

Nickel allergy – prevalence in a population of Swedish youths from patch test and questionnaire data

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Background: The prevalence of body piercing and orthodontic treatment has increased during recent decades. Such changes in lifestyle may influence the occurrence of nickel allergy.

Objectives: The aim of this study was to describe the prevalence of nickel allergy in a Swedish youth population.

Methods: In a cross-sectional survey, 6095 adolescents answered a questionnaire on their lifestyle and medical history, and 4439 consented to patch testing for contact allergy. Patch test results were adjusted for dropouts by a missing value analysis.

Results: The prevalence of self-reported dermatitis from contact with metal items was 14.8%. Patch testing showed nickel sensitization in 9.9% of the subjects, and in significantly more girls than boys, 13.3% versus 2.5%, respectively. Taking the dropout into account, the estimated true prevalence of nickel sensitivity evaluated by test reading at D4 is 11.8% in girls and 1.6% in boys.

Conclusions: The prevalence of nickel sensitization was higher for girls and slightly lower for boys compared with previous Swedish data. Self-reported information on metal dermatitis as an estimate of nickel allergy has low validity. When possible, missing value analysis should be performed to account for dropouts.

Key words: adolescent; lifestyle; missing value analysis; orthodontic treatment; patch test; questionnaire. © Blackwell Munksgaard, 2007.

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Nickel has been repeatedly shown to be the most common cause of contact allergy (1–3). Data from studies among Swedish schoolgirls and conscripts and from Danish populations suggest a prevalence of nickel sensitization among children and adolescents of 9.0–13.7% for girls and 1.9–2.5% for boys (4–7). As nickel allergy is associated to exposure rather than genetic factors; fluctuations in prevalence because of lifestyle changes are likely. The issue has been recognized by the European Union (EU) in a Nickel Directive (8) that fully came into force by July 2001. Reports from Denmark, where a regulation of nickel exposure had already been adopted in 1992, indicate a decreasing trend of allergy to nickel (9–11). There is no

recent population-based Swedish data on nickel sensitivity as diagnosed by patch testing. National evaluations of the impact from the Nickel Directive have been restricted to nickel release tests *in vitro*, on items intended for contact with the skin (2). The present study started in 2000, that is directly coinciding with the period during which the Nickel Directive was being implemented, and may thus serve as a baseline for future studies on nickel sensitivity in Swedish adolescents.

The aim of this study was to establish data of nickel allergy in a Swedish youth population as part of a project investigating the association between nickel allergy and orthodontic appliance treatment and lifestyle factors.

Subjects and Methods

Study design and target population

The study is a cross-sectional survey conducted among all upper secondary schools in Umeå, Sweden and between 2 upper secondary schools in Örebro, Sweden from September 2000 to May 2004 in Umeå, and from October 2003 to April 2004 in Örebro.

Following a briefing session a questionnaire on lifestyle, medical issues, and orthodontic treatment was administered to all pupils present. Patch testing to nickel and 23 other common contact allergens were performed on consenting adolescents. A flow-chart illustrating the participation proportions is shown in Fig. 1.

The sample size was calculated to give a sufficient number of adolescents for later case-referent analyses. Eligible upper secondary school students in Umeå and Örebro during this study period

(target population) amounted to 8358 and 6814, respectively (Fig. 1).

Study population

Out of 7543 adolescents (4409 girls and 3134 boys) in the study population (students on class lists in visited classes) 6364 individuals were present at briefings, 6095 (81%) students aged 14.9–23.4 years (mean age 17.4 years) completed the questionnaire. The response rate among pupils present at the briefing sessions was nearly 96% (6095/6364) for the questionnaire and 70% (4439/6364) consented to patch testing.

The majority of the questionnaires (81%) and patch tests (77%) were collected in Umeå. The participation rate was higher among girls (Fig. 1).

Of registered students, 1179 (14% girls and 18% boys) were not present at the briefing sessions.

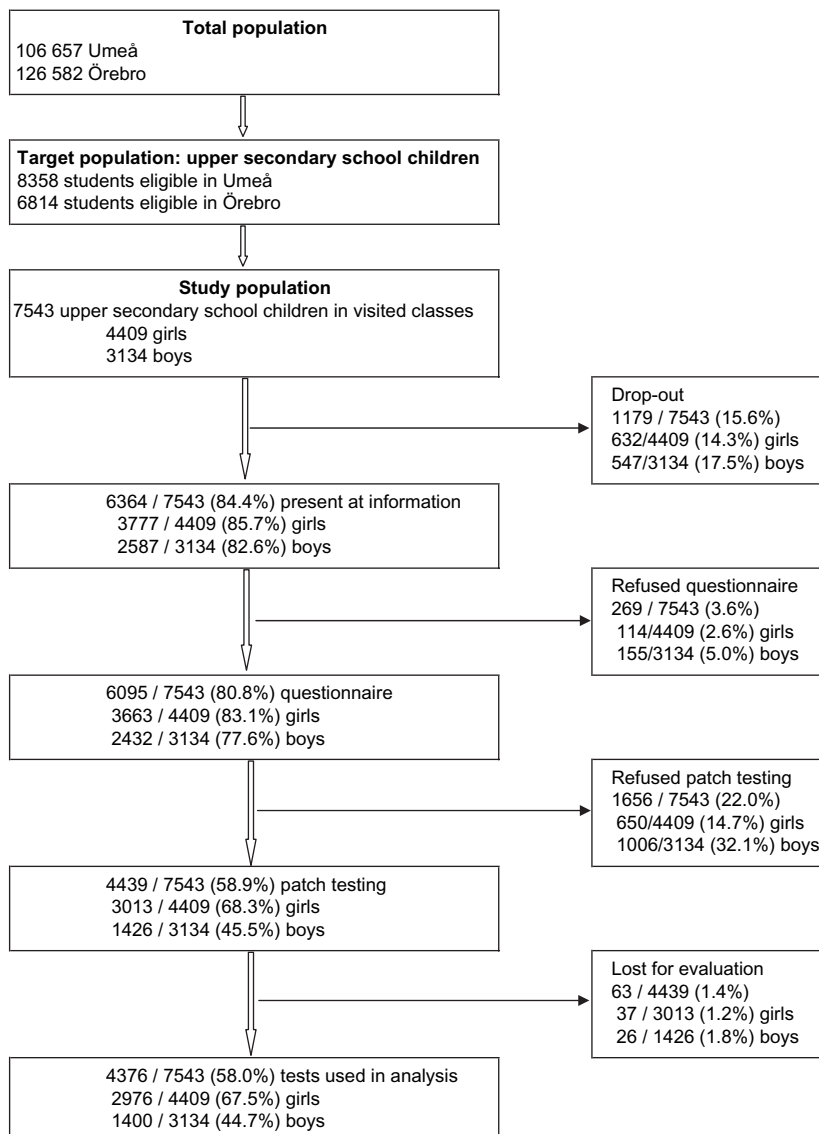


Fig. 1. Flow-chart and participation proportion in the cross-sectional study on nickel allergy and lifestyle factors.

For non-participants, we have information on age, sex, and educational programme, and the research nurse informally enquired as to their reason for non-participation. One individual refused to participate, because she suspected that she was allergic to nickel.

To adjust for the differences in characteristics among attendants and non-attendants in the patch test, a missing value analysis based on questionnaire data was performed.

In 63 students (1.4%) patch tests fell off and could not be evaluated.

Questionnaire

A few days after the briefing sessions, specially trained school nurses visited the classes to distribute the questionnaires. During this visit, the adolescents were offered a patch test. In case of absences in class, the school nurse returned after some weeks to collect any outstanding questionnaires. The questionnaire comprised questions on eczema caused by metal contact and a history of flexural eczema. For future analysis, questions on lifestyle factors and orthodontic appliance treatment (dental braces) were included. These factors were also used for a missing value analysis.

Definitions and descriptions of terms are as follows.

Nickel sensitivity (nickel allergy): This was defined as a positive patch test (+ to +++) (12).

Metal dermatitis: The self-reported point prevalence of eczema from skin contact with metal was evaluated using the question: 'Do you get itching eczema from metal parts that come into contact with your skin, for example from costume jewellery, jeans buttons, wrist watches etc.?' (13).

Flexural eczema (a surrogate variable for atopic eczema): This was defined from the question 'Do you have/Have you ever had itching eczema in flexural folds on arms or legs (flexural eczema)?'

Patch test method

TRUE Test[®] panels 1 and 2 (Mekos Laboratories A/S, Hillerød, Denmark) were used containing 24 of the most common contact allergens. No testing was performed during summer months (June to August).

The test was applied for 2 days. On day 4 (D4), the patch tests were read once either by a trained school nurse or a dermatologist. For calibration purposes, each school nurse together with one of the dermatologists read the patch tests during the initial weeks. Subsequently, all readings were performed by either one of the dermatologists or a school nurse. The reactions were classified according to international guidelines (12). In 3

cases of uncertainty in test readings, photographs were taken for evaluation by a dermatologist.

Statistical analysis

The prevalence of nickel sensitivity according to patch test results and metal dermatitis according to self-reported data from the questionnaire were calculated with 95% confidence interval (CI). The χ^2 -test was used for comparison of proportions.

To validate our data and investigate possible effects of dropouts on the results, a missing value analysis was performed. First, the association between test reaction to nickel, and the specific background variables (educational programme, time sequence orthodontic appliance and piercing, and number of piercings), was stratified by sex and summarized in a logistic model.

Assuming that the associations between a positive test and the background variables were also valid for those not tested, the logistic regression model was used to predict the outcome of the patch test if those that had dropped out would have been tested. The prediction was repeated 50 times, each time with a slight random disturbance on the impact of the background factors. An individual was classified as having a positive patch test if the probability calculated from the logistic model exceeded 0.5.

When estimating the prevalence in the target population (standardized prevalence), we have used weights based on the actual number in each educational programme.

All statistical analysis was performed using the SPSS 12.0.1 statistical software package.

Ethical considerations

The study was approved by the Ethics Committee of the Faculty of Medicine and Odontology, Umeå University.

Results

Questionnaire data

The self-reported frequency of metal dermatitis was higher, among both girls and boys, than that of positive tests to nickel and/or cobalt. Self-reported metal dermatitis may also reflect cobalt allergy, exclusively or in combination with nickel allergy. Self-reported metal dermatitis in boys was twice as common as test verified nickel and/or cobalt allergy.

Pupils in arts programmes reported the highest prevalence of metal dermatitis, and those in natural science programmes reported the lowest. The highest prevalence was reported by girls in the

Table 1. Prevalence of nickel sensitivity according to self-reported data from questionnaire (i.e. symptoms from metal skin contact), and patch test in Örebro, Umeå, and in total^a

Variable	Self-reported by questionnaire						Patch testing					
	Girls			Boys			Total			Girls		
	<i>n</i>	(%)		<i>n</i>	(%)		<i>n</i>	(%)		<i>n</i>	(%)	
Örebro												
Sex	135/654	20.6 (17.5–23.7)		23/476	4.8 (2.9–6.7)		158/1130	14.0 (12.0–16.0)		101/616	16.4 (13.5–19.3)	
Educational programme												
Natural science	29/175	16.6 (11.1–22.1)		5/185	2.7 (0.4–5.0)		34/360	9.4 (6.4–12.4)		25/169	14.8 (9.4–20.2)	
Social science	53/225	23.6 (20.8–26.4)		7/83	8.4 (2.4–14.4)		60/308	19.5 (15.1–23.9)		34/217	15.7 (10.9–20.5)	
Arts	47/221	21.3 (18.5–24.1)		3/58	5.2 (0.0–10.9)		50/279	17.9 (13.4–22.4)		34/200	17.0 (11.8–22.2)	
Vocational	6/33	18.2 (11.5–24.9)		8/150	5.3 (1.7–8.9)		14/183	7.7 (3.8–11.6)		8/30	26.7 (10.9–42.5)	
Umeå												
Sex	618/2991	20.7 (19.3–22.1)		118/1938	6.1 (5.0–7.2)		736/4929	14.9 (13.9–15.9)		296/2360	12.5 (11.2–13.8)	
Educational programme												
Natural science	93/505	18.4 (15.0–21.8)		29/661	4.4 (2.8–6.0)		122/1166	10.5 (8.7–12.3)		32/402	8.0 (5.4–10.6)	
Social science	259/1353	19.1 (17.0–21.2)		48/686	7.0 (5.1–8.9)		307/2039	15.1 (13.5–16.7)		116/1052	11.0 (9.1–12.9)	
Arts	43/206	20.9 (15.3–26.5)		8/72	11.1 (3.8–18.4)		51/278	18.3 (13.8–22.8)		13/163	8.0 (3.8–12.2)	
Vocational	223/927	24.1 (21.3–26.9)		33/519	6.4 (4.3–8.5)		256/1446	17.7 (15.7–19.7)		135/743	18.2 (15.4–21.0)	
Total												
Sex	753/3645	20.7 (20.3–21.1)		141/2414	5.8 (4.9–6.7)		894/6059	14.8 (13.9–15.7)		397/2976	13.3 (12.1–14.5)	
Educational programme												
Natural science	122/680	17.9 (15.0–20.8)		34/846	4.0 (2.7–5.3)		156/1526	10.2 (8.7–11.7)		57/571	10.0 (7.5–12.5)	
Social science	312/1578	19.8 (17.8–21.8)		55/769	7.2 (5.4–9.0)		367/2347	15.6 (14.4–17.1)		150/1269	11.8 (10.0–13.6)	
Arts	90/427	21.1 (17.2–25.0)		11/130	8.5 (3.7–13.3)		101/557	18.1 (14.9–21.3)		47/363	12.9 (9.5–16.3)	
Vocational	229/960	23.8 (21.1–26.5)		41/669	6.1 (4.3–7.9)		270/1629	16.6 (14.8–18.4)		143/773	18.5 (15.8–21.2)	

^a95% CI of the estimated prevalence given within brackets.

vocational programmes and by boys in the arts programmes. Differences in educational programmes between the 2 cities were observed as well (Table 1).

Patch test data

A positive reaction to nickel was found in 432/4376 (9.9%) subjects. More girls than boys reacted to nickel, 13.3% versus 2.5% (Table 1). The figures for a cobalt and/or nickel sensitivity by patch testing were comparable to the nickel prevalences, adding less than 0.5% to the overall proportion (data not shown).

Stratifying for educational programmes, the highest frequency of positive patch tests to nickel was seen in the vocational programmes (12.7%) and the lowest in the natural sciences programmes (6.2%). Girls in the vocational programmes (18.5%) and boys in the social science programmes (3.3%) had the highest prevalence of positive test to nickel, whereas girls in natural science programmes (10.0%) and boys in the same programmes (1.5%) represented the lowest prevalence. In addition, differences in results within educational programmes between the 2 municipalities were observed (Table 1).

Missing value analysis and weighted (standardized) results

The analyses predicted an occurrence of a positive patch test to nickel for girls of 11.8% (range 11.6–12.1) and for boys of 1.6% (range 1.5–1.7) (Fig. 2). The precision of the analysis was good, with a limited variation in predicted prevalence.

In order to estimate the prevalence that would have been obtained if all eligible students would have been tested, we standardized our results to the actual proportions of students in each educa-

Table 2. Measured, predicted^a, and weighted (standardized)^b prevalence of nickel sensitivity

	Measured prevalence		Predicted prevalence		Weighted prevalence	
	Girls (%)	Boys (%)	Girls (%)	Boys (%)	Girls (%)	Boys (%)
Örebro	16.4	2.1	15.8	1.9	21.7	1.7
Umeå	12.5	2.7	11.1	1.5	13.3	2.9
Total	13.3	2.5	11.8	1.6	14.6	2.8

^aPredicted prevalence is calculated from a missing value analysis.

^bStandardized using the actual proportion of students in each educational programme in the target population.

tional programme. The standardized/weighted prevalence for girls was 14.6% and for boys 2.8%. Detailed information on calculated prevalences according to the missing value analysis and weighted results are given in Table 2.

Validity of self-reported symptoms of metal dermatitis in comparison to patch test data

The sensitivity and specificity of questionnaire based metal dermatitis compared with nickel and/or cobalt sensitivity by patch test was 52.3% (CI 47.5–57.0) and 87.2% (CI 86.1–88.2), respectively (Table 3). Apart from boys showing a higher specificity (94.5% CI 93.1–95.6) than girls (83.3% CI 81.8–84.7), no difference in validity was seen when stratifying for educational programmes and sex (data not shown).

Because of more false-positive responses (76.2% versus 63.9%), individuals with a history of flexural eczema showed a lower specificity (79.0% CI 76.4–81.3) than subjects without flexural eczema (90.5% CI 89.3–91.6). A low sensitivity was found in subjects with as well as without flexural eczema (55.5% CI 46.4–64.2 and 48.8% CI 43.0–54.7) (Table 4).

Discussion

We consider the study sample representative of the current age group of a Swedish urban population

Table 3. Number of patch test to Ni/Co (gold standard) versus self-reported reactions from metal skin contact^{a,b,c}

Self-reports	Patch test		Total
	Ni/Co positive	Ni/Co negative	
Yes	232	502	734
No	212	3407	3619
Total	444	3909	4353

^a95% confidence interval of sensitivity and specificity are given within brackets.

^bSensitivity 52.3% (47.5–57.0).

^cSpecificity 87.2% (86.1–88.2).

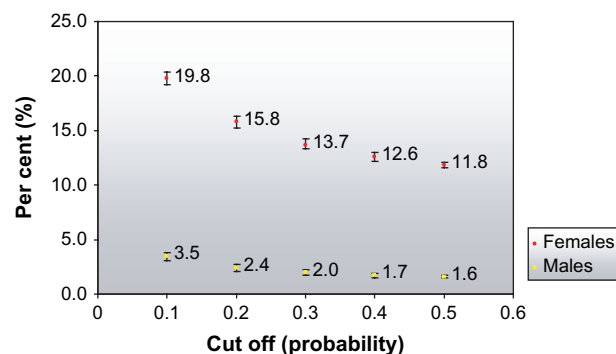


Fig. 2. Predicted prevalence (mean %; range values indicated by arrows) of positive patch tests to nickel according to the missing value analyses, and given for different cut off levels.

Table 4. Number of patch test to Ni/Co (gold standard) versus self-reported reactions from metal skin contact stratified for flexural eczema^a

Variable	Self-reports	Patch test		Total	
		Ni/Co positive	Ni/Co negative		
Flexural eczema	Yes	71	227	298	Sensitivity 55.5% (46.4–64.2); specificity 79.0% (76.4–81.3)
	No	57	852	909	
	Total	128	1079	1207	
No flexural eczema	Yes	144	255	399	Sensitivity 48.8% (43.0–54.7); specificity 90.5% (89.3–91.6)
	No	151	2438	2589	
	Total	295	2693	2988	

^a95% confidence interval of sensitivity and specificity are given within brackets.

as 98–99% of 9th grade students continue to upper secondary schools (14), the schools under study host students from both urban and rural areas, and all educational programmes are represented. The only dropout that we identified as a problem was that of individuals responding to the questionnaire but not consenting to patch testing. A risk of selection bias is evident. There was a 2 to 3 times higher proportion of boys than girls and a greater proportion of non-pierced adolescents in the non-consenting group. This selection bias is handled in the missing value analysis.

For practical reasons, a single D4 reading of the patch tests was performed, as has been recommended when only 1 reading is carried out (15, 16). Normally 2 readings at D3/D4, and D7 are performed (17). By performing only 1 reading, nearly 10% of patch test reactions to nickel may be missed because of delayed reactions (18).

Readings were made by 4 different people, either by 2 experienced dermatologists or by 2 especially trained research nurses. We did not evaluate the inter-investigator variation in patch test reading, which is a weakness of the study. However, a good inter-individual accordance among experts has been found (19).

Assuming a worse case scenario whereby none or all in the non-consenting group would have shown a positive patch test to nickel, the estimated occurrence of nickel allergy could have ranged between 7.1% and 35.3% (girls 10.8–29.6% and boys 1.4–43.9%). To increase quality of our data, we analysed possible effects of the 'non-consenting to patch test' population on the outcome (nickel sensitivity) by a missing value analysis. The prediction of nickel sensitivity according to the missing value analysis was about 1% lower than that seen from patch testing (girls 13.3% and boys 2.5%); thus indicating a selection bias causing an overestimation of nickel allergy in our population. One possible explanation for this is selective participation, whereby more adolescents who suspected that they were nickel sensitive consented to patch testing. However, the calculated

overestimation of 1–1.5% may be considered a moderate deviation from the patch test results. Importantly, the findings from the missing value analysis indicate that the dropout, although substantial, does not seem to have any major influence on the nickel prevalence in the present population. Further, standardizing to the target population indicates an underestimation in our patch test results. The measured prevalence of nickel allergy in female students of the vocational programme in Örebro was extremely high (26.7%), even higher than the self-reported allergy (18.2%) (Table 1). These results deviate from all the other groups and are based on a very small number of tested individuals ($n = 30$). Applying this prevalence on the true population in Örebro probably results in an extremely high estimate (21.7%) (Table 2). We consider this validity check to be highly important in prevalence studies, although we have not found any previous studies assessing a missing value analysis in a similar context as ours.

We found a large sex difference in prevalence of both self-reported metal dermatitis and in nickel sensitivity verified by patch test indicating a higher exposure to the allergen among girls than among boys. Compared with previous Swedish reports, our results showed a higher prevalence among girls (5) and slightly lower prevalence among boys (4). A possible explanation for this could be the younger female populations and older male populations in previous studies (4, 5) compared with the present study. Our sex-stratified prevalence figures in nickel sensitization are in accordance with studies from Denmark (6, 7).

The findings suggest differences in lifestyle and exposure situations between individuals in the different educational programmes, as well as between the 2 school districts (Umeå and Örebro). So far, no previous data on educational programmes in relation to nickel sensitivity exists; therefore, the data presented in this study may serve as a baseline. Our data on lifestyle factors

and their association to nickel sensitivity will be reported separately.

Self-reports on metal dermatitis usually tend to overestimate the occurrence of true nickel allergy, as metal intolerance may be because of skin irritation (1, 20, 21). Precision of the questions and recall among respondents are likely to influence the outcome, with risk of misclassification (22, 23). The validity of self-diagnosed metal dermatitis differed from most previous studies (22, 24–26). A possible explanation for the observed difference in validity compared with most previous studies may be a younger and less selected population with a lower occurrence of the 'disease'. Interestingly, in a study very similar to ours, Mortz et al. (20) in Danish adolescents found almost identical prevalence of self-reported metal dermatitis (15.5%) as we did (14.8%). Moreover, among those reporting reactions to metals, a positive patch test to nickel/cobalt was found in 30.7% and 31.6%, respectively. In summary, self-reporting of metal dermatitis using our wording has a low validity in predicting nickel allergy.

Subjects with atopic eczema, expressed as flexural eczema, had a higher proportion of 'false-positive' answers on metal dermatitis compared with those without eczema. In a study on a highly selected sample of hospital 'wet' workers with hand eczema, a similar finding of false-positive proportions was seen between atopics and non-atopics (25). A plausible explanation is that persons with atopic skin type more easily react with irritative dermatitis when exposed to nickel (27).

Conclusions

13.3% of girls and 2.5% of boys showed a positive patch test to nickel. The prevalence of nickel sensitization was higher for girls but slightly lower for boys compared with previous Swedish data. The results are in accordance with recent Danish data. Self-reported information on metal dermatitis as an estimate for nickel allergy has low validity.

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