sensitization to occupational allergens in smokers (13–15). But these results have not been confirmed in a recent pooled study of data from three cross-sectional studies including 1062 laboratory animal workers (12).

Although we found a high risk of sensitization to *Lycopodium* among the workers in the condom factory, we do not recommend that people should stop using condoms for fear of developing allergy to *Lycopodium*. There is only one report in the literature of allergic asthma in a condom user; thus, the risk of sensitization to *Lycopodium* is negligible compared to the risk of sexually transmitted disease or unwanted pregnancy (16).

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