Evaluation of Duotip-Test

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Duotip-Test (Lincoln Diagnostics) is a recently developed skin testing device used in detecting immediate hypersensitivity. It is a plastic disposable cylinder that measures 3 mm in diameter and 41 mm in length. At one end of the device there is a notched finish for grasping, and at the other end are two fine tapered points (Fig. 1). Duotip-Test is used with either a modified prick method or a rotation technique. We studied this new device, by using the rotation technique, to determine its reproducibility, sensitivity, and specificity with histamine and glycerosaline.

Abbreviation used
CV: Coefficient of variation

METHODS

This study was conducted in the outpatient Allergy and Immunology Clinic at St. Louis University Health Sciences Center. Subjects were recruited from patients seen in the clinic and from employees of St. Louis University Health Sciences Center. Institutional Review Board approval for the study was obtained, and each test subject gave written consent. Twenty subjects ranging in age from 26 to 65 years (mean age, 39.6 years) were tested. The subjects were nonatopic or atopic, were in good health, and had not used antihistamines or other inhibiting medications. Skin testing was performed on the volar surface of the arm, the right arm for 10 subjects and the left arm for 10 subjects.

The points of the device are loaded by capillary action after immersion in the test solution.

When the rotation technique is used, the shaft of the device is placed at a 90-degree angle to the skin, and just enough pressure is applied from the points to cause a small dimple in the test subject's skin. When rapidly rotated, the device makes a small circular abrasion in the epidermis and deposits the test solution.

In a blinded fashion, using the new device, one investigator administered a row of five epicutaneous tests spaced approximately 2.5 cm apart, four of which were 27 mg/ml histamine phosphate (10 mg/ml histamine base) in 50% glycerosaline and one of which was the negative control (50% glycerosaline). Another investigator, also in blinded fashion, read and recorded the wheal sizes at 15 minutes. A circular caliper disk, marked in 1 mm increments from 0 mm to 45 mm, was used to measure the wheals. Test solutions were obtained from Center Laboratories (Port Washington, N.Y.). Test devices were obtained from Lincoln Diagnostics (Decatur, Ill.).

RESULTS

A total of 80 histamine and 20 glycerosaline test sites were graded in the 20 subjects. Mean histamine wheal size was 7.5 mm (range, 4.0 to 10.5 mm) with a standard deviation of 1.5 mm.

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FIG. 1. Duotip-Test device.

The mean coefficient of variation (CV) was 8.8% (range, 0% to 21%). Ninety-five percent of wheals at the negative control site ranged in size from 1.5 to 3.5 mm, with a mean size of 2.6 mm. One of the 20 test subjects had a negative control site with a wheal size of 4.0 mm. When 4.0 mm was used as the minimum wheal size regarded as positive, Duotip-Test had a sensitivity of 100%, a specificity of 95%, and a low mean CV (8.8%).

DISCUSSION

In recent years there has been a proliferation of skin testing devices, each requiring evaluation for sensitivity, specificity, and reproducibility of test results. Establishing wheal size confidence limits for each device, as suggested by Nelson et al.,[1] appears to be practical. At the 4 mm wheal size for Duotip-Test, the sensitivity was 100% and the specificity was 95%. The low CV (8.8%) from this device reflects high reproducibility of results.

When comparing our findings from Duotip-Test with those obtained by other techniques, we note that Nelson et al.[1] reported sensitivity and specificity at a 3 mm wheal positivity level from several one-at-a-time devices with histamine (10 mg/ml) and glycerosaline: HS lancet (Hollister Stier Miles Inc.), 98% and 100%; ALK lancet (ALK Laboratories), 100% and 95%; BN bifurcated needle (ALO Laboratories) prick, 100% and 87%; BN bifurcated needle puncture, 100% and 81%; DermaPIK (Greer Laboratories), 100% and 20%. The sensitivity and specificity results from Duotip-Test are comparable to those from HS lancet and ALK lancet but superior to results from the bifurcated needle and DermaPIK.

The 8.8% mean CV from Duotip-Test is substantially lower than the CV from any of the devices evaluated by Nelson et al.[1] In the study by Nelson et al.,[1] the CV ranged from 15% for the HS lancet to 19% for the bifurcated needle.

The Duotip-Test procedure was well accepted by all 20 adult subjects, and its administration was rapid and convenient.

REFERENCE

1. Nelson HS, Rosloneic DM, McCall LI, Ikle D. Comparative performance of five commercial prick skin test devices. J Allergy Clin Immunol 1993;92:750-6.