

LETTER TO THE EDITOR

PERFORMANCES OF AN IMPROVED DEVICE FOR SKIN PRICK TESTS

D. CAIMMI, M.S. MASSE, A.M. CHIRIAC and P. DEMOLY

Allergy Department and INSERM U657, Hôpital Arnaud de Villeneuve, University Hospital of Montpellier, Montpellier, France

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Every day allergists deal with skin prick testing. Following a recent paper showing that the intravenous needle and the metal lancets are superior to the Stallerpoint® plastic lancet, the manufacturer has improved the device to reach better standards in terms of sensitivity, intra-patient reproducibility and inter-patient reproducibility, as demonstrated on 10 adult patients, comparing the results with skin tests performed with the intravenous needle. We evaluated the sensitivity of the device by calculating the ratio between the number of true-positive tests and the sum of true-positive and false-negative tests. To assess the reproducibility of the test, we calculated the interpatient and the intrapatient coefficient of variation between the mean diameters of the papules induced by the different techniques. The improved device shows performances similar to those obtained with the intravenous needle.

Skin prick testing is the standard method to assess IgE-mediated sensitization to allergens and therefore to identify an IgE-mediated response (1). The relevance of skin prick testing should then be interpreted on the basis of the patient's clinical history (2). Every specialist is familiar with the technique and with the devices that are available, and skin testing is the basis of the allergists' work. In order to perform a skin prick test (SPT), clinicians introduce a needle or a lancet into the upper layers of the skin through a drop of allergen extract and gently lift the epidermis up (3). Even though these tests are standardized, a significant variability has been reported among commercially available devices for SPTs (4, 5). In 2011, Masse et al. published a paper in which they compared 5 different techniques routinely used by allergists to perform skin prick tests (6). The devices tested included an intra-venous (i.v.) 23G needle, commercially available metal lancets, and the Stallerpoint® plastic lancet (Stallergenes,

Antony, France). In terms of sensitivity, intra-patient reproducibility and inter-patient reproducibility, the i.v. needle and the metal lancets were shown to be superior to the Stallerpoint® plastic lancet (6). Since the publication of the paper, the manufacturer initiated technical work on the plastic device to seek improvement of the robustness of the device. We were able to test a new generation of Stallerpoint® plastic lancet, presenting some differences compared to the previous one. One of the main changes applied to the device was the change in the point length (1.4 mm vs the previous 1.3 mm).

In order to assess the sensitivity and reproducibility of the different techniques of SPT in the same patient, we limited our selection to adults over 18 years of age so as not to cause such inconvenience in children. In addition, patients had to have ceased taking antihistaminic drugs at least 8 days prior to the experiment and had to be exempt of dermographism and needle phobia. All patients

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Mailing address: Dr Davide Caimmi,
Hôpital Arnaud de Villeneuve,
University Hospital of Montpellier,
371, Avenue du Doyen Gaston Giraud,
34295 Montpellier Cedex 5, France
Tel.: +33 467336127 Fax: +33 467042708
e-mail: davide.caimmi@gmail.com

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Table I. Skin prick test results: sensitivities, mean wheal size and reproducibility with the different instruments.

Instrument	True positives (n)	False negatives (n)	Sensitivity (%)	Mean wheal size, mm		Coefficient of variation, %	
				Median	25th-75th percentiles	Inpatient	Interpatient
i.v. needle (H)	40	0	100%	5.00	4.7-5.1	15.03	13.06
New Stallerpoint® (H)	37	3	92.5%	5.06	5.0-6.1	25.08	22.00
New Stallerpoint® (PC)	38	2	95%	5.02	4.5-5.5	19.09	12.09

H: histamine chlorhydrate at 10 mg/ml; CP: 9% codeine phosphate

provided their free and informed consent after being taught about the risks and benefits of the study by the investigator. In total, 10 adults were included in this part of the study. We compared the reproducibility and sensitivity of two different techniques to perform SPTs: the new Stallerpoint® plastic lancet, and the 23G i.v. needle 1" (BD Microlance™, Fraga, Spain). As positive control, we used both Histamine Chlorhydrate at 10mg/ml (Stallergenes SA) for both techniques, and codeine phosphate (CP) 9% for the new Stallerpoint® plastic lancet. We did not repeat CP tests for the i.v. needle, since this positive control had already shown good results in the previous study (6) and because it is not commercialized worldwide. As for the plastic lancet, taking into account our previous results (6), we crossed the drop being perpendicular to the skin and applied moderate pressure (corresponding to a skin depression of about 2–3 mm) and we then rotated by 90° the instrument axis while maintaining the depression of the skin, as now advised by the manufacturer. In total, we performed four SPTs to histamine chlorhydrate for each technique in every subject (8 histamine SPTs per subject) and four SPTs per subject to 9% CP with the plastic lancet. All tests were performed on the patients' forearms by one experienced investigator, taking care to distance each test by at least 3 cm. A different sterile instrument was used for each prick test. The drops were wiped off 1 min after the prick test was performed, and the wheals were measured after a period of 15 minutes by the same technician who had previously performed the tests. In order to do this, each test was first encircled with a pen and then transferred to a permanent record with transparent tape. We measured the mean diameter as previously described (6). To calculate the sensitivity

of each technique, we used a positive threshold of 3 mm for the mean diameter of each wheal. The results of the i.v. needle were considered as the reference, according to the previously published paper by Masse et al. (6). Sensitivity was calculated as equal to the ratio between the number of true-positive tests and the sum of true-positive and false-negative tests. To assess reproducibility in a same patient (inpatient reproducibility), we calculated the coefficient of variation (CV) as previously described (6). Also, we evaluated the interpatient reproducibility. We used non-parametric descriptive statistics (median) because of the non-normal distribution of the data.

In terms of sensitivity, the IV needle, if compared with our previous results, is still the most sensitive instrument (100% sensitivity) (Table I). The mean wheal sizes (average of the four mean diameters) induced by each technique are presented in Table I. When testing patients with the histamine solution, the i.v. needle (median 5.0 mm) induced smaller wheals than those obtained with the new Stallerpoint® plastic lancet. The improved instrument showed an acceptable variability between patients, as shown in Table I. As for the inpatient reproducibility, the i.v. needle gave the best median CV ($CV_{\text{inpatient}}$ 15.3%), followed by the new Stallerpoint® plastic lancet with CP (19.9%). In regard to the interpatient reproducibility, the new Stallerpoint® plastic lancet with CP gave the best median CV ($CV_{\text{interpatient}}$ 12.9%), followed by the i.v. needle (13.6%). The results obtained with the new Stallerpoint® plastic lancet, using CP as positive control, appear slightly different from those obtained with H, although the study was not powered to analyze such a difference.

In conclusions, the i.v. needle confirmed correct

performances for skin prick testing, but the improved Stallerpoint® plastic lancet showed similarly correct results, as well as improved results if compared with the old device.

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