

Optimizing the Use of a Skin Prick Test Device on Children

Betul Buyuktiryaki^a Umit Murat Sahiner^a Erdem Karabulut^b
Ozlem Cavkaytar^a Ayfer Tuncer^a Bulent Enis Sekerel^a

Departments of ^aPediatrics, Pediatric Allergy and Asthma Unit and ^bBiostatistics, Hacettepe University School of Medicine, Ankara, Turkey

Key Words

Children · Skin prick test · Stallerpoint · Technique

Abstract

Background: Studies comparing skin prick test (SPT) devices have revealed varying results in performance and there is little known about their use on children. **Methods:** We performed 2 complementary studies to test the sensitivity, reproducibility and acceptability of commercially available SPT devices (Stallerpoint, Antony, France) using different application techniques. In the first part, histamine/saline was put on as a drop by use of a vial (V), and in the second part it was transferred from a well with the aid of the test device (W). The techniques were as follows: apply vertical pressure (Stallerpoint-VP or Stallerpoint-WP), apply vertical pressure with 90° clockwise rotation (Stallerpoint-VC or Stallerpoint-WC) and apply vertical pressure with 90° clockwise and counter-clockwise rotations (Stallerpoint-VCC or Stallerpoint-WCC). For comparison, ALK Lancet was used with a technique of 'drop and apply vertical pressure'. **Results:** In the first part, sensitivities of the Stallerpoint-VC (96.6%), Stallerpoint-VCC (95.5%) and ALK Lancet (93.2%) techniques were superior ($p < 0.001$) to the other Stallerpoint-VP and Stallerpoint-WP techniques (76.1 and 46.6%). Inpatient coefficient of variation (CV) values were 15.0, 18.9, 15.4, 22.4 and 48.5%, respectively. Interpatient CV

ranged between 22.8 and 55.1%. In the second part, the Stallerpoint-WC (98.8%), WCC (97.5%) and ALK Lancet (98.8%) techniques yielded high sensitivities, whereas the sensitivity of Stallerpoint-WP (28.7%) was very low. There were false-positive reactions in the Stallerpoint-VCC and WCC techniques. **Conclusion:** In children, the SPT technique was found to be as important as the testing device. Stallerpoint-VC and WC techniques are reliable, tolerable and comparable with the ALK Lancet technique.

Copyright © 2013 S. Karger AG, Basel

Introduction

Percutaneous skin testing is the primary method in the diagnosis of immunoglobulin E (IgE)-mediated allergic diseases. It is recommended by both the US Joint Council of Allergy Asthma and Immunology [1] and the European Academy of Allergy and Clinical Immunology [2]. It has many advantages such as ease of use, minimal invasiveness, low cost and rapid results, and it also has high sensitivity and specificity if performed under appropriate conditions. Even though there is no doubt that skin prick testing is the gold standard for diagnosing IgE-mediated allergic diseases, there remains some concern about the appropriate devices and techniques to use. Previous studies comparing skin prick test (SPT) devices have reported

significantly different results in their performance [3–9]. New devices are continuing to be developed by manufacturers. The diversity of devices and techniques used to perform SPT makes it difficult to evaluate the test results and make comparisons between different studies. In addition, the majority of these studies have been conducted on adults, while limited data are available on children.

The purpose of this prospective study was to evaluate the sensitivity, reproducibility and the acceptability of two commercially available devices utilizing different techniques in children.

Methods

Study Population

In this prospective trial composed of two different parts, male and female subjects, with or without allergy and aged 6–16 years were recruited. Subjects were from the outpatient clinic of the department and had mild allergic rhinitis and/or asthma and/or atopic dermatitis. In the first and second parts of the study, 22 and 20 subjects were included, respectively. Subjects with systemic diseases, dermatographism, severe atopic dermatitis or asthma were excluded, and antihistamines were withheld for 1 week prior to study.

Study Design

We performed 2 complementary studies to test the sensitivity, reproducibility and acceptability of a commercially available device (Stallerpoint, Antony, France) with different techniques in children. The difference between the 2 parts was the method of histamine/saline application. In the first part, histamine/saline was put as a drop by the use of a vial (V) and in the second part it was transferred from a well with the aid of the test device (W). In both parts, an ALK Lancet device served as the reference, and here histamine/saline was put down as a drop by a vial.

Part 1. We used the Stallerpoint device (Stallergenes, Antony, France) with each patient as follows. (1) Drop and apply vertical pressure (Stallerpoint-VP). (2) Drop and apply vertical pressure, followed by 90° clockwise rotation (Stallerpoint-VC). (3) Drop and apply vertical pressure with 90° clockwise and counter-clockwise rotations (Stallerpoint-VCC). (4) Submerge device in a well containing histamine/saline before pricking (Stallerpoint-WP).

Part 2. Stallerpoint device was tested by taking the device from a histamine/saline containing-well and then applying pressure with 3 different techniques (fig. 1). (1) Apply vertical pressure (Stallerpoint-WP). (2) Apply vertical pressure with 90° clockwise rotation (Stallerpoint-WC). (3) Apply vertical pressure with 90° clockwise and counter-clockwise rotations (Stallerpoint-WCC).

During the SPT procedures, pain was assessed in each part of the study immediately after histamine/saline application by using the Wong-Baker FACES Pain Rating Scale [10]. This scale ranges from 0 to 10, where 0 indicates no pain and 10 represents the worst pain imaginable.

Using the ALK Lancet and Stallerpoint-WC techniques, the time for performing a set of 12 pricks was monitored and the number of pricks was measured, using 0.4 ml of antigen.



Fig. 1. Stallerpoint devices resting in the well plate.

Study Procedures

Two physicians performed tests on the backs of the patients in a rotating manner with a spacing of at least 20 mm between each test site. Before the study, the physicians underwent an evaluation and a 'coefficient of variation' (CV) of <20% was attained (BB 9.4% and UMS 8.9%) [11]. All subjects were tested 4 times for each technique with histamine (10 mg/ml of histamine phosphate) and sterile saline solutions. The total number of SPTs per subject was 40 for part 1 and 32 for part 2 of the study. The physician applying the pricks was blind to the content of the test solution. The second physician performing the readings was blinded to the content of the solution as well as the technique/device. The diameters of the wheal and flare reactions were recorded 15 min after application. The longest and orthogonal diameters were measured, and the mean diameter was used for analysis.

This study was approved by the local ethics committee of the Hacettepe University Faculty of Medicine, and informed consent was obtained from both patients and their parents.

Statistical Analysis

Instruments and the techniques used for performing the tests were evaluated in terms of sensitivity, reproducibility and acceptability. A standard deviation of 2 mm was estimated between the different techniques and devices according to the literature [8]. As 5 different techniques in 2 separate devices were tested, a total of 10 pairwise comparisons were possible. A type I error was set at 0.005 using the Bonferroni correction. A sample size of 18 subjects was determined to have 80% power to detect a difference of 2 mm diameter in the wheal reaction. Sensitivity of the techniques was calculated using a positive threshold of 3 mm for the mean diameter of each wheal and found as equal to the ratio between the number of true positive tests and the sum of true positive and false negative ones. To test the reproducibility of the results in the same patient and the results of the same technique from one patient to another,

Table 1. Outcome measures of different techniques (part 1)

	Histamine wheal, mean $\pm$ SD	Histamine flare, mean $\pm$ SD	CV % inpatient	CV % outpatient	Sensitivity % (95% CI)	Specificity % (95% CI)	Pain median (IQR)
Stallerpoint-VP	3.4 $\pm$ 0.8	15.5 $\pm$ 6.3	22.4	33.8	76.1	100	2.0 (2.0–2.5)
Stallerpoint-VC	4.8 $\pm$ 1.3	22.3 $\pm$ 5.3	15.0	30.6	96.6	100	2.0 (2.0–4.0)
Stallerpoint-VCC	4.8 $\pm$ 1.3	23.2 $\pm$ 4.9	18.9	32.9	95.5	98.9	4.0 (2.0–4.0)
Stallerpoint-WP	2.6 $\pm$ 1.2	12.4 $\pm$ 7.1	48.5	55.1	46.6	100	2.0 (2.0–4.0)
ALK Lancet	3.8 $\pm$ 0.6	18.8 $\pm$ 4.8	15.4	22.8	93.2	100	2.0 (2.0–4.0)
p	<0.001	<0.001					

inpatient and outpatient CV were calculated. The CV was defined as the standard deviation divided by the average of the mean diameters. To analyze the sensitivity and specificity, a true positive result was acknowledged as a histamine wheal of ≥ 3 mm and a negative result was a 0.9% saline wheal of <3 mm. As the histamine measurements were distributed normally (the Shapiro Wilk test), the differences in wheal diameter between techniques and devices were measured by a repeated-measure ANOVA test. Pain scores were analyzed by the Friedman test followed by the Dunn post-tests.

Results

Part 1

Twenty-two children with a median (interquartile) age of 9.7 (7.5–13.9) years were included in this part of the study. Sensitivity and specificity of the techniques along with the size of the reactions were summarized in table 1.

Wheal and Flare Reactions

There were significant differences among the devices and techniques for the size of the reaction diameters to histamine. The mean ($\pm$ standard deviation) ranged from 2.6 $\pm$ 1.2 mm to 4.8 $\pm$ 1.3 mm for wheals ($p < 0.001$) and from 12.4 $\pm$ 7.1 mm to 23.2 $\pm$ 4.9 mm for flares ($p < 0.001$) (fig. 2). Stallerpoint-WP technique gave the smallest wheal sizes compared to the other techniques. In addition, the VC and VCC techniques resulted in larger reaction sizes. The rate of false negatives in the Stallerpoint-VP, VC, VCC and WP techniques and ALK Lancet were 23.86, 3.41, 4.55, 53.41 and 6.82%, respectively.

Sensitivity of Different Devices and Techniques

The sensitivity of Stallerpoint-VC (96.6%), Stallerpoint-VCC (95.5%) and ALK Lancet (93.2%) were superior ($p < 0.001$) to the other techniques (Stallerpoint-VP and WP) and there were no differences between these techniques ($p < 0.001$). The Stallerpoint-WP and Staller-

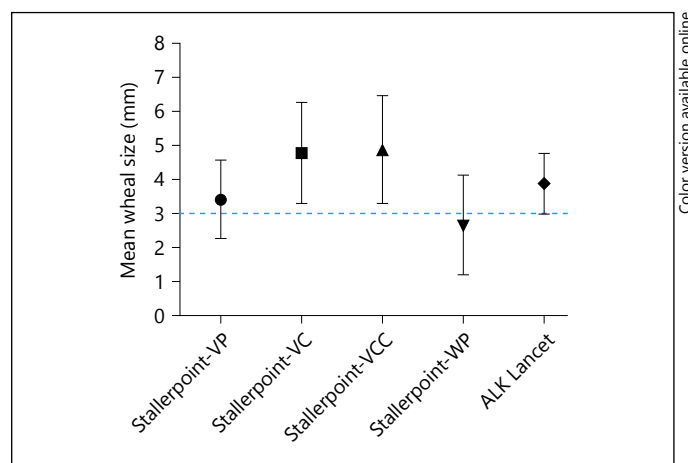


Fig. 2. Mean wheal sizes between different techniques (part 1). Error bars represent standard deviation.

point-VP techniques were less sensitive than the others ($p < 0.001$) and the Stallerpoint-WP was the worst technique ($p < 0.001$).

Reproducibility of SPTs

Comparisons of inpatient CV were best in the Stallerpoint-VC and ALK Lancet techniques (15.0 and 15.4%, respectively) and were worst in the Stallerpoint-WP (48.5%) ($p = 0.002$). Outpatient CV ranged between 22.8% (ALK Lancet) and 55.1% (Stallerpoint-WP) ($p < 0.001$). False positive reactions were only detected in the Stallerpoint-VCC technique (table 1).

Part 2

Twenty children with the median (interquartile) age of 11.6 (8.6–13.2) years were included in the second part of the study. The results are summarized in table 2. The sensitivity of the Stallerpoint-WC and WCC techniques as

Table 2. Outcome measures of different techniques (part 2)

	Histamine wheal, mean $\pm$ SD	Histamine flare, mean $\pm$ SD	CV % inpatient	CV % outpatient	Sensitivity % (95% CI)	Specificity % (95% CI)	Pain median (IQR)
Stallerpoint-WP	1.8 $\pm$ 1.0	8.6 $\pm$ 6.7	45.5	58.8	28.7	100	2.0 (2.0-2.5)
Stallerpoint-WC	4.8 $\pm$ 1.2	26.8 $\pm$ 3.9	16.8	25.6	98.8	100	2.0 (2.0-4.0)
Stallerpoint-WCC	4.7 $\pm$ 1.0	27.6 $\pm$ 2.8	16.3	22.0	97.5	99.0	4.0 (2.0-4.0)
ALK Lancet	4.0 $\pm$ 0.9	22.2 $\pm$ 4.5	9.0	22.8	98.8	100	2.0 (2.0-4.0)
p	<0.001	<0.001					

Table 3. Comparison of 2 techniques in terms of time and allergen cost (n = 5)

	ALK Lancet	Stallerpoint- WC
Time, s (for 12 pricks in standard panel)	150 $\pm$ 7	60 $\pm$ 3
Number of pricks (0.4 ml extract)	42 $\pm$ 4	96 $\pm$ 6

well as the ALK Lancet technique were found to be similar, but the Stallerpoint-WP revealed a much lower result ($p < 0.001$) (fig. 3). Wheal diameters varied among the different techniques ($p < 0.001$). The differences between sensitivity in the ALK Lancet technique versus the Stallerpoint-WP were significant ($p < 0.001$). In the ALK Lancet versus the Stallerpoint-WC ($p = 0.018$) and in the ALK Lancet vs. Stallerpoint-WCC they were not significant ($p = 0.024$). The Stallerpoint-WC and WCC techniques revealed similar results whereas the Stallerpoint-WP yielded the lowest measurements in wheal diameter. Comparisons of inpatient CV were best in the ALK Lancet technique (9.0%) and were worst in the Stallerpoint-WP technique (45.5%) ($p < 0.001$). Outpatient CV was similar in the ALK Lancet, Stallerpoint-WC and Stallerpoint-WCC techniques and was different from the Stallerpoint-WP technique, ranging from 22.0, 22.8 and 25.6% to 58.8%, respectively. Comparison of the ALK Lancet and Stallerpoint-WC in terms of time and allergen cost revealed the superiority of the Stallerpoint-WC technique (table 3).

Acceptability

Assessment of the pain induced by each of the techniques is presented in tables 1 and 2. All of the techniques revealed similar results, with the exception of the Stallerpoint-WCC and WCC techniques. The children perceived

**Fig. 3.** Performance of the different techniques (part 2).

these techniques as being more painful than the others ($p < 0.001$).

After completion of the study, a further 2 groups were allocated in order to investigate the possible differences between the results of adults and children and to determine the effect of severe atopic disease on skin response. The adult group included 14 subjects and the group with severe atopic disease included 15 children with moderate/severe asthma and allergic rhinitis sensitized to *Phleum pratense*. In these groups, the techniques of ALK Lancet, Stallerpoint-WC and Stallerpoint-WP were performed. In the adults, there was a mean wheal size of <3 mm with the histamine response with the Stallerpoint-WP technique, which was smaller than in the children. When we compared the histamine responses of children in group 1 (part 1) with those of children with severe

atopic disease, there was no difference (online suppl. table 1; for all online suppl. material, see www.karger.com/doi/10.1159/000350788). Furthermore, allergen-induced wheal responses were as reliable as histamine-induced reactions (online suppl. table 2).

Discussion

In this study, we found that the technique used in SPT was as important as the testing device used in children. In the matter of a reliable technique selection, the results of the ALK Lancet and Stallerpoint devices are comparable. Sensitivities of the Stallerpoint-VC, Stallerpoint-VCC and ALK Lancet techniques were superior to the Stallerpoint-VP and Stallerpoint-WP techniques. Intrapatient CV values were similar between the different techniques, with the exception of the Stallerpoint-WP. Interpatient CV ranged between 22.8 and 55.1%, with the Stallerpoint-WP technique performing the worst. In the second part of the study, we tested whether the low performance of the Stallerpoint-WP technique is the result of the histamine-taking method. The Stallerpoint-WC, WCC and ALK Lancet techniques yielded high sensitivities (all >95%), whereas the sensitivity of the Stallerpoint-WP (28.7%) was very low. False positive reactions were detected in the Stallerpoint-VCC and WCC techniques, which were also the least-tolerated methods by the patients. The results from the second part of the study showed that the histamine application technique, and not the method by which histamine is taken, is important to obtaining positive results.

In our pediatric allergy department, we have performed SPTs with the Stallerpoint instrument (with 90° clockwise rotation) for more than 5 years [12]. Following the published article by Masse et al. [9] that questioned the value of the Stallerpoint device in adult patients, we organized this study to expand the findings to the use of the device in children. We compared our results with the ALK Lancet device as it is commonly used worldwide and was also used in the multicenter study of The Global Allergy and Asthma European Network (GA2LEN) published in 2009 [13].

To accurately assess the precision and reproducibility of the devices and techniques, CVs (inpatient and interpatient) were calculated. Of the techniques, the ALK Lancet and Stallerpoint-VC achieved the best results, whereas Stallerpoint-WP elicited the highest inpatient and interpatient variability. The low precision and reproducibility of the Stallerpoint-WP technique appear to

make this technique inadequate for the diagnosis of immediate hypersensitivity. After completion of the study, we included another group to test whether these results can be extrapolated to the allergen as well, and showed that it is the case (online suppl. table 2).

In contrast to the adult study by Masse et al. [9], sensitivities of the Stallerpoint-VC and WC techniques were high in our study. Although the difference between these studies may depend on the other factors, e.g. the performance of the technicians or the potency of the solution, we speculate that these different results may be related to the relative skin thickness of adults and children. Children's skin is thinner and more fragile, so in adults, as a consequence, the penetration of the device may not be sufficient to induce reactions. This speculation is partly supported by our finding of a (histamine-induced) smaller wheal response in the adult group than in the children when using the Stallerpoint-VP technique (online suppl. table 1). However, it is interesting to see that Stallerpoint-VC produced reliable results in adults as in children, in contrast to the study by Masse et al. [9].

Contrary to expectations, SPT is not seen as a painful procedure in children, except when using the Stallerpoint-VCC and WCC techniques. As values <3.0 are considered mild pain in the Wong-Baker FACES Pain Rating Scale, the VCC and WCC techniques were less tolerable than the others, and had a median value of 4.0. The difference in pain perceived by children may be explained by the higher pressure that is exerted when using the Stallerpoint-VCC technique. Furthermore, Nelson et al. [4] observed that techniques producing larger wheals with histamine were prone to induce false-positive reactions and caused a parallel increase in patient discomfort. However, Carr et al. [7] and Masse et al. [9] have demonstrated an opposite relationship between the size of the reactions and the degree of pain. In our study, we were unable to clarify a relationship between wheal size and patient discomfort. Although the Stallerpoint-VC and VCC techniques produced larger wheal sizes, the Stallerpoint-VC technique was found more tolerable than the VCC technique.

As the Stallerpoint-WP technique was found to be the least precise technique, we conducted the second part of the study to elucidate whether this arose from inserting the device perpendicular to the skin through the drop or from taking the device from the well plate. ALK Lancet, Stallerpoint-WC and WCC techniques have demonstrated their superiority with higher sensitivity and reproducibility than Stallerpoint-WP. In order to perform SPT with a device yielding high sensitivity and reproducibility as well as minimal patient discomfort, we suggest that the

ALK Lancet, Stallerpoint-VC and Stallerpoint-WC techniques are comparable and can be used confidently in clinical practice.

Moreover, the Stallerpoint-WC technique confers some advantages over the ALK Lancet and Stallerpoint-VC. First, it reduces the cost of allergen. The tests can be applied to more than double the patients with the same amount of extract. Secondly, to submerge the instruments into the well plate before use is a timesaving procedure. By removing the use of bottles, the technicians are enabled to perform SPT over a shorter time. In daily practice, our technicians perform 12 pricks per set in each patient by the Stallerpoint-WC technique in approximately 1 min while the drop-and-apply method with the ALK Lancet technique takes approximately 2 min 30 s for the same application (table 3). Another consideration is that the Stallerpoint-WC technique prevents droplets from running together throughout the SPT procedure. These features are important, especially for physicians who work in pediatrics.

We performed these techniques under appropriate conditions. To confirm proficiency in skin testing, a CV of <30% in the USA and of <20% in Europe is required [11]. Our physicians underwent an evaluation and a CV

of <20% was attained. We recommend that all technicians should perform the same testing in their own clinics.

In conclusion, when performing prick testing, the technique is just as important as the device chosen. Therefore, optimizing techniques is essential for confirming the clinical immediate hypersensitivity reactions. When we considered the sensitivity and acceptability of the devices, the Stallerpoint-VC and WC techniques performed best in our studies. However, the Stallerpoint device used to set up the test devices in wells before they are used seems to be the more convenient and clinically useful method in children.

Acknowledgements

We are indebted to the Adult Allergy Department for their invaluable collaboration.

Disclosure Statement

This study was designed and financed by the corresponding author and conducted by the authors; there was no funding by any company.

References

- 1 Li JT, Lockey RF, Bernstein IL, Portnoy JM, Nicklas RA: Allergen immunotherapy: a practice parameter. *Ann Allergy Asthma Immunol* 2003;90(suppl):1–40.
- 2 The European Academy of Allergology and Clinical Immunology: Position paper: immunotherapy. *Allergy* 1993;48(suppl 14):7–35.
- 3 Adinoff AD, Rosloniec DM, McCall LI, Nelson HS: A comparison of six epicutaneous devices in the performance of immediate hypersensitivity skin testing. *J Allergy Clin Immunol* 1989;84:168–174.
- 4 Nelson HS, Rosloniec DM, McCall LI, Ikle D: Comparative performance of five commercial prick skin test devices. *J Allergy Clin Immunol* 1993;92:750–756.
- 5 Nelson HS, Lahr J, Buchmeier A, McCormick D: Evaluation of devices for skin prick testing. *J Allergy Clin Immunol* 1998;101:153–156.
- 6 Demoly P, Bousquet J, Manderscheid JC, Dreborg S, Dhivert H, Michel FB: Precision of skin prick and puncture tests with nine methods. *J Allergy Clin Immunol* 1991;88:758–762.
- 7 Carr WW, Martin B, Howard RS, Cox L, Borish L, Immunotherapy Committee of the American Academy of Allergy, Asthma and Immunology: Comparison of test devices for skin prick testing. *J Allergy Clin Immunol* 2005;116:341–346.
- 8 Yoon IK, Martin BL, Carr WW, Immunotherapy Committee of the American Academy of Allergy, Asthma, and Immunology: A comparison of two single-headed and two multi-headed allergen skin test devices. *Allergy Asthma Proc* 2006;27:473–478.
- 9 Masse MS, Granger Vallée A, Chiriac A, Dhivert-Donnadieu H, Bousquet-Rouanet L, Bousquet PJ, Demoly P: Comparison of five techniques of skin prick tests used routinely in Europe. *Allergy* 2011;66:1415–1419.
- 10 Jacob E: Pain assessment and management in children; in: Hockenberry MJ, Wilson D (eds): *Wong's Essentials of Pediatric Nursing*, ed 8. St Louis, Mosby, 2009, p 162.
- 11 Bernstein IL, Li JT, Bernstein DI, Hamilton R, Spector SL, Tan R, et al, American Academy of Allergy, Asthma and Immunology, American College of Allergy, Asthma and Immunology: Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol* 2008;100(3 suppl 3):S1–S148.
- 12 Şahiner UM, Civelek E, Yavuz ST, Büyüktiryaki AB, Tuncer A, Şekerel BE: Skin prick testing to aeroallergen extracts: what is the optimal panel in children and adolescents in Turkey? *Int Arch Allergy Immunol* 2012;157:391–398.
- 13 Bousquet J, Heinzerling L, Bachert C, Papadopoulos NG, Bousquet PJ, Burney PG, et al, Global Allergy and Asthma European Network: Allergic rhinitis and its impact on asthma. Practical guide to skin prick tests in allergy to aeroallergens. *Allergy* 2012;67:18–24.

Supplementary Table 1. Wheal mean sizes of study subjects.

	Wheal mean size				p ¹	p ²	p ³	p ⁴
	Group 1	Children with severe atopic disease		Adult				
	(part 1)							
	Histamine	Histamine	Phleum	Histamine				
	mean ± SD	mean ± SD	mean ± SD	mean ± SD				
	(n=22)	(n=15)		(n=14)				
Stallerpoint-P	3.4 ± 0.8	3.1 ± 1.6	5.1 ± 4.0	2.5 ± 1.3	>0.05	0.05	>0.05	0.015
Stallerpoint-C	4.8 ± 1.3	5.5 ± 1.5	10.6 ± 3.8	4.8 ± 1.9	>0.05	>0.05	<0.001	<0.001
ALK Lancet	3.8 ± 0.6	5.0 ± 1.8	9.6 ± 3.5	5.2 ± 1.1	0.007	0.004	<0.001	<0.001

p¹ : Group 1 vs severe atopic children's histamine wheal sizes

p²: Group 1vs. adults' histamine wheal sizes

p³ : Group 1's histamine vs. severe atopic children's Phleum wheal sizes

p⁴: Severe atopic children's histamine and *Phleum* wheal sizes

Supplementary Table 2. Outcome measures of different techniques in children with allergic asthma (n=15)

	Wheal, mean $\pm$ SD			Histamine			Phleum		
	Histamine	Phleum	p	CV % inpatient	CV % interpatient	Sensitivity % (95% CI)	CV % inpatient	CV % interpatient	Sensitivity % (95% CI)
Stallerpoint-VP	3.1 $\pm$ 1.6	5.1 $\pm$ 4.0	0.015	68.5	72.8	53.3	51.5	96.7	56.7
Stallerpoint-VC	5.5 $\pm$ 1.5	10.6 $\pm$ 3.8	<0.001	18.9	32.3	96.3	22.8	41.3	99.1
ALK lancet	5.0 $\pm$ 1.8	9.6 $\pm$ 3.5	<0.001	14.9	38.7	99.0	23.2	42.8	98.3
p	<0.001	0.004							