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Nickel allergy in Spain needs active intervention

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Introduction

Nickel is the most common contact allergen in Europe, both in patch-tested patients and in the general population (1). Nickel is ubiquitous, and skin sensitization mainly derives from contact with high-consumption objects such as buttons, clothing fasteners, mobile phones, and jewellery (2). The vast majority of nickel-allergic women are sensitized through ear piercing, often as early as in childhood (3, 4). In 1990, the Danish regulation of nickel was pioneering (5). In 1994, The EU approved the Nickel Directive, which entered into full force in 2000 (6). The limit of nickel release from consumer products with prolonged skin contact was set at 0.5 µg/cm²/week. In 2005, a new requirement specified the maximum nickel release level from any inserted, pierced object as 0.2 µg/cm²/week (7). Despite the fact that these regulations were shown, at least to some extent, to be effective in Denmark (8, 9) and Germany (10), it remains unclear whether the prevalence of nickel allergy in other European countries is decreasing. The aim of this study was to determine whether sensitization to nickel is still a human hazard and public health problem in Spain.

Materials and Methods

A total of 1161 patients with suspected allergic dermatitis were studied in five contact allergy units in five different Departments of Dermatology in Spain during 2008. Patch testing was conducted according to the International Contact Dermatitis Research Group criteria. The TRUE Test[®] system or Finn Chambers[®] covered with Scanpor[®], with allergens supplied by Trolab-Almirall[®] (Almirall Hermal, Barcelona, Spain) and Chemotechnique[®] (Sugelabor S.A., Madrid, Spain), were employed. The Spanish baseline series, which includes nickel sulfate 5% pet. (0.2 mg/cm² in TRUE Test[®] (Stallergenes Ibérica, S.A., Barcelona, Spain)), was always tested. Data were recorded with the Spanish version of the multilingual WINALDAT/European Surveillance System on Contact Allergies (ESSCA) software (11). Statistical analysis was performed with the support of the European Surveillance System on Contact Allergies, using SAS[®] software (version 9.2; SAS Institute, Cary, NC, USA). Prevalence was directly age-standardized and sex-standardized according to published criteria (12). Age was stratified into four groups, namely 1–20, 21–40, 41–60 and 61–99 years. Differences regarding nickel sensitization between age groups were tested with the chi-square test, stratified for male versus female patients.

Results

From a total of 1161 patients, 421 were men (33.2%) and 740 were female (63.7%). The mean age was 44.5 years. The MOAHLFA index was as follows: male, 36.3%; occupational, 14.6%; atopic, 10.8%; hand, 28.6%; leg, 9.3%; face, 15.2%; age 40 years and above, 65.4%. The overall prevalence of nickel sensitization was 25.9% [95%

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Table 1. Prevalence of sensitization to nickel in Spain in 2008 with regard to age and sex groups; no significant differences between age groups were found in males, whereas the prevalence of nickel allergy differed significantly between age groups in females ($p = 0.003$, chi-squared test)

Age range (years)		Males			Females		
		Negative	Positive	Total	Negative	Positive	Total
1–20	<i>n</i>	20	2	22	23	13	36
	%	90.9	9.1		63.9	36.1	
21–40	<i>n</i>	101	9	110	165	94	259
	%	91.8	8.2		63.7	36.3	
41–60	<i>n</i>	145	17	162	167	112	279
	%	89.5	10.5		59.9	40.1	
61–99	<i>n</i>	117	10	127	128	38	166
	%	92.1	7.9		77.1	22.9	
Total	<i>n</i>	383	38	421	483	257	740

confidence interval (CI) 23.4–28.4%], with important differences between males (9% and 95% CI 6–11.9%) and females (35% and 95% CI 31.5–38.6%), the female/male ratio being 4 : 1 in the 41–60-year age range. Regarding age groups in females, the nickel sensitization prevalence was very similar in the three youngest age groups and the group older than 60 years ($p = 0.003$; Table 1).

Discussion

We have found a high overall prevalence of nickel sensitization in Spanish patients, especially in young women up to 60 years of age. These figures are among the highest in Europe, and should not be tolerated in a country covered by the EU Nickel Directive.

The last results published by the ESSCA (13) show that sensitization to nickel is more frequent in southern Europe. In Spain, the frequency has remained stable, at approximately 25%, over recent years (14, 15). In Italy, Rui et al. (16) reported a prevalence of nickel allergy of 24.6% after studying 14 464 patients with suspected allergic dermatitis who underwent patch testing from 1997 to 2004. They also found a considerable difference

between males (10%) and females (31.6%). However, they found lower nickel sensitization among the youngest women, suggesting an effective impact of EU regulation in this country. In Greece, a recent study (17) compared patch-testing results in children with suspected dermatitis between two periods of time, namely 1980–1993 and 1994–2007. Increased overall prevalences of nickel allergy in girls, from 16.4% to 21.6%, and from 24.1% to 31.4%, respectively, were shown. The differences found between southern regions and the rest of Europe could be explained by: (i) a low level of enforcement of the existing regulations; and (ii) social and cultural factors, such as the trend for ear and body piercing at younger ages, or the use of inexpensive jewellery.

To strengthen the observance of the EU Nickel Directive, analysis of the release of nickel from consumer objects, especially from inexpensive jewellery, is strongly recommended. For this purpose, the dimethylglyoxime (DMG) test is a suitable tool, being cheap and quick. Thyssen et al. (18) suggested that the frequency of DMG-positive jewellery could be as high as 25–30% in unregulated markets (e.g. San Francisco, USA (19)) and approximately 10% in the regulated European market (e.g. Sweden (20) or Denmark (18)). Because of the moderate sensitivity of the DMG test of 59%, the true frequency of metallic objects releasing more than $0.5 \mu\text{g}/\text{cm}^2/\text{week}$ may even be higher (21). Such research has never been performed in Spain, where it would be interesting to extend the study to expensive jewellery and other items covered by the European directive.

Nickel allergy remains a major public health problem in Spain and probably in other southern regions of Europe. It is necessary to verify the enforcement of the actual regulations in these countries before blaming the problem entirely on social and cultural factors. Analysis of the release of nickel from consumer objects, such as inexpensive jewellery, with the DGM test is a quick, simple and cheap method that has proved to be useful for this purpose.

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