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Contact allergy to polidocanol, 1992 to 1999

- [Previous article](#) in Issue
- [Next article](#) in Issue
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To the Editor:

Previous small studies¹ have indicated that polidocanol (CAS 9002-92-0) can be a relevant contact allergen in patients with chronic dermatitis. To assess the current prevalence of and risk factors for polidocanol contact sensitivity in a clinical patch test population, we analyzed data from 8739 patients tested with a topical drugs patch test series in 30 centers of the Information Network of Departments of Dermatology (IVDK; <http://www.ivdk.gwdg.de>²) in Germany and Austria from January 1992 to December 1999. Test substances were supplied by Hermal/Trolab (Reinbek, Germany). Results were based on readings at 72 hours.

In total, 3186 patients were tested with 0.5% polidocanol in water, resulting in the following reactions: 0.94% questionable (erythematous), 0.88% slightly irritating, 0.97% weakly positive, and 0.25% strongly positive. In total, 6202 were tested with 3.0% polidocanol in petrolatum, resulting in the following reactions: 1.79% questionable, 0.48% irritating, 1.77% weakly positive, and 0.34% strongly positive. Among those 649 patients tested synchronously with both preparations, concordance was moderate (Cohen's simple κ , 0.53; 95% CI, 0.29-0.76). Current or previous clinical relevance was documented for 53% of

patients with positive reactions, based on probable or certain deterioration of pre-existing dermatitis by application of polidocanol-containing topical drugs.³ The proportion of relevant reactions was independent from the test preparation and the strength of the test reaction, respectively.

To elucidate the role of potential risk factors, namely age, sex, occupational cause of dermatitis, and site of current dermatitis, (1) the distribution of these factors in different subgroups was assessed and (2) a logistic regression analysis with the outcome “polidocanol positive versus negative” was performed (Table 1). Results show that elderly patients with lower leg dermatitis are particularly at risk, a phenomenon well known for a number of other topical drugs also, which were frequent cosensitizers in our patients, too. In contrast, atopic dermatitis, which is often treated with polidocanol-containing emollients (in Germany), was not a significant risk factor.

Table I. Comparative demographic characteristics of patients reacting positively to polidocanol (1992-1999) and results of a logistic regression analysis, outcome “polidocanol positive” versus “polidocanol negative” (ie, with 8739 patients contributing*)

Total (n = 75,233)	% in total population and 2 subgroups			Odds ratio (95% CI)
	Topicals (n = 8739)	Polidocanol positive (n = 163)		
Male	35.4	34.8	37.4	1.12 (0.81-1.54)
Occupational dermatitis	14.6	9.9	3.7	0.63 (0.23-1.41)
Atopic dermatitis	17.9	15.9	11.0	1.16 (0.67-1.90)
Hand dermatitis†	28.1	20.3	11.0	1.08 (0.42-3.33)
Leg dermatitis†	8.5	23.6	39.9	2.32 (1.02-2.35)‡
Face dermatitis†	14.8	14.3	9.2	0.97 (0.40-3.00)
Age 40+ years	57.9	72.1	90.2	2.91 (1.74-5.19)‡

†Additional sites contained in model to allow for full coding: arm, feet, head (excluding face) or neck, trunk with axillae, anogenital (as reference), other, and missing site. None of these sites was a significant explanatory factor.

‡Significant ($P < .05$).

*Hosmer and Lemeshow goodness of fit test: $P = .44$.

Both test preparations mainly caused weak positive reactions, as described earlier.¹ In cases of unclear clinical relevance, a repeated open application or provocative use test is recommended.³ Moderate concordance between the two test preparations may indicate considerable dependency of test results (and possibly also of clinical elicitation) on the galenic properties of the patch test vehicle.¹

In conclusion, polidocanol must be added to the list of topical agents capable of inducing contact allergy in a substantial number of elderly patients with lower leg dermatitis and should be tested for regularly in patients with chronic dermatitis and a history of epicutaneous exposure to polidocanol.

*Centers of the IVDK contributing to this analysis (in alphabetical order): Aachen (H. Dickel), Augsburg (O. Hirschsteiner, A. Ludwig), Berlin Charité (B. Laubstein, J. Grabbe, T. Zuberbier), Berlin UKRV (J. Grabbe, T. Zuberbier), Bochum (C. Szliska), Dortmund (P. J. Frosch, B. Pilz, C. Pirker), Dresden (G. Richter), Duisburg (J. Schaller), Erlangen (K. P. Peters, M. Fartasch), Essen (H-M. Ockenfels, U. Hillen), Göttingen (T. Fuchs), Graz (W. Aberer, B. Kränke), Halle (G. Gaber, D. Lübke), Hamburg (M. Kiehn, D. Vieluf), Heidelberg (A. Schulze-Dirks, M. Hartmann), Homburg/Saar (P. Koch), Jena (M. Gebhardt, A. Bauer), Kiel (J. Brasch), Lübeck (J. Kreusch, J. Grabbe), Magdeburg (U. Jappe, E. Weisshaar), Mannheim (C. Bayerl), Marburg (I. Effendy), München LMU (F. Enders, B. Przybilla, F. Rueff), München TU (J. Rakoski), Nürnberg (I. Müller), Osnabrück (W. Uter), Ulm (H. Gall [deceased]), and Wuppertal (O. Mainusch, J. Raguz).

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