

Skin prick testing using allergen-coated lancets: a comparison between a multiple lancet device and a single lancet applied with varying pressures

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Summary

Allergen-coated lancets have been developed to simplify skin prick testing. The effect of variation in application pressure on the response to prick tests was assessed in 20 atopic subjects, and the results compared to the response obtained with a newly devised multiple lancet device (MLD), capable of holding up to eight lancets and of providing a standardized application pressure. A positive weal ($\geq 7 \text{ mm}^2$) using light pressure occurred in 2/20 subjects, compared with 14/20 after moderate pressure. The largest weals were obtained using hard pressure and with the MLD (all 20 subjects obtained positive weals) and there was no significant difference in weal size between the two. There was evidence of a late reaction in 4/17 subjects with the MLD and with hard pressure applied to a single lancet, but in only one with moderate and in none with light pressure. Thus both the early and late skin responses are dependent on the pressure applied. The newly designed MLD allows skin prick tests to be performed using a standard pressure. It is also convenient for multiple allergen testing of uncooperative children.

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Introduction

Skin prick tests (SPT) are widely used in the assessment of allergic disorders. Recently a convenient allergen-coated lancet has been developed for simplified, dry, skin testing (Phazet, Pharmacia Diagnostics AB, Uppsala, Sweden) [1]. The lancets have been designed to limit skin penetration to 1 mm. This allegedly overcomes the variation in response that can arise from differing depth of allergen penetration [2,3]. Although it has been claimed that SPT using fixed penetration lancets can reliably be performed by inexperienced operators [3,4], no information is available about the effect of varying the pressure applied. The first objective of our study was an assessment of the response to the application of lancets using light, moderate and hard pressure.

Skin testing is quite an ordeal for young children if several allergens are being assessed. A possible advantage of the precoated lancets is that multiple skin prick tests

could be performed simultaneously if a number of lancets were held in a device which allowed uniform penetration into the skin at each site. Therefore, the second aim of this study was to compare the results of SPT obtained using a specially designed multiple lancet device (MLD) capable of holding up to eight lancets, with the response following varying pressure applied to a single lancet. Because, as part of the study the same lancet was repeatedly used in the same subject, an assessment of repeated lancet usage on the skin weal response was also included.

Materials and methods

Subjects

Twenty-seven subjects (range 21–42 years old) were included in the study. They all had a history of atopic symptoms and a previous positive response (defined as a weal size $\geq 7 \text{ mm}^2$ or $\geq 3 \text{ mm}$ diameter) to conventional skin testing performed using the Pepys method [5]. Each was tested with an appropriate allergen. None of the subjects had taken any medication which might affect the skin response, and antihistamines were withheld for the preceding 72 hr.

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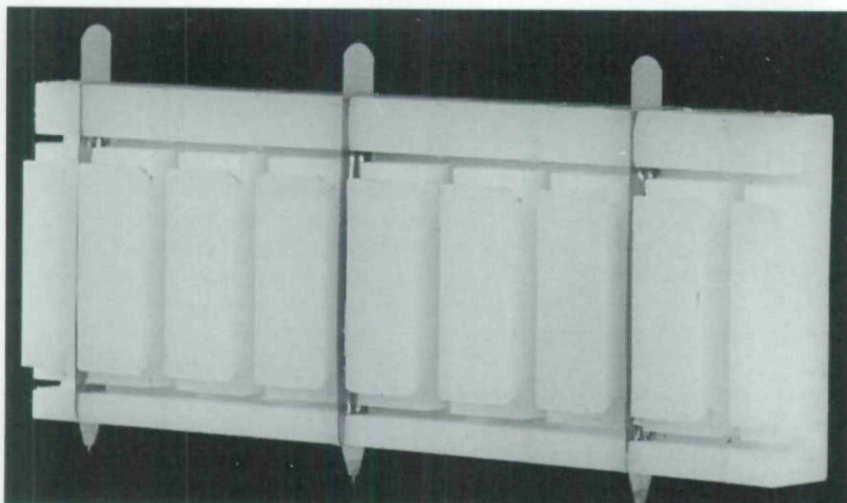


Fig. 1. The multiple lancet device (MLD).

Assessment of skin prick test response

All SPT were performed on the volar aspect of the arm by the same investigator. The test sites for individual lancets were always at least 30 mm apart and the area near the wrist and elbow joint were avoided. The early skin responses were recorded after 15 min and read 'blind' by a trained nurse. Using a skin test reaction gauge, the largest and smallest weal diameters were measured to the nearest 1 mm. The mean of the two diameters were used to calculate the 'weal area'. A positive early skin response was taken as a weal area of $\geq 7 \text{ mm}^2$.

Comparison of SPT response using the MLD and a single lancet applied with three different pressures

For multiple simultaneous SPT, a plastic block was designed to accommodate up to eight lancets with a minimum separation of 10 mm. The internal construction of the MLD with the sliding cover removed is shown in Fig. 1. The lancets were easily loaded and held firmly in place so that each shoulder projected from the block by 3.0 mm.

Twenty subjects were tested. Timothy grass coated lancets were used in 13 subjects, *Dermatophagoides pteronyssinus* in five, and cat and dog in one each. The MLD was loaded with an uncoated (negative control) lancet, a histamine-coated (positive control) and an appropriate allergen-coated lancet at positions 1, 4 and 7 respectively, allowing a separation distance of 30 mm. The MLD was applied at an angle of 90° to the volar surface of the right forearm for 2 sec. Sufficient pressure was applied so that the edge of the block rested against the skin. The procedure was then repeated on the left forearm.

The same allergen-coated lancet was then used to perform SPT by applying light, moderate and hard pressures to the volar surface of the forearm at 90° for 2 sec. Light pressure was defined as a skin depression of 1 mm, moderate pressure 2.5 mm, and hard pressure 5 mm measured from the shoulder of the lancet. Hard pressure was not sufficient to cause bleeding. Each subject was given a record sheet and asked to assess any diffuse swelling, soreness or itchiness after 6 hr in the test sites. A positive late skin response was taken as a swelling ≥ 10 mm diameter. Subjects were also instructed not to scratch or apply ointments to the forearms for this period.

Assessment of skin prick test response with repeated lancet use

To assess the effect of repeated lancet use, 11 subjects were repeatedly tested with an uncoated lancet, a histamine-coated and an appropriate allergen-coated lancet (Timothy grass in nine and *Dermatophagoides pteronyssinus* in two). Each lancet was pressed against the volar surface of the right arm at 90° for 2 sec guided by the index finger on the top of the lancet. For each lancet this was repeated five times. Each prick test was performed using the same hard pressure.

Statistical analysis

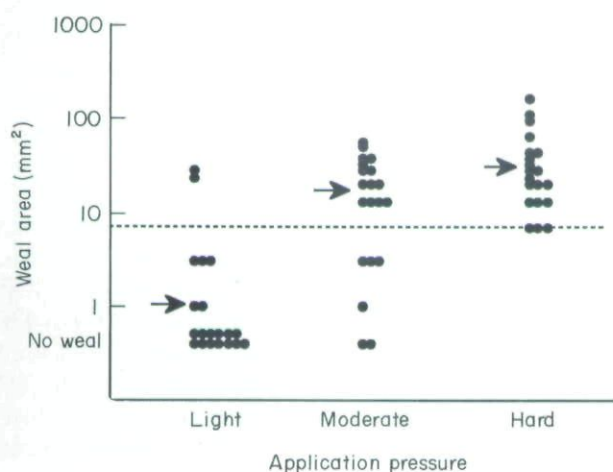
The distribution of skin responses obtained with the different pressures and the MLD were non-normal. For the repeatability skin studies, which were combined for all subjects, the distribution was also non-normal. Wilcoxon's test was used to study the difference between the results for single allergen lancets at different pressures and

Table 1. Early skin responses (weal size in mm²) using single allergen lancet and multiple lancet device (MLD) holding an allergen, histamine and uncoated lancet in 20 subjects

	Single			MLD					
	Pressure			Allergen		Histamine		Uncoated	
	Light	Moderate	Hard	r	l	r	l	r	l
Median	1	20	29	32	26	28	21	0	0
Range	0-28	0-57	7-165	7-227	7-177	3-64	3-79	0-3	0-3

r, right arm; l, left arm.

Significance of difference by Wilcoxon's test: moderate vs hard pressure, $P < 0.01$; hard pressure vs MLD allergen (r or l), n.s.; r vs l (for allergen, histamine & uncoated lancet), n.s.

**Fig. 2.** Individual weal areas obtained using different pressures applied to the allergen-coated lancet. Arrows indicate median values; dashed line indicates 7 mm², the criterion of a positive response.

the results for the MLD, and to compare the results obtained with the MLD on the right and left arms for the allergen, histamine and control lancets. The repeatability of the response using a single lancet was assessed using Friedman's and Wilcoxon's tests and the coefficient of variation. Values of P less than 0.05 were considered significant. Calculations were performed with all responses included, although only those with an area of ≥ 7 mm² (3 mm diameter) are normally regarded as being clinically significant.

Results

Effect of varying pressure

The median weal size of the skin reaction increased with increasing lancet pressure and maximal weals were

obtained using hard pressure (Table 1, Fig. 2). There was a significant ($P < 0.01$) difference between the weal sizes obtained with moderate and hard pressure. Using light pressure, only 2/20 subjects showed a positive response compared with 14/20 after moderate and 20/20 with hard pressure (Table 2).

A late response was looked for 6 hr after testing in 17 out of 20 subjects. Four subjects reported a late reaction when the lancet was applied with hard pressure, but only one when applied with moderate, and none with light pressure (Table 2).

Assessment of the multiple lancet device

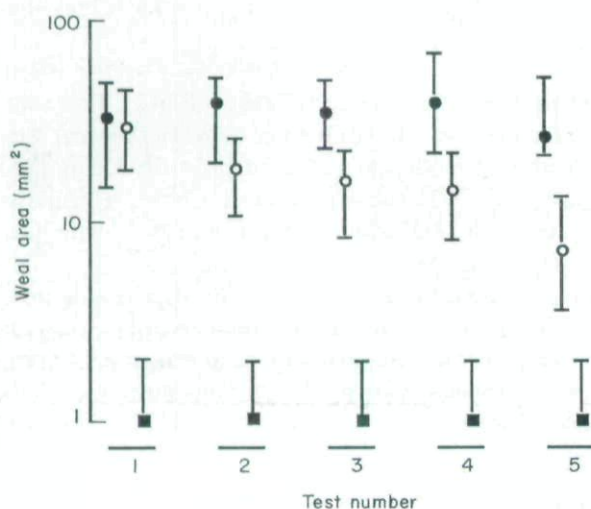
A positive skin response to allergen was obtained in all subjects on both arms using the MLD. There was no significant difference between the weal areas produced by the allergen lancet in the MLD on either arm (right arm median 32, range 7-227 mm²; left arm median 26, range 7-177 mm²). There was also no difference between the responses to the MLD and the response to a single allergen-coated lancet applied with hard pressure (median 29, range 7-165 mm²) (Table 1). Late responses were also similar with the two methods. The same four subjects who obtained a late response using the allergen lancet with hard pressure also obtained a late reaction with the MLD on both arms. Dermographic responses obtained with the uncoated lancet occurred in 8/20 subjects tested but the weals were not greater than 3 mm² (2 mm diameter).

Response to repeated use of lancet

All responses obtained with an individual allergen-coated lancet used five times with hard pressure were positive (≥ 7 mm², 3 mm diameter). There was no significant difference in the skin responses between the first to the fifth test (first median 33, range 7-71 mm²; fifth median

Table 2. Numbers of early and late responses to allergen obtained using the individual lancet and multiple lancet device (MLD)

	<i>n</i>	Single allergen lancet			MLD	
		Pressure			Arm	
		Light	Moderate	Hard	Right	Left
Early (15 min) response	20	2	14	20	20	20
Late (6 hr) response	17	0	1	4	4	4

**Fig. 3.** Weal areas (median and upper and lower 95% confidence intervals for the median) obtained with repeated lancet use. ●, allergen; ○, histamine; ■, uncoated (negative control) lancets.

26, range 13–104 mm²) using the Friedman's and Wilcoxon's analyses (Fig. 3). The reproducibility was good with a median intra-subject coefficient of variation of 34% (range 22–63%) for five repeats with the same allergen-coated lancet. The size of the responses obtained by repeated application of a histamine-coated lancet, consistently declined (Fig. 3). However, there was no significant difference between the first and second tests (first median 29 mm², second median 18 mm²).

Discussion

We have found that the weal response using a single lancet is related to the pressure with which it is applied to the skin. Performing the SPT with light pressure produced only 10% positive responses in subjects with a positive clinical history and known prior SPT response. A 'critical' pressure between moderate and hard was found to be

necessary to minimize the risk of false negative results. The presence of a late skin response was also found to be related to the pressure used during testing. The pressure applied is particularly important when assessing subjects with borderline skin responses, as we found that almost all of the false negatives (weal size range < 7 mm²) obtained when moderate pressure was applied, occurred in subjects who had the smallest weal sizes following the hard pressure test (range 7–20 mm²).

Allergen-coated lancets produced consistent skin reactions after repeated application, indicating that there was ample allergen on the lancet tip, sufficient for up to five tests. In this study, using the same lancet several times did not affect the size of the response. This feature of pre-coated lancets, was noted by Osterballe and Nielsen [6], who recommended that the lancets be used for routine double controls. Skin weals with the histamine lancet were diminished after the second test; we only used them twice in the experiments. Judging by the good reproducibility of the allergen responses, the problems with the histamine lancet do not appear to be related to inconsistent technique.

Although the lancet is designed to give a standardized prick depth of 1 mm, the shoulder preventing excessive penetration, the shoulder itself is only 3 mm in width and by applying hard pressure, the tip can penetrate deeper. It has been shown that the size of the response and the reproducibility of the method are related to penetration depth [3]. Kemeny *et al.* [7] found a discrepancy in the frequency of a positive response using a histamine-coated lancet and suggested that the duration of the lancet application was important. By accurate timing, they significantly increased the percentage of positive responses. It is possible that this difference in skin response could also have been due to a difference in pressure applied to the lancet.

The response with the allergen lancet in the MLD was similar to that obtained with the single lancet applied with hard pressure. Because all lancets protrude from the block by the same distance, and the face of the block

prevents undue penetration of the skin, skin tests are performed with similar penetration, reducing the likelihood of false negative responses due to errors in technique.

A multiple test-head applicator (Multi-Test) [8] is commercially available for simultaneous skin prick testing using allergen solutions. This plastic device which has eight heads, each containing nine points, has been found to be inadequate in comparison to other epicutaneous skin testing devices, particularly because of its high rate of false positive reactions [9]. The MLD described in this study compares very favourably to Multi-Test in its simple design and ease of use.

Skin prick testing with the MLD has obvious advantages for use with children. The device can be preloaded for use and only a few seconds are required to perform tests using several lancets simultaneously. Duplicate testing is quick and easy to perform. We have used this device extensively in 3 year olds, and found it to be well tolerated and much less frightening than standard skin testing.

Allergen-coated lancets are deceptively easy to use. However, unless consideration is given to the pressure applied, early and late skin responses may be inconsistent and comparisons between groups of subjects studied by different investigators may not be valid. The use of the MLD overcomes the difficulty of standardizing the pressure applied to the lancet and is convenient and humane for use with young children.

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