

Discrepancy in patch test results with wool wax alcohols and Amerchol® L-101

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Wondering why Amerchol® L-101 (containing wool wax alcohols obtained from the hydrolysis of wool fat) appears as a test material (100%) in a cosmetics series (Chemotechnique Diagnostics AB), as wool wax alcohols were already tested in the European standard series, we added Amerchol® L-101 (100%) systematically to the standard series. From 8 April 1991 to 28 February 1992, a total of 393 patients were tested: 3.05% ($n=12$) showed positive test results (+, ++, +++) for wool wax alcohols as well as Amerchol® L-101 (100%), 0.3% ($n=1$) for wool wax alcohols only, and 11.1% ($n=44$) for Amerchol® L-101 (100%) only. Thus, the positive tests for Amerchol® L-101 (100%) had a higher frequency of 3.4 compared to those for wool wax alcohols. In the meantime, we also added Amerchol® L-101 50% (Trolab) to the standard series. Of all patients tested ($n=223$) 2.7% ($n=6$) had positive reactions to wool wax alcohols and 12.1% ($n=27$) to Amerchol® L-101 100% and/or 50%. Thus, positive reactions to Amerchol® L-101 (100% and 50%) were 4.5 higher, whereas the rate of concordancy decreased. It is remarkable that 8 patients only had a positive reaction to Amerchol® L-101 50% and 9 only to Amerchol® L-101 100%. It seems that we miss many diagnoses in contact allergy by using only the standard wool wax alcohols test (30%).

Key words: lanolin; wool wax alcohols; Amerchol® L-101; patch testing technique; false-negative patch test results; allergic contact dermatitis; medicaments; cosmetics. © Munksgaard, 1997.

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In lanolin contact allergy, the wool wax alcohols are considered to be the major sensitizer. (1). Since 1969, wool wax alcohols (30% pet.) have been included in the standard series as a marker for lanolin contact allergy. Although the incidence of positive patch test reactions to wool wax alcohols is low, at 2-3% (2), it increases considerably in patients with leg ulcers, stasis dermatitis (3) and other proven contact allergies (4). Amerchol® L-101 (AL-101) is a commercial product obtained from the hydrolysis of wool fat, containing 10% wool wax alcohols in mineral oil. It is included in the cosmetics and oil and cooling fluid series of Chemotechnique Diagnostics AB. Although we expected to find as many positive reactions to wool wax alcohols as to AL-101, we were surprised to observe more positive patch test reactions to AL-101. Therefore, we analyzed the patch test reactions to both 50% and 100% AL-101 and to wool wax alcohols (30%).

Patients and Methods

From April 1991 until the end of February 1992 all 393 patients who consulted our Dermatology Department with dermatitis were patch tested with a

standard series (containing wool wax alcohols 30% pet.: supplied by Chemotechnique Diagnostics AB) and with AL-101 100% (containing 10% wool wax alcohols: supplied by Chemotechnique Diagnostics AB - ref. A004). From September 1991 until the end of the study, 223 patients were also tested with AL-101 50% pet. (containing 5-10% wool wax alcohols: supplied by Trolab - ref. E0020).

The age of the patients varied from 16 to 71 years, the female to male sex ratio being 1.9:1.

Patch tests were performed as recommended by the ICDRG, with readings at 2 and 4 days. Although slight erythematous reactions can be interpreted as weak allergic reactions, we only considered undoubtful positive reactions: erythema with infiltration (+) and/or papulo-vesicles (++) and/or bullae (+++) (5).

For statistical analysis, we used the McNemar test, as the experiment was a nominal one with 2 readings in the same individual (6).

Results

Of the 393 patients, 11.5% ($n=45$) showed positive reactions to wool wax alcohols and/or to AL-101

(100%). Positive AL-101 test results with negative wool wax alcohols tests occurred in 8.1% ($n=32$). 1 patient reacted to wool wax alcohols only. Corresponding reactions were found in 3.1% ($n=12$). Positive AL-101 tests occurred 3.4× more.

In other Belgian University centres, 3× (Gent) and 1.6× (Leuven, Brussels) more positive reactions to AL-101 were observed (personal communication).

Of the 223 patients tested with the standard series including the wool wax alcohols, and AL-101 50% and 100%, 12.6% ($n=28$) showed a positive reaction to wool wax alcohols and/or to one or both AL-101s. 4% ($n=9$) of the patients reacted only to AL-101 100%, and 3.6% ($n=8$) only to AL-101 50%. 2% ($n=5$) of the patients reacted to both AL-101s. 1 patient (0.4%) reacted to wool wax alcohols and AL-101 100% and 1 patient (0.4%) had a positive wool wax alcohols test result only. Thus, the rate of concordant reactions decreased to 1.8%, whereas positive reactions to AL-101 occurred 4.5× more.

Statistically, we found a significant difference in both tests: first wool wax alcohols against AL-101 100% $p<0.01$ and wool wax alcohols against AL-101 50% $p<0.05$.

Discussion

Our test results in 393 patients show a significant difference in positive reactions between Amerchol® L-101 and the standard wool wax alcohols. Similar observations have previously been reported in the literature (2, 3).

An exact explanation for the higher incidence of positive reactions to AL-101 is lacking, as the sensitizing substances in lanolin have not yet been fully identified. Clark et al. (1) stated that the allergenic potential of lanolin decreased considerably by reducing its content of free fatty alcohols. Because the wool wax alcohols are considered to be the major sensitizers of lanolin (7), a higher incidence of positive test reactions would be expected when increasing the concentration of wool wax alcohols. However, the wool wax alcohol concentrations in AL-101 100% and 50% are 10% and 5%; much lower than the 30% wool wax alcohols of the standard series.

Another fact that has to be considered is the almost equal number of patients who reacted only to AL-101 100% ($n=9$) and only to AL-101 50% ($n=8$). Thus, the results of our study cannot be

explained by differences in concentration of the wool wax alcohols. A possible explanation could be the presence of preservatives or impurities in the lanolin used for hydrolysis, or maybe in the mineral oil, containing wool wax alcohols. However, the Amerchol Corporation assured us that their product was completely free of additives and contained no acids, alcohols, esters, amines, soaps, glycerol or resins.

Furthermore, the rôle of detergent residues in lanolin contact allergy remains uncertain (1). Because lanolin is a complex natural material with variable constituents, depending on race, origin, and age of the sheep, differences in composition, or in proportions of wool wax alcohols and/or sterols, could be responsible for varying allergenic potential.

If we had only used the standard wool wax alcohols, 8.1% and 9.9% of lanolin-sensitive patients would have been missed. Adding AL-101 to the standard series significantly increases the detection of lanolin contact allergy.

Due to this research, and with confirmation of these test results by other Belgian University Hospitals, the Belgian Contact and Environmental Dermatitis Group has included AL-101 (50%) in the Belgian standard series since 1994.

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