Comparison of two disposable plastic skin test devices with the bifurcated needle for epicutaneous allergy testing

W Thomas Corder, MD; Mary Beth Hogan, MD; and Nevin W Wilson, MD

Background: The Greer DermaPIK and the Lincoln Diagnostics Duotip-Test are frequently used plastic, disposable, allergy skin testing devices.

Objectives: To compare the prick method of using the bifurcated needle and DermaPIK with the Duotip-Test using both the scratch (rotation) and prick methods for sensitivity, precision, and level of discomfort.

Methods: Skin-testing was done with histamine and saline on the back in triplicate on 24 volunteers (mean age 32.8, seven males). Wheal and erythema were measured and a photograph was taken. Discomfort was rated on an analog scale.

Results: The bifurcated needle and the Duotip-Test prick technique had significantly smaller histamine wheal and erythema responses than either the DermaPIK prick or Duotip-Test scratch techniques ($P < .05$). The Duotip-Test scratch produced significantly larger wheals (mean 1.1 mm, $P < .001$) to saline than the other three methods. Erythema to saline by Duotip-Test scratch (mean 3.16 mm) was significantly larger than the bifurcated needle (mean 1.2 mm, $P < .001$) and Duotip-Test prick method (mean 1.6 mm, $P < .01$). There was no statistical difference in the histamine coefficient of variation among the four methods. The Duotip-Test scratch method was rated significantly higher in patient discomfort (mean 21.6, $P < .05$) than the bifurcated needle (mean 7.8). No differences in discomfort were noted between the other methods.

Conclusions: The Duotip-Test scratch method had the largest mean wheal/erythema to histamine and the lowest CV. It had the most dermatographism and was more uncomfortable than the other methods. The other devices and methods were very similar in response to histamine and saline, and to precision and discomfort.

Ann Allergy Asthma Immunol 1996;77:222–6.

INTRODUCTION

The primary tool for the diagnosis of immediate hypersensitivity reactions is the allergy skin test.[1] A variety of intradermal, percutaneous, and epicutaneous methods have been successfully utilized for testing.[2] The first widely accepted method was the scratch technique. This method involves placing a drop of extract on a superficial scratch through the outer layer of the skin. Today, the modified prick method[3] is more commonly used in clinical practice. This technique uses a small bore needle such as the bifurcated needle, to elevate the epidermis gently under a small drop of extract. This method should not induce any bleeding. Positive scratch and prick method results have a strong correlation with clinical symptoms and are safe.[2]

Unfortunately, the prick technique requires experience to obtain consistent results. The needle must be completely cleaned before each prick and the droplets must be kept separated during the prick-puncture process to ensure accuracy.[4] In addition, the operator must avoid self-induced needle sticks when wiping the needle between pricks. Recently, operator safety issues have been raised secondary to the potential for acquiring blood-born pathogens from a contaminated needle. These concerns are particularly important when inexperienced personnel perform the tests. Governmental regulations requiring a modification of the two-handed method of cleaning metal needles between prick applications have been published.[5] Disposable plastic skin test devices based on conventional designs have been developed to circumvent these difficulties.[6] The DermaPIK and the Duotip-Test are two such devices.

Studies comparing these plastic, disposable devices with the metal, reusable, needles for size of response, precision, and discomfort are few in number. We compared three devices, the metal bifurcated needle, with the two plastic, disposable devices, the DermaPIK and the Duotip-Test for response to histamine and saline. Skin testing with the bifurcated needle and the DermaPIK were performed using the prick methods that were previously shown to provide the greatest accuracy and consistency.[7–9] We used both of the manufacturers recommended techniques for the Duotip-Test; the modified prick method and the rotation (scratch) technique.[10] To our knowledge this is the first study comparing the two Duotip-Test techniques with other devices.

METHODS

Subjects

Subjects consisted of 24 volunteers between the ages of 7 to 44 years (mean 32.8 years). Seven were male. None had taken antihistamines for 2 weeks prior to the study. No volunteer had

From the Section of Pediatric Allergy and Immunology, Department of Pediatrics, West Virginia University, School of Medicine, Morgantown, West Virginia.

Funded by the Department of Pediatrics, West Virginia University, School of Medicine, Morgantown, West Virginia.

Received for publication February 1, 1996.

Accepted for publication in revised form May 16, 1996.

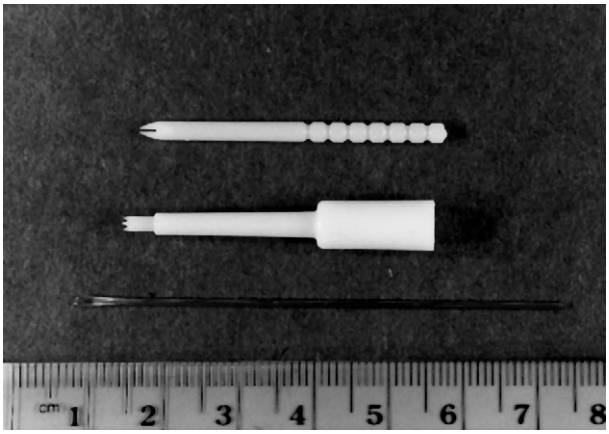

Figure 1. Photograph comparing the Duotip-Test, DermaPIK, and bifurcated needle. The DermaPIK has six 0.81-mm tines arranged at the tip in a 2-mm circle. The Duotip-Test has two 2-mm tines at the tip.

taken astemizole within the past 3 months. The protocol was approved by the Institutional Review Board of West Virginia University and informed consent was obtained from each subject or guardian prior to enrollment in the study. In addition, assent was obtained from each child participating in the study.

Skin Testing

Figure 1 illustrates the design differences between the bifurcated needle, DermaPIK, and Duotip-Test. Each volunteer had the four methods of skin tests placed in columns on the subject's upper back by the same experienced operator (NWW). The upper back was chosen as the test site to decrease differences in reaction size due to anatomic placement.[11] The four columns consisted of three 0.9%-saline controls and three 1-mg/mL histamine controls.

The bifurcated needle (ALO Laboratories, Columbus, Ohio) was utilized in the first column. The bifurcated metal needle is well established as an accurate and precise device for use in prick-puncture testing.[7,8] The prick technique was performed by passing the bifurcated needle through the drop of test solution at a 45° angle to catch the outer layer of the epidermis. This outer layer was then gently lifted. Cleaning of the needle between applied pricks was done by wiping the device with a isopropyl alcohol swab. The two handed technique was used as this study was completed prior to passage of governmental guidelines recommending a one-handed technique.

The DermaPIK (Greer Laboratories, Lenoir, NC) was used in the second column. For each test, the DermaPIK was first inspected to assure appropriate placement of a drop of solution on the tines. The prick technique was performed using the loaded device in a similar fashion to the bifurcated needle.[7] The DermaPIK was discarded after it was used.

The Duotip-Test (Lincoln Diagnostics, Inc, Decatur, IL) was used to place skin tests by the prick method in column three and the rotation method in column four. For each method the device was inspected in a fashion similar to the DermaPIK. The Duotip-Test prick technique utilized the same methodology as the bifurcated needle and DermaPIK. The Duotip-Test rotation technique was performed by holding the device between the index finger and thumb and kept perpendicular to the plane of the skin. Enough pressure was then applied to indent the skin slightly. The pressure was maintained and the shaft was rotated 360°. The device was discarded after one application.

The relative levels of discomfort experienced by the subject were recorded for each device with an analog scale. After completion of each column, the subject was shown a scale that ranged from 0 (no pain) to 100 (severe pain). The patients communicated their discomfort ratings by sliding an indicator on a plastic scale.

All skin tests were read and measured by the same operator (NWW) exactly 15 minutes after placement. Using calipers, vertical and horizontal measurements were made of both wheal and erythema and recorded in millimeters. For analysis, the vertical and horizontal measurements were summed and divided by two. As a permanent record, a photograph of each subject's back was taken immediately following the skin test reading.

Statistical Analysis

One-way analysis of variance (ANOVA) was used to compare the different techniques for the size of the wheal and erythema as well as the relative level of discomfort.

The coefficients of variation for both wheal and erythema were calculated from the three histamine tests done for each technique. The following formula was used: standard deviation/mean $\times$ 100% = coefficient of variation.[6]

Statistical analysis was performed by using the InStat program (GraphPAD, San Diego, CA) on an IBM compatible computer.

RESULTS

Response to Histamine

The wheal and erythema response to histamine is shown in Figure 2. The largest wheal and erythema responses to histamine were by the DermaPIK prick (5.6 mm $\pm$ 0.9/29.6 mm $\pm$ 1) and Duotip-Test rotation (5.7 mm $\pm$ 0.7/29.4 mm $\pm$ 1.1) methods. The Duotip-Test prick had the smallest wheal to histamine (4.2 mm $\pm$ 1.0). The bifurcated needle had the smallest erythema response to histamine (22.9 mm $\pm$ 6.7). The bifurcated needle and the Duotip-Test prick technique had significantly smaller erythema responses than either the DermaPIK or Duotip-Test scratch techniques ($P < .05$).

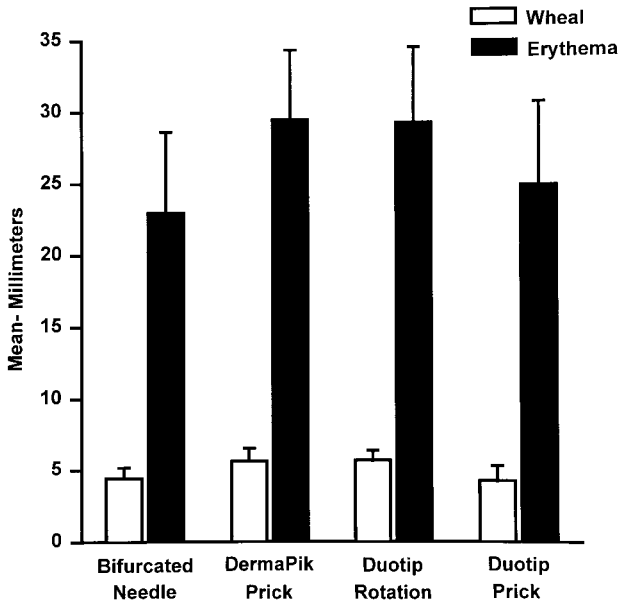

Figure 2. Mean wheal and erythema responses to histamine for the four methods. Error bars signify one standard deviation (SD).

Response to Saline

The Duotip-Test rotation method produced a larger wheal (1.1 mm ± 0.9, $P < .001$) to saline than the other three methods. The erythema response (3.2 mm ± 2.0) was also larger than the bifurcated needle prick (1.2 mm ± 1.5, $P < .001$) and Duotip-Test prick (1.6 mm ± 1.6, $P < .01$). There was no significant difference among the other three methods. Wheal and erythema responses to saline are shown in Figure 3.

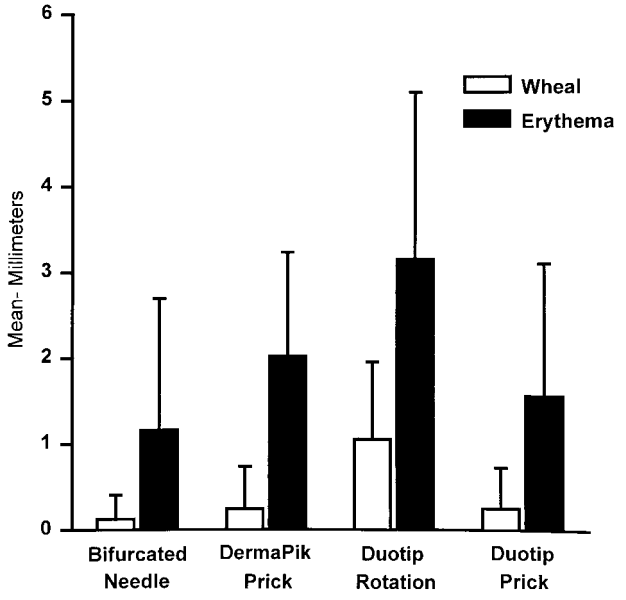

Figure 3. Mean wheal and erythema response to saline for the four methods. Error bars signify one SD.

Precision

Coefficients of variation of wheal and erythema to histamine are compared in Figure 4. The Duotip-Test rotation method had the smallest mean coefficient of variation for histamine wheal/erythema (11.7% ± 6.2/9.8% ± 12.2) and the Duotip-Test prick method had the largest (22% ± 22.5/18.8% ± 24). Two patients had individual negative histamine tests using the Duotip-Test prick method. No other method had a false negative histamine response; however, there was no significant difference in the coefficient of variation for histamine wheal or erythema for any of the techniques.

Relative Discomfort

The Duotip-Test rotation method was rated highest in discomfort (mean 20.5 on a scale of 100) and the bifurcated needle lowest in discomfort (mean 7.8) by our volunteers. Seventeen of the 25 volunteers rated the Duotip-Test rotation method highest in discomfort and four others rated it equal to the Duotip-Test prick as least comfortable. The difference in discomfort reached statistical significance between the Duotip-Test rotation and the bifurcated needle ($P < .05$). There was no other significant difference found between the other techniques (Fig 5).

DISCUSSION

In this study, we compared the scratch and prick methods of skin testing using the Lincoln Duotip-Test, with the prick puncture method of using the Greer DermaPIK and the bifurcated needle. No previous published studies have compared the Duotip-Test with other devices and methods. For the most part, the three devices and four methods tested produced similar results and most differences did not reach statistical significance. Some observations can still be made about differences in these devices and methods.

The bifurcated needle, the DermaPIK prick method, and the Duotip-Test prick method were similar in precision and size of the wheal and erythema to saline and histamine. The dermal abrasion produced by the

Duotip-Test rotation method resulted in the largest skin response to both histamine and saline. It also produced the smallest variation in size. It is evident that larger wheal and erythema responses to saline occur with traumatic skin test techniques.[7–9] This dermatographism may make interpretation of allergen skin tests more difficult and lead to more false positive tests.

Increased dermal abrasion also produces a greater pain response. This is probably why the Duotip-Test rotation method was rated the most uncomfortable of the four methods. The Duotip-Test prick method was rated considerably more comfortable than the Duotip-Test rotation method. The bifurcated needle, the DermaPIK prick method, and the Duotip-Test prick method caused essentially the same amount of discomfort.

The DermaPIK has been directly compared with other commercially available skin test devices in a few studies. Nelson et al[8] compared the DermaPIK scratch technique to several needle devices including the bifurcated needle. The DermaPIK scratch technique produced a significantly larger histamine and glycerosaline wheal than the bifurcated needle with similar levels of precision. In addition, the scratch method was rated less acceptable by the volunteers than the bifurcated needle. We previously compared three methods of using the DermaPIK to the bifurcated needle, and found the DermaPIK prick method to be very similar in precision and patient acceptability to the bifurcated needle.[7]

The skin test reliability of the bifurcated needle has made it a common device used in clinical allergy practice; however, concerns about operator safety during cleaning of these reusable needles have been raised. Disposable devices such as the Duotip-Test and DermaPIK were designed to eliminate these safety concerns. The Duotip-Test scratch technique was found to be the most precise method in our comparison of these two plastic devices with the bifurcated needle. It also produces the largest response to histamine. This scratch technique should be used with the knowledge that it also produces more dermatographism and may lead to more false positive tests. The increased discomfort with this particular Duotip-Test technique may be a problem in testing children. The Duotip-Test prick technique was associated with two false negative

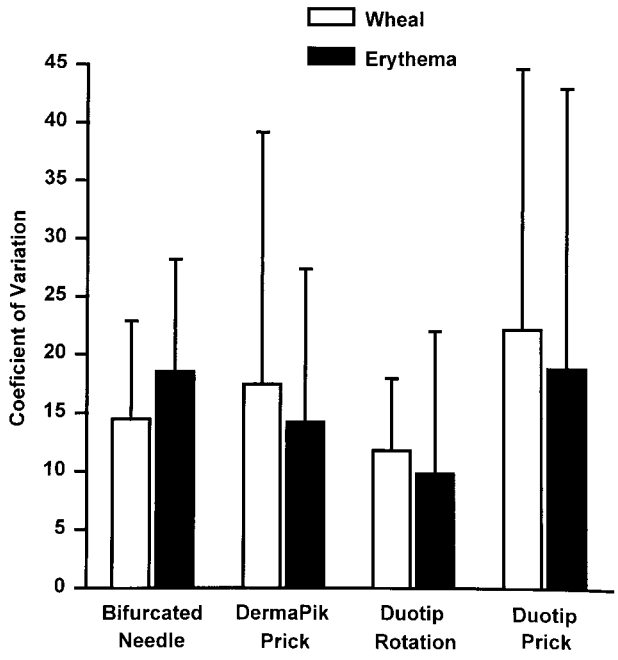

Figure 4. Coefficients of variation for wheal and erythema to histamine for the four methods. Error bars signify one SD.

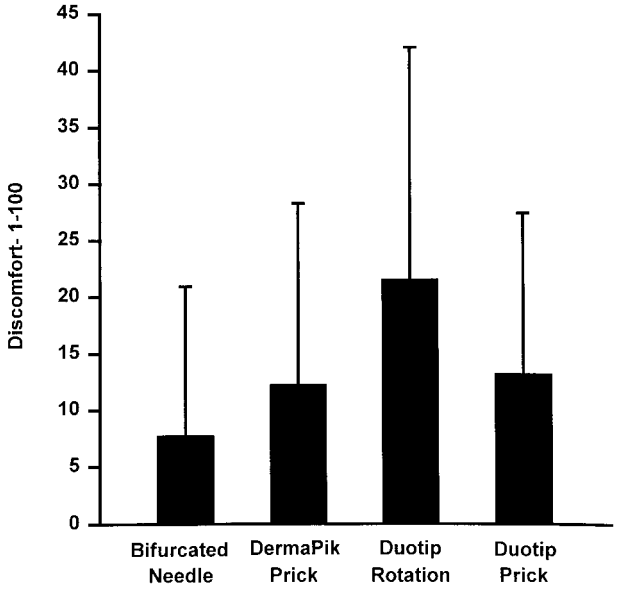

Figure 5. Relative discomfort of the four techniques on a scale from 0 to 100. Error bars signify one SD.

histamine responses. The bifurcated needle, DermaPIK, and Duotip-Test when used with the prick technique were very similar in histamine and saline responses, precision and discomfort. Decisions concerning clinical use of these skin test devices should be based on cost, operator safety, convenience, and personal preference.

REFERENCES

1. Nelson HS. Diagnostic procedures in allergy. I. Allergy skin testing. Ann Allergy 1983;51:411–8.
2. Bousquet J. In vivo methods for study of allergy: skin tests, techniques, and interpretation. In: Allergy principles and practice. Middleton E, Reed CE, Ellis EF, et al eds. St. Louis: CV Mosby, 1988:420–6.
3. Pepys J. Skin testing. Br J Hosp Med 1975;14:412–7.
4. Santilli J, Potsus RL, Goodfriend L, Marsh DG. Skin reactivity to purified pollen allergens in highly ragweed allergic individuals. J Allergy Clin Immunol 1980;65:406–12.
5. OSHA Hazard Information Bulletin: Potential for occupational exposure to bloodborne pathogens from cleaning needles used in allergy testing. Occupational Safety and Health Administration, US Department of Labor, Washington, DC, Sept. 1995.
6. Malling H-J, Andersen CE, Boas M-B, et al. The allergy pricker. Allergy 1982;37:563–7.
7. Corder WT, Wilson NW. Comparison of three methods of using the DermaPIK with the standard prick method for epicutaneous skin testing. Ann Allergy Asthma Immunol 1995;75:434–8.
8. Nelson HS, Rosloniec DM, McCall LL, Ikle B. Comparative performance of five commercial prick skin test devices. J Allergy Clin Immunol 1993;92:750–6.
9. Engler DB, DeJarnatt AC, Sim TC, et al. Comparison of the sensitivity and precision of four skin test devices. J Allergy Clin Immunol 1992;90:985–91.
10. DUOTIP-TEST Package insert. Lincoln Diagnostics, Inc, Decatur, IL, 1994.
11. Adinoff AD, Rosloniec DM, McCall LL, Nelson HS. A comparison of six epicutaneous devices in the performance of immediate hypersensitivity skin testing. J Allergy Clin Immunol 1989;84:168–74.

Request for reprints should be addressed to:
Nevin W Wilson, MD
Section of Pediatric Allergy & Immunology
Department of Pediatrics
Robert C Byrd Health Science Ctr
West Virginia University
Morgantown, WV 26505