

Pain perception and performance of three devices for single-site allergen skin testing

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ABSTRACT

Skin testing remains the preferred method for most allergists for establishing the presence of allergen sensitization. This study examined the performance of a new single-site skin test device that incorporates initial pressure to reduce the sensation of pain. Comparators were a conventional skin testing system and a smallpox needle. Twenty subjects were tested on the back, four sites with histamine and four sites with saline with each of the three skin testing devices. The single-site skin test device was applied with downward pressure, the conventional skin testing system, and smallpox needle (SPN) by pricking at a 45° angle. Outcomes were size and reproducibility of the skin test reactions and discomfort, as graded by the subject. The whealing responses to histamine were larger with the conventional skin testing system than with the single-site skin test device and both produced larger wheals than the SPN. The conventional skin testing system also produced greater intrasubject variability. Only the conventional skin testing system produced wheals of >3 mm with saline. There was no significant difference in perception of pain, which was low with all three devices. All three devices were well tolerated, without a significant difference in perception of discomfort. Testing with histamine revealed differences in wheal size and reproducibility among the three devices and testing with saline revealed differing likelihood of inducing a significantly sized wheal.

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Skin testing remains the preferred method for most allergists in establishing the presence of allergen sensitization.¹ Prick/puncture testing is the preferred initial approach, because of its greater specificity and safety compared with the alternative of intradermal testing.² Prick/puncture testing may be performed on the back or forearm and with devices that perform a single test or that apply tests at multiple sites with a single application. A web-based survey of allergists' skin testing practices was conducted in 2006.¹ At that time more than one-half of the respondents used single testing devices (Table 1). In the past, skin-prick testing was commonly performed with a smallpox needle (SPN) or other needle that was wiped free of allergen after each test and reused for the entire battery of tests. This practice has been largely abandoned because of concerns that technicians could puncture themselves in wiping the needle and potentially expose themselves to the human immunodeficiency virus. By 2006 only 4% of respondents continued to use the SPN, and the most frequently used single test device was the Greer Pick (GP; Greer Laboratories, Lenoir, NC) used by 27.7% of respondents. Since that survey, use of the GP has remained about the same and it continues to be the

most frequently used single test device, and use of the Duotip-test and the QUINTIP (Hollister-Stier, Spokane, WA) have increased (Gary Hein, Lincoln Diagnostics, personal communication).

A new system for skin testing has been developed that incorporates the gate control theory to reduce the sensation of pain experienced by the patient undergoing skin testing.^{3,4} This approach uses activation of nerves in the skin by gentle pressure that then causes blocking of pain transmission at the level of the spinal cord. This approach is the basis for several therapeutic procedures including transcutaneous electrical nerve stimulation, massage, and local application of heat or cold to relieve pain.⁵ The skin test device using this principle consists of a circle of sharp plastic prongs for penetration of the skin in the center of which is a solid rod extending slightly beyond the prongs. It is marketed both as a multiple-headed device—MultiTest PC⁶—and as a single test device—UniTest PC (UT; Lincoln Diagnostics, Decatur, IL; Fig. 1). The device is pressed vertically against the skin, applying gentle pressure by the solid rod in the center that activates the inhibitory nerves. After 1 second, the test head is pressed firmly, causing penetration of the surrounding prongs into the skin with introduction of the allergen extract.

METHODS

This was a partially blinded study designed to compare the pain perception and performance with histamine and saline of the three skin test devices (Fig. 1), each used by the preferred method: pricking

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Table 1 Devices and techniques used by allergists for prick/puncture skin testing

SPN (prick)	4.1%
Duotip (twist)	2.7%
Duotip (prick)	12.2%
DermaPik (twist)	7.2%
DermaPik (prick)	20.5%

Source: Modified from Ref. 1.

SPN = smallpox needle.



Figure 1. Three skin testing devices are shown. From left to right are the tips of the smallpox needle (SPN), the Greer Pick (GP), and the UniTest PC (UT).

at a 45° angle with an SPN (Hollister-Stier) through a drop previously placed on the skin; pricking at a 45° angle with the GP, which had been previously loaded by dipping into a reservoir vial⁷; and with downward contract followed by further pressure with the UT after first dipping the device in the reservoir vial to pick up a drop of extract. All testing was performed on the back in adult patients who had avoided antihistamines for 1 week and were not taking antidepressants.² Testing was performed with each device at eight sites from the top to the bottom of the back. Four of the eight sites were tested with 50% glycerosaline and four with 1 mg/mL of histamine base in 50% glycerin. One study coordinator filled the vials or placed the drops on the back in a random order. A second coordinator, who was an experienced skin test technician, performed the skin testing. The first coordinator then outlined the wheals after 15 minutes, the images were transferred by transparent tape to case report forms and later the longest and midpoint orthogonal diameters were measured and averaged. Subjects were counseled before application of the devices to be prepared to rate the degree of discomfort on a scale of 0 (none) to 10 (intense or unbearable). They were also asked to rate their overall preference among the three devices. The protocol was

approved by the Institutional Review Board of National Jewish Health and all subjects provided written informed consent before participation.

RESULTS

Twenty-two subjects were tested. The results of two subjects who reacted with whealing to histamine with all three devices >3 mm were not included in the analysis. The results from the remaining 20 subjects are presented in Table 2. The whealing response to histamine was larger with GP than with UT ($p = 0.05$) and both produced significantly larger wheals than the SPN ($0 < 0.001$). Not only were the wheals larger with the GP than the two other devices, but also there was significantly greater variation in the four wheals within individual subjects (46% greater than with SPN and 52% greater than with UT; $p = 0.001$). Wheals less than the conventional positive of 3 mm diameter were recorded in one subject with GP, but seven times in five subjects with SPN. Only the GP produced any whealing at sites of glycerosaline application and in two test sites the reaction was larger than the 3-mm conventional threshold for a positive skin test. On a scale of 0 (none) to 10 (unbearable discomfort), none of the devices was particularly painful and there was no significant difference among them. It was noted, however, that the nature of the discomfort differed, with the two prick devices causing a sharp pain whereas the puncture device caused a pressure-like pain.

The technician performing the skin testing was also queried regarding ease of performing skin tests with the three devices. The UT was considered to be the easiest, because it required only removing the device from the well, placing it on the skin, and pressing downward. Preparation with the GP was similarly simple but sometimes the tine did not penetrate the epidermis and the pricking motion had to be repeated. The SPN was least favored. The nonsterile needles had to be wrapped and autoclaved and the same problem as with the GP of nonpenetration of the epidermis and need for repeat pricking was encountered.

A final consideration in selecting a skin testing device may be the cost. In this case, all of the devices specifically designed for performing single skin tests fall in the range of \$0.09–0.19 per device depending in part on quantity purchased.

DISCUSSION

This comparison of three devices for prick/puncture skin testing revealed that all were well tolerated, without a significant difference in perception of discomfort or in subject preference among the three. This confirms previous studies indicating that patients do not find prick/puncture skin testing very painful.^{6,8} Using the

Table 2 Results of skin testing with histamine and saline

	GP	SPN	UT	<i>p</i> Value
Wheal with histamine mean, mm (SD)	5.59 (0.99)	3.98 (0.70)	5.00 (0.87)	GP > UT, <i>p</i> = 0.05; GP and UT > SPN, <i>p</i> < 0.001
Intrasubject variation in histamine wheal mean, mm (SD)	1.02 (0.45)	0.70 (0.29)	0.67 (0.23)	GP > SPN and UT, <i>p</i> = 0.001
Wheals <3 mm with histamine	1 <i>n</i> = 80	7 (In 5 subjects) <i>n</i> = 80	0 <i>n</i> = 80	0.31
Sensitivity	0.99	0.91	1.00	
Reaction >3 mm with saline	2 <i>n</i> = 80	0 <i>n</i> = 80	0 <i>n</i> = 80	0.32
Specificity	0.98	1.00	1.00	
Pain (0–10 basis); (SD)	2.0 (1.14)	2.01 (1.30)	2.30 (1.29)	0.75
Patient preferred device	6	9	5	0.48

GP = Greer Pick; SPN = smallpox needle; UT = UniTest PC.

same 0–10 scale used in this study, multiple-headed devices resulted in pain ratings of 1.8–2.15⁶ and single-headed devices in ratings of 1.0–2.0, except when twisting the device was used, which resulted in greater pain.⁸

The performance of the three devices did show some differences: the GP produced larger wheals with histamine and both GP and UT produced significantly larger wheals than the SPN. The variation in replicate tests at the histamine sites in the same subject was significantly larger with the GP than with the other two and also only the GP produced wheals that could be interpreted as positive tests at sites of testing with saline. This observation of reactions ≤ 3 mm with the GP has been observed before and might suggest that a larger threshold for a positive test should be used when interpreting the results with testing with the GP.⁹

The GP, and even more so the SPN, failed to produce wheals ≥ 3 mm in some subjects. This may be attributable to the difficulty noted by the technician in consis-

tently penetrating the epidermis with the pricking maneuver.

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