

Table IV. Characteristics of the cases with negative skin tests and positive Phadiatop

Patient	Total IgE (kU/L)	Specific IgE (kU/L)	Clinical history of allergy	Positive allergen in <i>Prick</i>
FCF	79	Grasses (5)	Negative	–
IPD	18	Negative	Negative	–
DGS	274	Cat (1, 2)	Positive	–
PGG	81	<i>D pt</i> (0,7)	Positive	–
PGT	10	Negative	Positive	–
CIP	152	<i>D pt</i> (18)	Positive	–
DME	27	Negative	Negative	–

At the end of the past decade, Businco *et al.*² compared Phadiatop and a number of diagnostic tools including the anamnesis, total and specific IgE and skin tests in a paediatric population. They used a panel of five allergens in intradermal tests, and achieved 87% sensitivity with 100% specificity.

The analysis of the discordances between the two tests reveals that most of the cases correspond to the use of allergen panels that were not adequate to the local aerobiological characteristics. This is particularly important in the case of monosensitized patients such as the ones with *Salsola* hypersensitivity in our own study. One patient with sensitization to hamster epithelium and two with sensitization to guinea pig epithelium were not detected by the habitual skin test panel, even though the data derived from the anamnesis caused us to extend the investigation. Sensitization to *Alternaria* also appears to be problematic, particularly in monosensitized patients. Other investigators have also pointed out that the loss of sensitivity might be more perceptible in these patients, possibly because the amount of specific IgE that might bind to a single allergen which is not quantitatively well represented in the panel might be insufficient for later detection. All these disadvantages might possibly be solved if and when the panel of tested allergens is enlarged, and also through qualitative improvement of those already included in the panel, for instance *Alternaria*.

We conclude that Phadiatop is an effective method for the detection of patient sensitization to a number of common pneumoallergens. Nevertheless, the allergen panel included in the kit requires the most rigorous possible adequation to the local

aerobiological characteristics, diversifying as required the actual allergen contents of the kits.

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Practical usefulness of Phadiatop

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UNICAP-PHADIATOP is an *in vitro* test based on the IMMUNOCAP technology (fluoro-enzyme-

mo-immunoassay) for the determination of various specific IgE antibodies to inhalant and alimentary allergens in human serum and plasma.

There are at present two different presentations available. The first one to be introduced, UNICAP-PHADIATOP, is a balanced pneumoallergen mixture. The second one, UNICAP-fx5, is the result of a balanced mixture of five food allergens (peanut, milk, egg, wheat and fish).

A positive result in the test demonstrates the presence of specific IgE antibodies to one or more of the allergens included in the mixture. A negative result is indicative of the absence of specific IgE antibodies.

The technique has been validated by sensitivity and specificity assays.

The first clinical study of Phadiatop pneumoallergens was carried out on 894 consecutive patients, and demonstrated 91% sensitivity and 92% specificity. The first study of the UNICAP-fx5 variant yielded 89% sensitivity and 96% specificity. If these data should be extrapolable to our own population, Phadiatop would represent an absolutely interesting screening technique¹⁻⁵.

In order to assess the efficacy of Phadiatop for the identification of allergic conditions in patients with chronic respiratory symptoms, we designed a comparative study in which the "gold standard" was the result of the complete allergological study.

The estimated required size of the sample, considering a population of 500,000 inhabitants and an estimated 20% prevalence of atopy, was 1500 patients in consecutive sampling.

All the patients referred to our Service for assessment of possible respiratory allergy between June 1st 1997 and July 31st 1998 were included in the study.

The participating investigators were four specialists in Allergology with an experience in habitual activity in clinical Allergology ranging between 8 and 16 years. A protocolised clinical procedure was used in order to ensure comparability.

As already stated, the "gold standard" used in this study was the result of the complete allergological investigation as determined by the specialist who studied that particular patient.

Skin prick tests were performed in all cases with our standard allergen panel, together with total IgE quantitation, specific IgE determination (*Phleum pratense* in those patients with seasonal

symptoms, and *D. pteronyssinus* in those with perennial symptoms) and the UNICAP-Phadiatop determination.

Up to the time of this presentation, 1064 patients have completed the study protocol. Fifty per cent of these patients are males and 36.2% are children, and their mean age is 24 years.

As expected in our geographic environment, 60% of the allergic patients were sensitized to mites, 15% to grass pollens, 8% to moulds, 3% to animal epithelia and 11% evidenced multiple sensitizations. No allergens responsible for the respiratory condition could be detected in 37% of our sample.

The Phadiatop technique has shown itself to be highly useful in discriminating respiratory allergy, with sensitivity and specificity in excess of 90% regardless of the patients' age and of the severity of the respiratory condition.

The statistical analysis confirms that Phadiatop is a completely different technique from that of total IgE quantitation; it shows 27% discordance, and must be considered to be highly useful for inclusion in referral protocols for cases of suspected respiratory allergy.

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