

The Utility of the TRUE Test in a Private Practice Setting

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Background: Studies suggest that the Thin-Layer Rapid-Use Epicutaneous Test (TRUE Test) may be inadequate to completely diagnose a significant number of patients with allergic contact dermatitis (ACD).

Objective: To study the usefulness of the TRUE Test as a triage tool in a private practice setting.

Methods: A retrospective chart review of patients who were patch-tested with the TRUE Test between July 1, 2000, and June 30, 2004, in four private dermatology practices was conducted.

Results: Of the 183 patients evaluated, 50.8% had at least one positive reaction, 31.7% had a diagnosis of ACD, and 24.0% were suspected to have ACD from other allergens. Of the patients with positive reactions, 62.4% were determined to have reactions that were of present relevance.

Conclusions: The TRUE Test allows patients with dermatitis to be triaged systematically in a private practice setting. It is important to supplement patch testing with the patients' personal products, especially in cases of facial or periorbital dermatitis, and to be aware of potential false negatives, particularly with fragrance and rubber additives.

CONTACT DERMATITIS is one of the most common reasons for dermatology clinic visits and has considerable morbidity and economic impact.¹ Patch testing, first described in 1895, is still considered the "gold standard" for the diagnosis of allergic contact dermatitis (ACD) and has been shown to lead to an early resolution of symptoms and improved quality of life.² Traditionally, patch testing is conducted with the Finn Chamber technique (Epitest Ltd Oy, Tuusula, Finland). Although this method allows a wide range of allergens to be tested and the ability to customize allergens, it is time consuming and expensive and requires trained office personnel.

In 1995, the Thin-Layer Rapid-Use Epicutaneous Test (TRUE Test) (Mekos Laboratories A/S, Hillerød, Denmark) was approved by the Food and Drug Administration. The TRUE Test was developed with 23 of the most common allergens and allergen mixes responsible for ACD.³ The advantages of this ready-to-use contact allergen test are that it is convenient, requires less time, and allows a standardized dosage, an even surface spread, and a high bioavailability of

antigens. As a result, the TRUE Test has been widely used as the initial screening test in the evaluation of contact dermatitis. Since its introduction, there has been a significant increase in the proportion of dermatologists who perform patch tests⁴; 74% of dermatologists,⁴ 72% of allergists,⁵ and 40% of American Contact Dermatitis Society members⁶ who perform patch tests use the TRUE Test.

Recently, however, there has been increasing concern that the TRUE Test has significant limitations in detecting relevant allergens because of the small number of allergens tested and the current questionable relevance of certain allergens contained in the test. Additionally, because the product's allergens are fixed, they cannot be tailored to a patient's occupation or vocation.

A retrospective study of 732 patients to determine the value of supplemental testing relative to a fixed panel of 20 allergens revealed that only 15.7% of patients with clinically relevant positive reactions would be completely evaluated with the fixed panel, 25.6% would be completely missed, and 19.6% would be partially evaluated, with clinically relevant positive reactions to at least one fixed panel and one supplementary allergen.⁷ Another study (involving 898 patients) found that the TRUE Test would completely identify all clinically relevant allergens in only 28% of patients; 25% of patients would not have any of their allergens detected, and 47% would be partially evaluated.⁸ In the North American Contact Dermatitis

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Group (NACDG) study from 1994 to 1996 (involving 3,120 patients), it was found that if the additional allergens on the NACDG screening series were not used, the then-standard 20 screening allergens alone would be able to completely diagnose only 54.1% of patients with positive reactions; 12.4% would be completely missed, and 34.4% would be only partially diagnosed.⁹

Of note, all these published studies thus far have recruited patients from referral centers, and their results are therefore biased toward a selective tertiary care patient population. Patients first present to their primary care dermatologists, who may perform the TRUE Test for initial screening. Those who are accurately diagnosed and treated (with resolution of symptoms) are never evaluated by dermatologists in subspecialty clinics at referral centers. Studies that recruit patients from referral centers likely consist of a majority of patients who were unable to be diagnosed by the TRUE Test, and such studies may therefore underestimate the diagnostic value of the test. Thus, this retrospective study was conducted with the objective of evaluating the results of patch-testing with the TRUE Test in a private practice setting in Pennsylvania, to obtain a better estimate of its usefulness as an initial screening tool.

Methods

Data Collection

Approval by the University of Pennsylvania Institutional Review Board was obtained prior to the initiation of this retrospective chart review. All patients who were patch-tested between July 1, 2000, and June 30, 2004, with the TRUE Test at the clinics of four dermatologists (referred to as physicians 1, 2, 3, and 4) in private practice in Pennsylvania were included in the study.

TRUE Test strips were applied to the upper back of each patient. Patients returned to the clinic for removal of the test strips 48 hours later. At the time of removal and 96 hours after the initial application of the strips, the dermatologists examined the patients and interpreted the results. In one of the clinics (that of physician 4), patients were instructed to remove the strips after 48 hours; only a 72-hour reading by the dermatologist was recorded, and patients were asked to call the clinic if subsequent changes at the test site were noted.

For all patients, demographic data (age, sex, race), occupation, atopic history, and dermatitis site as defined in the NACDG studies were recorded.³ Also recorded were the test interpretations (48-hour, 72-hour and/or 96-hour readings) and relevance for each TRUE Test allergen, the

potential sources of exposure, the final diagnosis, and follow-up data if available.

Definitions

Based on the TRUE Test interpretation key, patch-test results were recorded with the following scale: + for erythema, infiltration, and/or discrete papules; ++ for erythema, infiltration, papules, and/or discrete vesicles; +++ for coalescing vesicles and/or a bullous reaction; “doubtful” for faint macular or homogenous erythema without infiltration; “irritant” for discrete patchy erythema or homogenous erythema without infiltration, patchy follicular erythema, petechiae, or follicular pustules; and “negative.” A +, ++, or +++ reaction was interpreted as a positive patch-test result whereas doubtful, irritant, and negative reactions were all classified as negative results.

Clinical relevance was defined as (1) “present” if (a) the patient had a positive reaction to a product to which he or she was exposed and which contained the reactive allergen or (b) the patient had a documented known or probable cutaneous exposure to such a product; (2) “past” if the patient had prior episodes of ACD after being exposed to the proposed allergen; or (3) “unknown” if the allergen’s relevance could not be determined.

Statistics

Data were analyzed with a univariate logistic regression model. The odds ratio (OR) of association of a positive patch-test result with the clinical judgment of ACD as the dependent variable was calculated with 95% confidence intervals (CIs). Statistical analyses were conducted with *Intercooled Stata version 6.0 for Windows* (StataCorp, College Station, Texas).

Results

Population Characteristics

The study population included 183 patients: 116 females (63.4%) and 67 males (36.6%). The majority (95.6%) were Caucasians. The average age of the patient population was 50 years (range, 9 to 93 years); 47.5% were aged between 40 and 59 years, and distribution was equal above and below this age group. The frequency of atopy among patients with positive reactions irrelevant of the final diagnosis was 34.4%, as opposed to 24.4% among patients with negative reactions. The most frequently reported sites of dermatitis were hands (24.6% of cases), face (17.5%), generalized areas (16.9%), and eyelids (14.8%).

TRUE Test Results

Of the 183 patients, 50.8% had at least one positive reaction. The interpretation and relevance of the patch-test reactions for individual TRUE Test allergens are tabulated in Table 1. The top 10 allergens causing a positive reaction were nickel sulfate (13.8%), neomycin sulfate (10.1%), thimerosal (7.4%), p-phenylenediamine (PPD) (6.4%), quaternium-15 (5.9%), formaldehyde (5.9%), balsam of Peru (4.3%), cobalt dichloride (4.3%), potassium dichromate (3.2%), and caine mix (3.2%).

Of the patients who had positive reactions, 62.4% had reactions that were of present relevance. The most common allergens that were clinically relevant were nickel sulfate, PPD, neomycin sulfate, quaternium-15, and formaldehyde. For patients with hand dermatitis, the most common causes of reactions of present relevance were similar to those for the entire patient population, namely, nickel sulfate, PPD, neomycin sulfate, and cobalt dichloride. For facial dermatitis, the most clinically relevant allergens were PPD (from hair dyes) and quaternium-15 and formaldehyde (both from cosmetics or other personal products). For periorbital

dermatitis, PPD from hair dyes and balsam of Peru from cosmetics were the most common causes.

Of note, PPD had the highest clinical relevance; 10 of 12 reactions were determined to be of present relevance. In contrast, only 4 of 14 positive reactions to thimerosal and 1 of 6 positive reactions to caine mix were found to be of present relevance. It was also observed that whereas nickel sulfate and neomycin sulfate frequently led to positive reactions, a significant proportion of the reactions (relative to other allergens) were deemed to be of only past relevance (6 of 26 for nickel and 7 of 19 for neomycin).

Final Diagnoses

Each patient was given one final diagnosis. In a total of 183 patients tested, 58 (31.7%) had at least one reaction that had present clinical relevance; these patients were diagnosed with ACD. Forty-four patients (24.0%) were still suspected of having ACD from allergens that were not on the TRUE Test panel, and the remaining 81 patients (44.3%) were given another diagnosis, such as irritant contact dermatitis (ICD), atopic dermatitis, or psoriasis.

Table 1. Interpretation and Relevance of TRUE Test Allergens, Ranked by Positive Reaction Frequency for Entire Study Population

Allergen	Reactions						Relevance	
	Positive		Doubtful		Irritant			
	No.	%	No.	%	No.	%	Present	Past
Nickel sulfate	26	13.8	2	1.1	2	1.1	12	6
Neomycin sulfate	19	10.1	1	0.5	0	0.0	9	7
Thimerosal	14	7.4	0	0.0	3	1.6	4	0
p-Phenylenediamine	12	6.4	0	0.0	0	0.0	10	0
Quaternium-15	11	5.9	1	0.5	1	0.5	8	0
Formaldehyde	11	5.9	1	0.5	1	0.5	7	0
Balsam of Peru	8	4.3	0	0.0	0	0.0	6	0
Cobalt dichloride	8	4.3	0	0.0	0	0.0	6	0
Potassium dichromate	6	3.2	4	2.1	0	0.0	4	0
Caine mix	6	3.2	2	1.1	0	0.0	1	0
Methylchloroisothiazolinone	5	2.7	1	0.5	1	0.5	3	0
Fragrance mix	5	2.7	0	0.0	1	0.5	2	0
Ethylenediamine dihydrochloride	5	2.7	2	1.1	0	0.0	3	0
Paraben mix	4	2.1	0	0.0	2	1.1	3	0
Wool alcohols	4	2.1	0	0.0	0	0.0	3	0
p-tert-Butylphenol formaldehyde resin	3	1.6	1	0.5	0	0.0	2	0
Colophony	3	1.6	0	0.0	0	0.0	1	0
Epoxy resin	2	1.1	1	0.5	2	1.1	1	0
Mercapto mix	2	1.1	0	0.0	0	0.0	1	0
Mercaptobenzothiazole	1	0.5	0	0.0	0	0.0	1	0
Black rubber mix	1	0.5	0	0.0	1	0.5	0	1
Carba mix	1	0.5	0	0.0	0	0.0	0	0
Thiuram mix	1	0.5	0	0.0	0	0.0	0	0

Patients with hand dermatitis had the highest frequency of ACD as a final diagnosis (41.2%) whereas only 28.1% of patients with facial dermatitis and 14.8% of those with periorbital dermatitis were considered to have ACD. The proportions of patients suspected to be allergic to allergens not on the TRUE test were 22.2%, 25.0%, and 33.3% for those with hand, facial, and periorbital dermatitis, respectively.

Ten of the 58 patients who had reactions of present relevance were felt to have occupation-related ACD, and 6 of these patients had hand dermatitis. The most common causative allergens were PPD ($n = 3$), nickel ($n = 2$), and cobalt ($n = 2$). Occupational allergy to PPD was seen among hairdressers whereas nickel and cobalt were common allergens for factory workers who worked with metal tools.

Follow-Up

Of the 58 patients with ACD, only 33 had documented follow-up. The dermatitis of 7 patients was noted to have resolved with avoidance of the causative allergens, 24 patients were noted to have experienced clinical and/or symptomatic improvement with such avoidance, and 2 patients were reported to have no change in their condition with avoidance.

Statistics

As determined with univariate analysis, there was a statistically significant association between a clinical diagnosis of ACD and a positive patch-test result (OR, 11.0; 95% CI, 5.49–22.07).

Discussion

Comparisons to Published Studies

The characteristics of the study population were in concordance with those of populations of prior NACDG studies, which similarly include a female predominance (about 62%) and an average age of 46 to 47 years.^{9,10} The distribution of the dermatitis sites in our study was also similar to that reported in the NACDG studies, in which the most frequently involved sites of dermatitis were the hands (27.4–31.0%), face (16.1–16.3%), generalized areas (15.2–17.8%), and eyelids (5.1–5.6%).^{11,12} The reported frequency of positive reactions in patch-tested patients has varied widely, from about 50 to 70%.^{7,11,12} The value found in our study is at the lower end (50.8%) but still within the reported range.

The top 10 allergens in terms of the frequency of positive reactions were identical in both the 1996–1998 and 1998–2000 NACDG studies.^{11,12} From 1998 to 2000, the top allergens were nickel sulfate (16.2%), balsam of Peru (12.3%), neomycin (11.5%), fragrance mix (10.9%), thimerosal (10.8%), sodium gold thiosulfate (10.5%), formaldehyde (9.2%), quaternium-15 (9.2%), bacitracin (9.2%), and cobalt chloride (7.6%).¹² In a recent meta-analysis of 15 years of published TRUE Test data, the most prevalent allergens were found to be nickel (14.7%), thimerosal (5.0%), cobalt (4.8%), fragrance mix (3.4%), and balsam of Peru (3.0%).¹³

Of the 10 most prevalent allergens in the NACDG studies, seven of the eight that are on the TRUE Test were among the top 10 allergens in our study. As for the top five allergens in the TRUE Test meta-analysis, all except fragrance mix were among our 10 most prevalent allergens. However, there are notable differences between our results and the published data. PPD, which is ranked fourth in our study, was ranked fourteenth in the NACDG study¹² and was not one of the more prevalent allergens in the meta-analysis. However, PPD was noted to be one of the allergens that had a high degree of clinical relevance (100%),¹³ and this may explain its low frequency in studies conducted at referral centers, as the majority of patients who present to their primary care dermatologist are diagnosed and hence are not seen at referral clinics. It should also be noted that many of the 14 studies included in the meta-analysis recruited highly selected patient populations,^{14–17} and all but one study were conducted at referral centers.^{14–26} Moreover, in five of the studies, only 12 allergens on the TRUE Test were used.^{14,18–20,22} These selection biases may also account for the differences in the results from our study.

Another difference observed was the low frequency of reactions to fragrances and rubber additives in our study when compared to the NACDG studies. The frequencies for balsam of Peru, fragrance mix, carba mix, and thiuram from the NACDG 1998–2000 study were 12.3%, 10.9%, 4.8%, and 4.7%, respectively¹² whereas the corresponding values from our study were 4.3%, 2.7%, 0.5%, and 0.5%. One reason for this may be false-negative findings with fragrance and rubber additives when the TRUE Test is used, as suggested by prior studies.^{27,28} This possibility is supported by a study of patients who were previously patch-tested with the TRUE Test and who were referred to a contact dermatitis clinic, where some of the patients subsequently had relevant positive reactions to fragrance mix and balsam of Peru that had been missed by the TRUE Test.²⁹

With respect to the clinical relevance of allergens, consistent with the current study, positive reactions to nickel and neomycin were often found to be of past relevance (24.3% and 29.4%, respectively).¹² Also, prior studies have noted thimerosal to have low clinical relevance, as was also observed in our study. Positive reactions to thimerosal are frequently due to past exposure (because of its wide use in the past as a preservative in cosmetics and in ophthalmic and otolaryngologic medications) or due to asymptomatic sensitization (as a result of its use in vaccines).³⁰

The TRUE Test is marketed to a wide audience. Thus, one study of particular interest is a postmarketing survey of the TRUE Test that compiled data from sources in the community less experienced in the evaluation of patch-test results.³¹ In the 3,209 patients, there was a female predominance similar to our study (70.2%), and 62.7% of the 3,209 patients had at least one positive reaction. The allergens with the highest reaction rates included nickel (17.8% of positive reactions), quaternium-15 (10.6%), thimerosal (9.4%), formaldehyde (8.7%), neomycin (7.9%), and PPD (7.4%), all of which were among the most frequent allergens in our study. In the postmarketing survey, 75.5% of patients with positive reactions had reactions that were clinically relevant, which is higher than the 62.4% reported in this study. This may be because the results from the survey were biased because the findings are based on data obtained from returned surveys, which are more likely to be from physicians who found more clinically relevant results in their patients.

With regard to the final diagnoses, NACDG studies have found a distribution of ACD in 47.2 to 48.5% of patients, ICD in 15.0 to 15.6%, atopic dermatitis in 6.6 to 7.7%, and other diagnosed disorders in 11.1 to 23.2% of patients.^{11,12} Although the frequency of ACD is lower in our study (31.7%), the OR of 11.0 indicates that the likelihood of a final diagnosis of ACD is much higher for patients who have a positive patch-test result. This supports the patch test as a useful triage tool in the private practice setting, allowing early diagnosis and treatment of ACD in a subset of patients, particularly those with sensitivities to allergens of high relevance such as PPD.

Of interest, in a retrospective chart analysis of 85 patients with facial dermatitis (including those with eyelid and lip involvement), it was found that only 43% of relevant reactions would have been detected with the TRUE Test alone whereas 64% would have been detected by the NACDG standard series.³² The most common relevant allergens found on the NACDG standard series that are not tested with by the TRUE Test were formaldehyde-releasing preservatives (FRPs) and propylene glycol. Of note, the

most frequently encountered relevant reactions were reactions to the patients' own personal care products (including cosmetics, moisturizers, and shampoos), followed by preservatives and fragrances. Other large-scale studies of patients with periorbital dermatitis also found most of the relevant reactions to be to the patients' personal products.^{33–37} Thus, in these instances, neither the TRUE Test nor the NACDG panels would be good screening tests unless supplemented by the patients' products.

As did prior studies, our study found preservatives in cosmetics and personal products to be among the most common allergens for patients with facial and periorbital dermatitis. However, the frequency of ACD in our study was low for these patients (28.1% for facial dermatitis, 14.8% for periorbital dermatitis), and a large proportion (25.0% for facial dermatitis, 33.3% for periorbital dermatitis) were felt to be allergic to other allergens. This is consistent with the above-mentioned reports that the causative agents are often the personal products of the patients, and the responsible allergen is often difficult to identify. As indicated by the studies mentioned above, even the expanded standard series may miss a significant portion of cases. Thus, it is important to patch-test with the patient's own personal products in this subset of patients to increase the yield of patch testing. Also, although it was observed that FRPs are common relevant allergens that are not included in the TRUE Test, 8 of 9 patients who reacted to FRPs also reacted to formaldehyde and/or to quaternium-15.³² Hence, although the TRUE Test lacks the sensitivity of expanded screening trays, its clinical usefulness can be further enhanced by the physician's knowledge of probable cross-reacting allergens.

A recent retrospective analysis of 193 patients who had hand dermatitis found that 56% of the hand dermatitis was related to occupations, most commonly those of health care workers, machine operators, and workers in professional cleaning.³⁸ Our study similarly found occupation-related ACD to be more common among patients with hand dermatitis (particularly in machine operators). However, it should be noted that the TRUE Test was not designed for screening for occupation-related dermatitis; in cases in which occupational disease is suspected, patients should be promptly referred for supplemental testing.

Limitations of this Study

This study was limited in terms of the ethnicity and geographic location of the patient population, and almost half of the patients were from a single practice. Also, the involved dermatologists are not subspecialists in ACD.

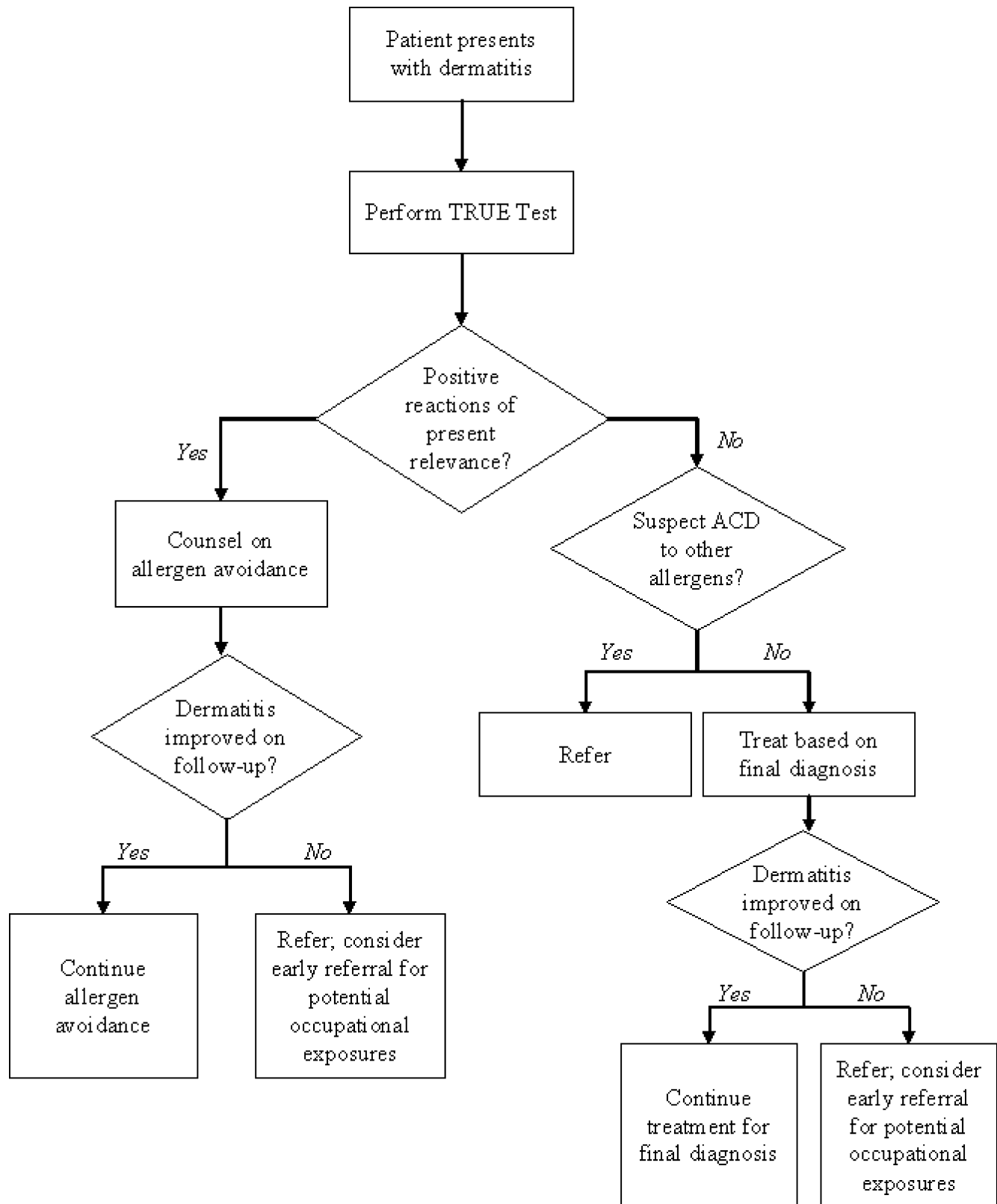


Figure 1. Algorithm for using the TRUE Test to triage patients who present with dermatitis. (ACD = allergic contact dermatitis)

Since the interpretation of patch-test results and the determination of clinical relevance is often based on experience, there is a risk of misclassification in determining the final diagnosis. As a retrospective chart review, the reading and interpretation of patch-test results was not standardized. Also, for 20% of the patients, only a 72-hour reading was obtained, so delayed reactions may have been missed. Data were also often incomplete in terms of details of the possible exposure as well as patient follow-up. Furthermore, unlike other trials, there was no comparison with the NACDG standard panel or other supplemental testing, so it is unknown how many cases of ACD were missed.

Conclusion

It has been suggested that the appropriate use of patch testing should yield a positive test result 30 to 65% of the time.³⁹ If the percentage of patients who have positive results is much higher, the physician may be underusing the test. On the other hand, an inordinately low yield suggests that the test was misapplied (ie, given to people not likely to benefit from it).

On the basis of the results of this retrospective chart review, the TRUE Test appears to be an adequate screening test that is appropriately used in the private practice setting. With its ease of use, it enables the private practitioner to patch-test more patients; more importantly, it allows patients with dermatitis to be systematically triaged (Fig 1) rather than simply treated symptomatically. As a result, a subset of patients can be diagnosed with ACD early and counseled on allergen avoidance whereas another subgroup can be identified for early referral to an ACD subspecialty clinic for supplemental testing.

However, the TRUE Test serves as a good screening test only if the physician is aware of its limitations. First, as previously mentioned, reactions to certain allergens such as fragrance and rubber additives may be missed by the TRUE Test. Thus, a negative patch-test result does not mean that ACD can be ruled out. Patient follow-up is essential, and patients whose dermatitis does not resolve with allergen avoidance or appropriate treatment for other presumed diagnoses should be referred for further testing to identify allergens that may not have been adequately screened for with the limited allergens on the TRUE Test. Second, for patients with facial or periorbital dermatitis, the causative agents are often the patients' personal products, and the allergen is often difficult to identify. With this subgroup, therefore, it is especially important to also patch-test with the patients' personal products to increase the yield. Last, because the TRUE Test was not designed

as a screen for occupation-related ACD, patients who may have occupational exposures may benefit from early referral for supplemental testing.

Although this is the first study to examine the use of the TRUE Test in the private practice setting, it does have the limitations of a retrospective chart review. Further studies need to be performed, particularly with standardization of the interpretation and relevance determination of patch-test results as well as with follow-up of patient outcome and further testing as necessary. It would also be of benefit to record the various reasons for patch testing, to further delineate the usefulness of the TRUE Test within a general dermatology practice.

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