ORIGINAL REPORT

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Prevalence of Contact Sensitization in Patients with Atopic Dermatitis: A Retrospective Study from China

Ao WANG[1], Chengbin YE[1], Chengwen FEI[1], Yingfang LI[1], Yuelong MA[1], Ting CAO[1], Yue WU[1], Yanchun CHENG[1], Fei HAO[1,2*] and Ying ZOU[1*]

[1]Department of Allergy, Shanghai Skin Disease Hospital, School of Medicine, Tongji University, Shanghai, China, and [2]Dermatology and Plastic Surgery Center, The Third Affiliated Hospital of Chongqing Medical University, Chongqing, China

The prevalence of contact sensitization in atopic dermatitis (AD) has been controversial and remains poorly studied in the Chinese population. This retrospective study aimed to assess the prevalence and differences in contact sensitization between AD and non-AD patients undergoing patch testing in China. We analysed clinical records of 3,487 patients who underwent patch testing from 2018 to 2023, including 146 AD patients and 3,341 non-AD patients. Results demonstrated that contact sensitization prevalence was similar in AD and non-AD groups (82.88% vs 84.71%, *p*=0.55). Common allergens included nickel, methylisothiazolinone, dodecyl gallate and cobalt chloride hexahydrate in both groups. AD patients showed higher positive reactions to hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine (11.11% vs 5.85%, *p*<0.01), methyldibromo glutaronitrile (10.27% vs 4.97%, *p*<0.01), quaternium-15 (7.53% vs 3.68%, *p*=0.02), ethylenediamine dihydrochloride (3.42% vs 0.72%, *p*<0.01), propylene glycol (2.86% vs 0.60%, *p*=0.01) and 2-bromo-2-nitropropane-1,3-diol (2.74% vs 0.78%, *p*=0.03), compared to non-AD, particularly females. Contact sensitization prevalence increased with age in both groups. This study showed that the prevalence of contact sensitization was comparable between the AD and non-AD groups in China. However, AD patients exhibited heightened sensitivity to formaldehyde releasers and propylene glycol, commonly found in moisturizers.

Key words: atopic dermatitis; contact dermatitis; patch testing.

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Corr: Fei Hao, No. 1 Shuanghu Branch Road, Dermatology and Plastic Surgery Center, The Third Affiliated Hospital of Chongqing Medical University, Chongqing, 401120, China and Ying Zou, Department of Allergy, Shanghai Skin Disease Hospital, School of Medicine, Tongji University, Shanghai, No.1278 Baode Road, 200443, China. Emails: haofei62@126.com; zouyingsh@163.com

SIGNIFICANCE

The prevalence of contact sensitization in atopic dermatitis has been controversial, and it remains insufficiently researched among the Chinese population. This study confirms that its prevalence is similar between people with and without atopic dermatitis in China. However, individuals with atopic dermatitis, especially females, had a significantly higher risk of developing allergy to propylene glycol and formaldehyde releasers, such as 2-bromo-2-nitropropane-1,3-diol and quaternium-15, than those without atopic dermatitis. Meanwhile, the rate of positive reaction increased with advancing age, particularly among non-atopic dermatitis patients.

Atopic dermatitis (AD) is a common skin inflammatory disease exhibiting recurrent pruritus and erythema (1). When contact sensitization results in clinically relevant dermatitis at exposure sites, allergic contact dermatitis (ACD), a delayed-type hypersensitivity reaction, develops (2). Although AD and ACD may coexist in the same individual, the relationship between AD and contact sensitization remains inconclusive.

The pathogenesis of AD is mainly dominated by Th2 inflammation, skin barrier destruction and microbiome disturbance (1). ACD is mainly related to Th1 inflammation (3). Given that a Th2-skewed immune response may inhibit the Th1 inflammatory response, it is hypothesized that the risk of contact sensitization in AD may be reduced (4). However, due to the frequent exposure to topical drugs and moisturizers, the impaired skin barrier may allow for increased penetration of contact allergens in AD patients (5). In addition, AD patients could also develop a Th1/17 inflammatory response (6). Currently, studies evaluating the prevalence of contact sensitization in patients with AD have reported inconsistent findings. Some studies showed a higher prevalence (7, 8), others reported a lower prevalence (9), while some concluded no significant difference between AD and non-AD cases (10, 11).

Patch testing is the standard diagnostic method for detecting contact sensitization, and a positive reaction indicates the possibility of contact sensitization. In this retrospective study, we aimed to compare the prevalence and patterns of contact sensitization between patients with and without AD who underwent patch testing at Shanghai Skin Disease Hospital from 2018 to 2023 in China.

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MATERIALS AND METHODS

Patients

This was a retrospective study. The data were collected from patients who were referred for patch testing at Shanghai Skin Disease Hospital from 2018 to 2023 based on clinical indications and suspected contact sensitization. Patients were diagnosed with AD according to the Williams criteria (12). These criteria were selected because of their simplicity, usability and reliance on clinical features without requiring laboratory investigations, thereby making them suitable for routine outpatient assessment and our retrospective study design. Patients who met the Williams criteria were assigned to the AD group, while those who did not were assigned to the non-AD group. The local ethics committee of Shanghai Skin Disease Hospital approved this study.

Procedure of patch testing

Allergens for patch testing were selected from the Cosmetic Series (C-1000) and European Baseline Series (S-1000, Chemotechnique Diagnostics), with modifications based on our previous research data and published evidence on the sensitization profile of the Chinese population (the Chinese Baseline Series) (13, 14). These allergens were kindly grouped into 3 combinations and applied according to patients' medical history. A total of 85 allergens were analysed in this study.

The test substances were applied to healthy skin on the back and removed after 48 h. Patch testing reactions were evaluated at 48, 72 and 96 h by experienced dermatologists and interpreted according to the International Contact Dermatitis Research Group guidelines (15). Based on the previously proposed classification, polysensitization was defined as positive reactions to 3 or more allergens, whereas oligosensitization means positive reactions to 1 or 2 allergens (16, 17).

Statistical analysis

Continuous variables, expressed as means with standard deviations (mean±SD), were analysed using the Mann–Whitney *U* test. For categorical variables, expressed as frequencies with percentages, we used Pearson's χ^2 test or Fisher's exact test according to data distribution. Multivariable logistic analysis was employed to examine the relationship between AD status and contact sensitization, adjusting for age and sex. Adjusted odds ratios (aORs) with 95% confidence intervals (CIs) were reported. All data were analysed using GraphPad Prism 9.3.1 and SPSS 22.0.0.0. $p<0.05$ was considered statistically significant for all analyses.

RESULTS

Patients' characteristics

This study included 3,487 patients. Among them, 4.19% (146/3,487) had AD, while 95.81% (3,341/3,487) did not. Females accounted for 71.23% (104/146) in the AD group, and 91.89% (3,070/3,341) in the non-AD group. The AD group was younger than the non-AD group. **Table I** presents these characteristics, including the proportions of age cohorts.

Positive reactions of patch testing

The proportion of patients with positive reactions to at least 1 allergen did not significantly differ between the AD and non-AD groups [82.88% (121/146) vs 84.71% (2,830/3,341), $p=0.55$, aOR 0.97, 95% CI 0.62–1.52]. The number of positive results was similar between AD and non-AD groups (3.71±3.82 vs 3.29±3.19, $p=0.76$). Furthermore, the proportion of patients demonstrating oligosensitization [32.88% (48/146) vs 35.32% (1,180/3,341), $p=0.55$, aOR 0.87, 95% CI 0.61–1.25] and polysensitization [50.00% (73/146) vs 49.39% (1,650/3,341), $p=0.88$, aOR 1.11, 95% CI 0.79–1.55] did not significantly differ between such groups.

Most common allergens

Table SI shows the positive response rates of 85 allergens in each patient group. In the AD group, the 5 most common allergens were nickel (II) sulphate hexahydrate, dodecyl gallate, methylisothiazolinone, cobalt (II) chloride hexahydrate and formaldehyde (**Fig. 1**). Those in the non-AD group were nickel (II) sulphate hexahydrate, methylisothiazolinone, cobalt (II) chloride hexahydrate, dodecyl gallate and methylchloroisothiazolinone–methylisothiazolinone, which were therefore slightly different from those in the AD group (Fig. 1).

Table I. Characteristics of study population

Demographics	Total (*n*=3,487)	AD (*n*=146)	Non-AD (*n*=3,341)	*p*-value
Sex: Female, %	91.02% (3,174/3,487)	71.23% (104/146)	91.89% (3,070/3,341)	<0.001
Age (mean±SD)	37.02±13.02	33.94±13.07	37.15±13.00	0.01
<18 years, %	1.75% (61/3,487)	7.53% (11/146)	1.50% (50/3,341)	<0.001
18–60 years, %	90.59% (3,159/3,487)	86.30% (126/146)	90.78% (3,033/3,341)	0.07
>60 years, %	7.66% (267/3,487)	6.16% (9/146)	7.72% (258/3,341)	0.49

AD: atopic dermatitis; SD: standard deviation.

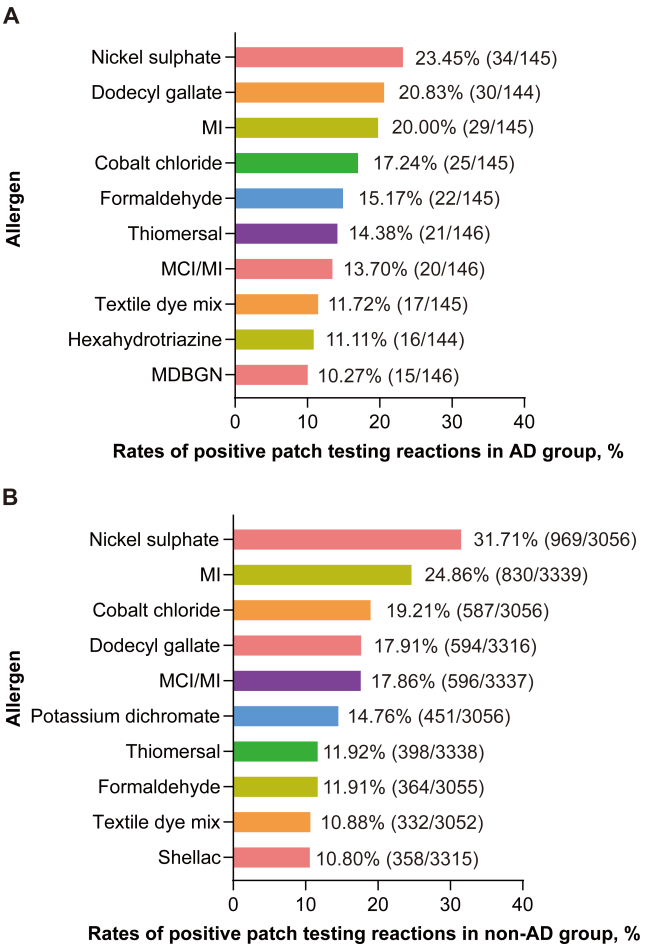


Fig. 1. Top 10 allergens in patients with and without atopic dermatitis (AD). (A) Top 10 allergens in AD group. (B) Top 10 allergens in non-AD group. Allergens are ranked according to their positive reaction rates. Cobalt chloride: cobalt (II) chloride hexahydrate; Hexahydrotriazine: hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine; MCI: methylchloroisothiazolinone; MI: methylisothiazolinone; MDBGN: methyldibromo glutaronitrile; Nickel sulphate: nickel (II) sulphate hexahydrate.

Compared with non-AD groups, the AD group showed significant differences in the positivity rates of some allergens. The positivity rates of hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine, methyl dibromo glutaronitrile, quaternium-15, ethylenediamine dihydrochloride, propylene glycol and 2-bromo-2-nitropropane-1,3-diol were higher in the AD group. The positivity rates of nickel (II) sulphate hexahydrate were lower in the AD group than in the non-AD group. However, this difference was not maintained in the AD group after adjustment for age and sex (**Table II**).

Sex and age groups

Positive reaction for at least 1 allergen did not significantly differ by sex between the 2 groups (Table SII). However, female AD patients were more likely to develop contact sensitization to specific allergens. They had higher positive rates of formaldehyde, hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine, methyl dibromo glutaronitrile, quaternium-15, colophonium, dimethylol dimethyl (DMDM) hydantoin, tert-butylhydroquinone, methenamine, propylene glycol, 2-bromo-2-nitropropane-1,3-diol, ethylenediamine dihydrochloride and polysorbate-80. Of note, the rate of balsam of Peru was lower in female AD patients, but the association with AD was relatively weak (Table SIII). Meanwhile, the contact sensitization emerging from Amerchol L 101 was higher among male patients with AD (Table SIII).

The positive reaction rate by age also showed no significant difference between the AD and non-AD groups (Table SIV). In both cohorts, the positive reaction rate increased as age increased, particularly among patients without AD (**Fig. 2**).

DISCUSSION

The relationship between AD and contact sensitization has long been controversial. Although the Th2-dominant immune response in AD has been proposed to limit contact sensitization (4), impaired skin barrier function and frequent exposure to topical products may increase allergen penetration and potentially promote sensitization (5). In addition, the heterogeneity of study populations may contribute to the inconsistent findings reported in previous studies.

In our study, the rate of contact sensitization was similar among patients with AD vs those without AD. Our findings also align with a meta-analysis showing no overall difference in contact sensitization between individuals with and without AD (18). Notably, both groups showed a relatively higher proportion of patients

Table II. Differences in contact allergen positivity between patients with and without AD

Allergen	AD positive reactions, %	Non-AD positive reactions, %	*p*-value	Adjusted OR (95% CI)[a]
Nickel (II) sulphate hexahydrate, 5% pet	23.45% (34/145)	31.71% (969/3,056)	0.04	0.84 (0.56–1.26)
Hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine, 1% aq	11.11% (16/144)	5.85% (194/3,316)	<0.01	1.93 (1.12–3.35)
Methyldibromo glutaronitrile, 0.5% pet	10.27% (15/146)	4.97% (166/3,340)	<0.01	2.23 (1.25–3.98)
Quaternium-15, 1% pet	7.53% (11/146)	3.68% (123/3,340)	0.02	2.42 (1.26–4.65)
Ethylenediamine dihydrochloride, 1% pet	3.42% (5/146)	0.72% (24/3,339)	<0.01	4.21 (1.51–11.74)
Propylene glycol, 5% pet	2.86% (4/140)	0.60% (20/3,313)	0.01	5.15 (1.66–15.94)
2-bromo-2-nitropropane-1,3-diol, 0.25% pet	2.74% (4/146)	0.78% (26/3,337)	0.03	3.77 (1.24–11.47)

Only allergens showing statistically significant differences in positive patch testing reaction rates between patients with and without AD are shown.
[a]Adjusted for age and sex.
AD: atopic dermatitis; aq: aqueous; CI: confidence interval; OR: odds ratios; pet: petrolatum.

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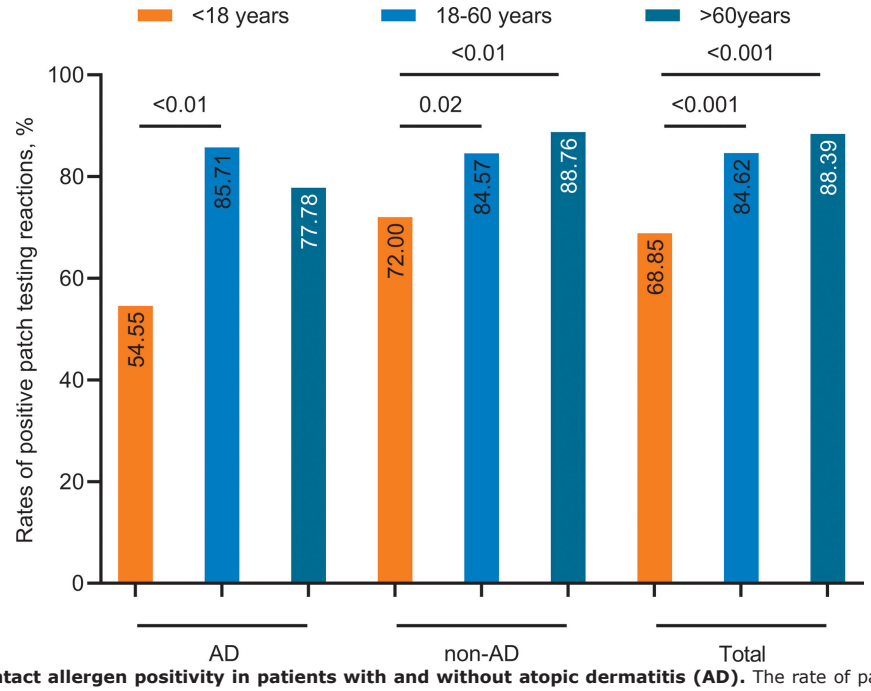


Fig. 2. Age-related contact allergen positivity in patients with and without atopic dermatitis (AD). The rate of patients with positive patch test reactions is shown for each age group. The numbers of patients with AD were 11, 126 and 9 in the <18, 18–60 and >60 years age groups, respectively, while the corresponding numbers in the non-AD group were 50, 3,033 and 258, respectively. *p*-values indicate comparisons between different age groups within the AD, non-AD, and total populations. Detailed numerical results are provided in Table SIV.

with positive patch testing reactions than those reported in previous Chinese patch testing studies (19, 20). The clinical nature of our study population may explain this finding, given that all participants were referred for patch testing according to clinical indications and suspected contact sensitization rather than being recruited from the general population. Therefore, our cohort was likely enriched for individuals at higher risk of contact sensitization. Our findings should be interpreted primarily as a comparison of patch testing positivity patterns between AD and non-AD patients within a clinically selected patch-test population, rather than as an estimate of the population prevalence of contact sensitization in China. Similarly, the proportion of patients with AD in our patch-tested population (4.19%) should not be interpreted as the prevalence of AD in the general population.

The proportions of oligosensitization and polysensitization were also similar between patients with and without AD. However, these findings should be interpreted cautiously because of the lack of a universally accepted approach to defining oligosensitization and polysensitization. Multiple positive reactions may involve chemically or clinically related allergens, such as formaldehyde and formaldehyde-releasing preservatives (21); thus, they may not necessarily represent independent sensitization events. Furthermore, differences in allergen panels, grouping strategies and counting methods may consequently contribute to variations in the reported prevalence of oligosensitization and polysensitization across studies.

In both groups, the prevalence of positive patch testing increased with age, which was consistent with a previous study (22). It was predictable that the weaker skin barrier and more frequent exposure to environmental allergens in older adults increased the risk of contact sensitization. Conversely, immunosenescence might decrease the reaction to allergens. The density of Langerhans cells, an important antigen-presenting cell in the epidermis, and the effector T cells had been found to be decreased in older adults (23, 24). Thus, generalization of the trend of contact sensitization in older patients was challenging.

We further examined patterns of contact sensitization to individual allergens, focusing on allergens with significant between-group differences or particular clinical relevance to patients with AD. The most common allergen in both groups was nickel, consistent with previous studies (9–11). Nickel is widely used in jewellery and metallic substances, and dietary nickel contaminants have been reported to provoke systemic dermatitis (25). Nickel could induce potent activation of innate immunity, Th1/Th17 and a Th22 component (26). In AD patients, filaggrin mutation increased the penetration of nickel (27). However, evidence regarding the clinical relevance of dietary nickel exposure remains limited (28); thus, routine avoidance of nickel-containing foods cannot currently be recommended for all nickel-allergic patients. Instead, the clinical relevance of nickel sensitization should be evaluated alongside the patient's history and clinical presentation. Specialized healthcare professionals may

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provide individualized health education regarding dietary nickel exposure in patients with documented systemic reactions or suspected systemic nickel hypersensitivity. They may also consider dietary nickel restriction when clinically indicated.

AD patients often required long-term use of moisturizers and topical medications (29); however, frequent exposure to contact allergens increased the probability of contact sensitization. In a recent study, patients with a history of atopy had a higher positive rate to propylene glycol (30). A similar phenomenon was observed in our patients with AD, especially in females. Although propylene glycol was nominated as the American Contact Dermatitis Society "Allergen of the Year" in 2018, allergic reaction to this substance remains uncommon (31). In our study, only 0.60% (20/3,313) of non-AD patients showed a positive reaction to propylene glycol. Although propylene glycol may also cause irritant reactions, a large patch-testing study reported that 5% propylene glycol yields only a low rate of irritant reactions (0.95%) (30), suggesting that irritant reactions may not fully account for the higher positivity observed in our patients with AD. A possible explanation for this may be attributed to the impaired skin barrier permitting the passage of propylene glycol through the epidermis, thereby inducing an immune response. Given the prolonged need for moisturizing products and topical drugs, attention should be paid to propylene glycol and other potential contact allergens in AD patients.

Formaldehyde releasers, such as quaternium-15, DMDM hydantoin, imidazolidinyl urea and 2-bromo-2-nitropropane-1,3-diol, were commonly used as preservers in food, cosmetics, drugs, detergents and many other consumer products (21). Our study demonstrated the prevalence of positive reactions to quaternium-15, and 2-bromo-2-nitropropane-1,3-diol was significantly higher among individuals with AD than among those without AD. A previous study also showed that AD patients might react more frequently to formaldehyde releasers (32). Additionally, after stratifying by sex, we found that female AD patients also had a higher positive response to formaldehyde and DMDM hydantoin. The difference was not observed in male patients, probably because males use cosmetics less often than females. The emission of formaldehyde or the chemical structure itself may trigger allergic reactions to formaldehyde releasers (33). Formaldehyde in skincare products and the environment may aggravate dermatitis in formaldehyde-allergic individuals and AD patients (34, 35), and even low concentrations of formaldehyde could increase the expression of Th2-related cytokines in NC/Nga mice (36). Given the increased risk of allergic reaction to formaldehyde releasers in AD patients, caution should be exercised when selecting products containing these preservatives.

While individuals with AD reportedly have a higher prevalence of allergy to fragrance than those without (37), our data did not support this conclusion. Among patients with AD, 9.66% had positive patch testing reactions to fragrance mix I and 4.83% to fragrance mix II. These rates were similar to those reported among adults with a history of AD in the North American Contact Dermatitis Group study, in which the corresponding rates were 10.6% and 4.6%, respectively (11). Notably, the positive reaction to balsam of Peru in female AD patients was significantly lower. According to a recent study, balsam of Peru can be bound by CD1a, thereby inducing the release of interferon-γ (38), but the mechanism of contact sensitization was not yet fully elucidated. Another study also suggested that the rate of positive reaction to balsam of Peru in AD patients might decrease (9), indicating that balsam of Peru and fragrance mix might induce different immune responses, and further research may be needed to clarify this.

Our study has several limitations. First, this research did not systematically assess the severity of AD and the clinical relevance of positive patch testing reactions and could not evaluate the relationship between patch-test results and patients' actual exposure to relevant products or substances. Second, patients with AD were fewer than patients without AD, and this was a retrospective, hospital-based study conducted at a specialized dermatology centre. Therefore, our study population may not be representative of the general Chinese population, and the findings should be interpreted with caution when generalized to other clinical settings. Third, oligosensitization and polysensitization have no universally accepted definition, and different approaches to counting or categorizing related allergens may affect the classification of sensitization patterns and comparisons across studies. Future studies should involve larger and more diverse patient populations to further validate our findings and clarify the clinical relevance of contact sensitization in patients with AD.

In conclusion, our results confirm that the prevalence of contact sensitization was similar between individuals with and without AD, but those with AD, especially female patients, had a significantly higher risk of allergy to preservers and components of moisturizing products. Therefore, patients with AD should exercise caution when using products containing these ingredients, and patch testing may help identify clinically relevant contact allergens.

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Data availability statement: The data underlying this article cannot be shared publicly due to patient privacy concerns and institutional policy restrictions. The data that support the findings of this study are available from the corresponding author upon reasonable request.

IRB approval status: The study (approval no: 2022-27) was approved by the local ethics committee of Shanghai Skin Disease Hospital. Written informed consent was obtained from participants or their legal guardian.

The authors have no conflicts of interest to declare.

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