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Evaluation of Three Methods for Using the Duotip-Test Device for Skin Testing

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SUMMARY **The sensitivity and precision of rotation, prick and puncture methods of using the Duotip-Test for epicutaneous allergy skin testing were evaluated. Forty-one volunteers who had not taken any antihistamines within the previous two weeks were recruited. The mean age was 21.6 years (range 18 to 25 years). Histamine hydrochloride 1 mg/ml and 50% glycerol saline were used as positive and negative controls, respectively. Each method of testing was performed in triplicate on the volar surface of both forearms. Wheal and flare were measured 15 minutes later. Rotation, prick and puncture methods produced histamine mean wheal diameter ± standard deviation of 6.61 ± 0.87 mm, 3.86 ± 1.03 mm, and 3.00 ± 0.65 mm, respectively ($p < 0.01$). The coefficient of variation of rotation method was 13.13%. It was the only method that gave coefficient of variation lower than 20%. False negative and false positive proportions of rotation method using a 4 mm criterion for positive reaction were 1.5% and 0.75%, respectively. Rotation method was well accepted by the volunteers although it was ranked highest in pain. We concluded that the rotation method of using Duotip-Test is a highly reliable technique for skin testing.**

In recent years, there have been many skin testing devices. Each device requires an evaluation of reproducibility. Duotip-Test (Lincoln Diagnostics) is a plastic disposable device used for epicutaneous allergy skin testing (Fig. 1). The operator is able to apply antigen and penetrate the skin with Duotip in a single step. Duotip-Test single step is easily performed in small children. Corder *et al.*[1] compared two plastic skin testing devices, i.e. DermaPIK and Duotip-Test, and demonstrated that Duotip-Test rotation method caused more distinct dermatographism and pain. Only few studies directly compared various methods of using the Duotip-Test. The objective of this study was to compare the performance of the Duotip-Test when used with rotation, prick and puncture methods.

MATERIALS AND METHODS

Subjects

Healthy volunteers who had previously not taken antihistamines within two weeks prior to the study were recruited. The protocol was approved by the Institutional Review Board of the Faculty of Medicine, Prince of Songkla University, Thailand.

Methods of skin testing

Prick method

The Duotip device, with a drop of extract in its tines, was applied so that it entered the skin at a 45-degree angle and gently lifted the upper layer of the epidermis without causing any bleeding.

Puncture method

The device was held perpendicular to the skin at the test site

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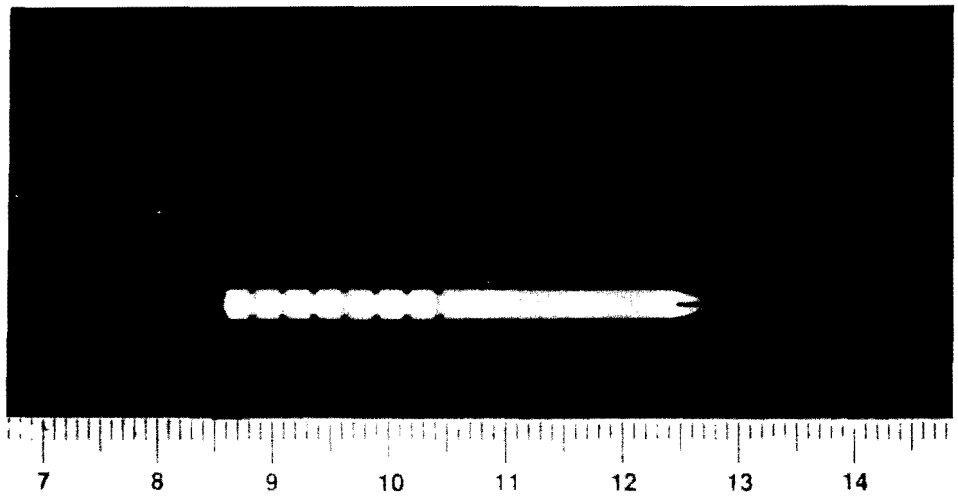

Fig. 1 Photograph of the Duotip-Test device showing its two 2-mm tines at the tip.

and then was pressed to allow its tines to enter the skin leaving two small indentations.

Rotation method

The device was held perpendicular to the skin with its tip pressed to assure that all tines were in contact to the skin. The device was then rapidly rotated to make a small circular abrasion in the epidermis. The test solution was deposited directly onto the abrasion created.

Study design

The entire study was performed by the same well-trained investigator between 9.00 to 12.00 hours to avoid circadian variations. Each volunteer recieved three methods of epicutaneous skin testing placed in columns on the volar surface of both forearms. Each method was performed six times spaced approximately 3 cm apart, three of which were histamine hydrochloride 1 mg/ml (positive control) and three of which were 50% glycerol saline (negative control). The results were recorded 15 minutes thereafter by an experienced investigator in a blinded fashion. Wheal and flare outlines were marked with a felt tip pen and transferred with transparent tape to a permanent record. The longest and the orthogonal diameters were measured and the mean diameters employed for analysis. Test solutions and devices were obtained from Center Laboratories (Port Washington, N.Y.) and Lincoln Diagnostics (Deatur, Ill.), respectively.

At the end of the testing session, each subject was asked to rank on a scale of 1 (lowest) to 4 (highest) the degree of discomfort of each method.

Statistical analysis

The coefficient of variation (CV) of each technique was calculated by: CV = (standard deviation/ mean) x 100. One-way analysis of variance (ANOVA) was used to compare the different techniques for the size of the wheal and flare. All tests of hypotheses were two-tailed at the 0.05 level of significance. Statistical analysis was performed by using SPSS program on an IBM compatible computer.

RESULTS

Subjects consisted of 41 normal volunteers (21 males and 20 females), with ages ranging from 18 to 25 years (mean age 21.6 years).

The mean wheal and flare sizes of three skin test methods are presented in Table 1. There were highly significant differences among the methods for the sizes of the mean wheals and flares with histamine ($p < 0.01$). The mean histamine wheal from rotation method was significantly greater than with any other method ($p < 0.01$). CV of the rotation method was significantly less than with other methods ($p < 0.01$).

There was a significant difference in the sizes of the wheals at the negative control sites among

Table 1 Mean wheal and flare diameters to histamine by three methods of Duotip skin testing

Methods	Wheal diameter Mean ± S.D. (mm)	Flare diameter Mean ± S.D. (mm)	CV of wheal diameter (%)
Duotip (rotation)	6.61± 0.87*	30.12 ± 4.90*	13.13
Duotip (prick)	3.86 ± 1.03	19.50 ± 6.16	26.68
Duotip (puncture)	3.00 ± 0.65	13.02 ± 3.90	21.50

CV = coefficient of variation
*$p < 0.01$

devices. For the prick and puncture methods, neither produced any wheals with glycerol saline. The mean wheal diameter ± S.D. of the rotation method with the negative control solution was 2.24 ± 0.51 mm. The proportions of false negative and false positive reactions with different criteria for a positive test are shown in Table 2.

Table 2 False negative and false positive rates produced by the Duotip (rotation method) using different cut-off values for a positive test

Cut off values	% False negative	% False positive
3 mm	0	14.6
4 mm	1.5	0.75

Mean (S.D.) wheal size with negative control solution = 2.24 (0.51) mm

The rotation method was ranked highest in pain and discomfort. Prick and puncture methods, were ranked lower, respectively. However, all methods were well tolerated and well accepted by the volunteers.

DISCUSSION

The precision of epicutaneous skin testing has been examined by a number of investigators and is usually expressed as a coefficient of variation. The Nordic Society of Allergology has recommended a CV of less than 20% for histamine wheal size diameter for optimal results.[2] We found that prick and puncture methods were too imprecise with high coefficients of variation. The rotation method had a good precision and produced the largest wheal and flare. Wheal size depends on abrasion of the skin produced by the skin testing device; therefore, the rotation method was ranked highest in discomfort among the three methods.

Another area of concern with skin testing is the cut-off level of the wheal diameter to indicate a positive result. It is clear that the size of any allergen-induced wheal and flare from skin testing must be interpreted by comparison with a positive (histamine) and a negative control solution (glycerol saline). The traditional prick test is performed by placing a drop of extract on the skin and pricking through this, at an angle, with a hypodermic or solid bore needle. This method usually creates minimal trauma, so that a wheal of 3 mm diameter and a flare of 10 mm diameter may be assumed to indicate the presence of specific IgE.[3] Some devices, such as DermaPik may induce a wheal of 5 mm in diameter with the negative control solution and any wheal reaction smaller than 5 mm may be considered as negative result.[4] This dermatographism makes interpretation of skin tests more difficult. In our study, the results from the rotation method yielded no false negative results and gave 14.6% false positive results when a wheal diameter greater than 3 mm is considered as the cut-off for a positive test. It would then be inappropriate to use a 3 mm as a criterion for positive reaction because the mean diameter of wheal reactions with the negative control solution (glycerol saline) in our study was 2.24 ± S.D. 0.51) mm. If we used the 99th percentile of wheal diameters (4 mm) at the glycerol saline site as the criterion for a positive skin prick test, the results from the rotation method would yield 1.5% false

negative and 0.75% false positive results. Stryk *et al.*[5] reported 5% false positive and no false negative reactions at a 4 mm wheal size when using Duotip-Test rotation method with histamine 10 mg/ml.

The accuracy of results using the prick method depends on experience of the operator in gently elevating the epidermis. Since the tip of the Duotip-Test is not as sharp as a needle, pricking the skin with this device is not easy. Thus, the antigen may not penetrate the skin, which could result in a high proportion of false negative tests. The puncture method is an easy method; however, it also produced many false negative results. Since the end of the Duotip-Test is blunt, it may not produce dermal abrasion when pressing on the skin and the test solution may, therefore, not penetrate the skin.

A number of devices for performing allergy skin testing have been tested. Those which produce the least trauma will result in the smallest wheal with the antigen or histamine. They will be the least apt to produce a wheal at the negative control site and thus will give the clearest distinction between positive and negative tests. On the other hand, they are most apt to fail to penetrate the epidermis, which could result in a "false negative" reaction. The more traumatic devices, on the contrary, will produce larger reactions with both allergen and histamine and even at the saline control sites. It is necessary for each operator to learn how to distinguish between positive and negative results when using different devices.

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