The Contact Allergen Replacement Database and Treatment of Allergic Contact Dermatitis

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Objective: To determine whether the Contact Allergen Replacement Database would improve clinical outcomes for patients with allergic contact dermatitis associated with topical skin care products by helping patients avoid known allergens.

Design: This study was a randomized, single-blind, controlled trial.

Setting: The study was conducted at the outpatient facilities at Mayo Clinic, Scottsdale, Ariz, and Rochester, Minn.

Participants: Of the 29 patients enrolled, 21 completed the study.

Intervention: All patients were randomly assigned to either a Contact Allergen Replacement Database group or a traditional therapy group. Patients in the database group received an individualized list of topical skin care products free of the antigens identified by the results of their individual patch tests. Otherwise, the 2 groups received identical therapy.

Main Outcome Measures: To evaluate erythema, scale, and pruritus at 3-month follow-up, each variable was given a severity score from 0 to 3. A 1-point change was considered clinically notable. We also evaluated total physician-patient counseling time and patient satisfaction.

Results: We found no statistically significant differences (P>0.05) between the 2 treatment groups on measures of disease activity and counseling time. However, 91% of the database group reported the allergen-free product list to be either somewhat helpful or very helpful in managing contact dermatitis. All the patients without access to the database said it would have been helpful.

Conclusions: Although this small study, with its limited follow-up, did not yield objective evidence supporting the use of the Contact Allergen Replacement Database, the database-generated product lists were favorably received by patients. We anticipate an expanded clinical role for this database as an Internet-based resource.

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Allergic contact dermatitis (ACD) is an adverse cutaneous reaction that may be caused by topical skin care products and that typically presents as an eczematous eruption affecting the face, eyelids, forearms, and, less commonly, other sites. Despite the lack of data on the frequency of ACD associated with topical skin care products in the general population, researchers have reported frequencies of 0.3% to 1.0%. Although the diagnosis of ACD due to topical skin care products may be made clinically, patch testing is an effective, economical means of identifying and confirming specific allergens. Traditionally, after relevant allergens are identified, patients are educated to avoid contact with these substances. Unfortunately, the ever-expanding array of skin care products and ingredients renders successful allergen avoidance a daunting task even under optimal conditions.

The Contact Allergen Replacement Database (CARD) was developed at Mayo Clinic to promote successful allergen avoidance. Updated quarterly, it contains information on more than 2000 topical skin care products and their ingredients. The database can be used to generate an extensive list of skin care products free of all of a given patient’s allergens. In addition, the database allows users to exclude products containing known cross-reactors with a patient’s relevant allergens, as described by patch tests.

For more than 3 years, CARD has been used at Mayo Clinic (Rochester, Minn; Scottsdale, Ariz; and Jacksonville, Fla) in the treatment of ACD associated with skin care products.
care products. Anecdotally, physicians, patients, and nurses have found CARD to be a helpful tool when treating this subset of ACD. The purpose of our investigation was to determine whether the use of CARD would result in objective improvements in patient outcome and patient satisfaction, as well as in a reduction of physician counseling time.

### METHODS

#### PARTICIPANTS AND SETTING

All patients were at least 18 years of age. Patients had relevant, positive results on patch tests to allergens found in topical skin care products. They were permitted to use topical corticosteroids but not systemic corticosteroids and other topical or systemic immunomodulatory agents.

#### STUDY PROTOCOL

A prospective, randomized, single-blind study of patients with relevant, positive reactions on patch tests to ingredients in topical skin care products was conducted at Mayo Clinic, Scottsdale, Ariz, and Rochester, Minn. Patients were enrolled in the study between February 1999 and May 2000 and were randomly assigned to either the CARD treatment group or the “traditional” treatment group, with stratification by sex. Patients in the CARD group received an individualized, database-generated topical skin care product list based on the reading and interpretation of their patch test results. In all other respects, the 2 groups received identical therapy, consisting of traditional, physician-provided education on avoiding allergens and using topical corticosteroids. This study was approved by the Mayo Foundation institutional review board, and all patients signed informed consent documents.

#### CLINICAL ASSESSMENTS

The end points evaluated in this study, namely, clinical efficacy, physician counseling time, and patient satisfaction, were measured at the baseline patient visit and monthly thereafter during a 3-month period.

Clinical efficacy was determined by the physicians’ assessment of erythema, scale, and pruritus. These variables were scored 0 through 3 (0, “none”; 1, “mild”; 2, “moderate”; and 3, “severe”) to indicate their degree of severity. A nontreating, “blinded” physician performed these assessments. Anatomical distribution of dermatitis was also recorded at this time. At the conclusion of each encounter between the patient and the treating physician, the treating physician recorded total time (minutes) spent counseling.

The question used to elicit the extent of patient satisfaction was dependent on the treatment group. Patients in the CARD treatment group were asked, “Did the list help you to avoid products to which you are allergic?” Patients in the traditional treatment group were asked, “Do you think a specific list of products ‘okay to use’ would help you avoid the products to which you are allergic?” The responses were categorized according to whether patients thought the list had been helpful (1, “very helpful”; 2, “somewhat helpful”; 3, “unsure”; 4, “somewhat unhelpful”; and 5, “very unhelpful”).

#### STATISTICAL ANALYSIS

Outcomes for clinical efficacy were calculated as the mean change from baseline score. Physician counseling time was measured as the mean time (minutes) spent with patients. These results were analyzed for statistical significance (P < .05) using the 2-sample t test. Because data were missing for some patients at certain visits, the sample sizes for the various outcomes differ slightly. All collected data are represented herein.

### RESULTS

#### PATIENT CHARACTERISTICS

Of the 29 patients enrolled, 21 completed the study. Of the 8 patients who withdrew, 4 were in the CARD group and 4 were in the traditional treatment group. Patient withdrawal was not associated with any adverse events; inconvenience of follow-up was the only reason cited. This population illustrated characteristics previously reported as being typical of patients with ACD due to cosmetics use. Namely, there was a female predominance (3:1), the most frequently involved sites were the face and extremities, and fragrances and preservatives were the most commonly implicated contactants.

#### CLINICAL EFFICACY

Clinical improvement was measured as a change from baseline scores for erythema, scale, and pruritus. Although there were no statistically significant differences between the CARD and the traditional treatment groups, the CARD group demonstrated a greater mean improvement for each condition at every visit. At the final follow-up visit, CARD patients (n=9) exhibited reductions in mean±SD erythema, scale, and pruritus scores of 0.8±1.1, 0.6±1.1, and 0.6±1.5 from baseline, respectively (on a 0–3 severity scale). Although modest, these reductions are several-fold greater than those observed in patients in the traditional group. In the traditional group (n=8), reductions in mean±SD were noted for erythema (0.26±0.67) and pruritus (0.18±0.84). For the condition of scale, the traditional group actually worsened relative to baseline, with a final reduction score of –0.06±0.81. The sample was too small to assess differences of less than 1.5 (erythema, 95% confidence interval [CI], –0.4 to 1.5; scale, 95% CI, –0.4 to 1.7; pruritus, 95% CI, –0.9 to 1.7).

#### PHYSICIAN COUNSELING TIME

The total mean±SD counseling time for all outpatient visits was lower for the CARD group (48±25 minutes; n=10) than for the traditional group (62±26 minutes; n=10). However, this difference and differences in mean counseling time for each patient visit were not statistically significant (95% CI, –38 to 10 minutes).

#### PATIENT SATISFACTION

In the CARD group, 10 (91%; 95% CI, 59% to 100%) of the 11 patients described the product list as either very helpful or somewhat helpful. Similarly, 10 (100%; 95% CI, 69% to 100%) of the 10 patients in the traditional group expressed the belief that access to such a list would...
have been helpful to them. These findings did not change with respect to the number of clinic visits patients had.

This study formally introduces CARD to the dermatologic community and is intended to evaluate the validity of its use. Our findings suggest that use of this database confers a therapeutic advantage in the treatment of ACD associated with topical skin care products. Although clinical measures of improvement did not demonstrate statistical superiority with the use of CARD, the measure of patient satisfaction showed that CARD was strongly preferred over the traditional method.

Several elements of the design and execution of this study may have minimized the apparent benefits of CARD. First, the study population was limited in number. A larger sample size might have achieved statistical significance in the apparent differences in therapeutic response. Second, patients were permitted to use topical corticosteroids. Data concerning the amount, potency, and frequency of corticosteroid use were not collected. Because steroids have a suppressive effect on the signs and symptoms of dermatitis, the relative benefit of allergen avoidance may have been underappreciated. Because steroids potentially exert nontrivial adverse effects, it would be worthwhile to evaluate the time to corticosteroid discontinuation and the steroid-free remission duration (steroid-sparing effect) associated with CARD intervention. Finally, patients in the traditional treatment group were subjected to rigorous allergen avoidance directed by physicians experienced in the management of allergic contact dermatitis. Differences in outcome between the 2 treatment groups might have been greater, favoring CARD, if the patients in the traditional group had received less sophisticated education, which may be customary in treatment settings other than a tertiary referral center specializing in ACD.

This study did not show a significant difference in patient counseling time associated with CARD use. This finding indicates that CARD did not require extensive additional time to be incorporated into a patient’s treatment plan. The treating physician was aware of whether a patient was in the CARD group or the traditional treatment group and may thus have been biased to spend less time with CARD patients. Because the CARD-generated product lists were favorably received by the study population and required little, if any, additional time, they represent a time-effective, patient-friendly addition to standard management of ACD.

Despite the limitations of this study, CARD is an exciting therapeutic and prophylactic development. The main objective of CARD, allergen replacement, was first described by Calnan and later championed by Fisher. To this end, the dermatologic literature is replete with recommendations for allergen replacements. Inspired by this literature, CARD is uniquely suited to handle the myriad number of topical skin care products, the frequent substitutions of product ingredients, and the incorporation of new potential contact allergens. Furthermore, because CARD allows for the simultaneous entry of an unlimited number of patient allergens and because this interactive tool is Internet-based (http://www.contactderm.org), it represents the most responsive and potentially far-reaching tool available to dermatologists for the treatment of ACD. We are therefore optimistic that CARD will be well received by the dermatologic community and will enhance patient care.

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REFERENCES