Study of Tolerance of the Stheborex in Patients with Pollen Allergy

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The term pollen allergy covers the totality of pathological processes that occur when pollen grains come into contact with the conjunctival and respiratory mucosa of specifically sensitized individuals. But what happens if the contact takes place with a different mucosal surface, such as that of the digestive tract?

This is the question that one is entitled to ask in relation to the drug STHENOREX, an appetite-stimulant drug composed of water-soluble and lipid-soluble extracts of pollens, comprising:

- 2 species of tree pollen: pine and alder.
- 4 species of grass pollen, viz:
  2 cerals: rye and maize, and
  2 species of hay-grasses, timothy and cocksfoot.

These extracts are contained in a 'gelule' which only releases the active compounds contained in it in the presence of gastric juice.

Research carried out several years ago by Madame VAN CAMPO, Director of Research at CARS, demonstrated the presence of numerous pollens in ordinary white bread and rye bread.

Thus:

- in 18g of ordinary white bread she found 364 grains of all kinds of pollens, representing, 20 grains of pollen per gram of bread, of which 17 were grains of cereal pollen (table A);
- in 10g of crumb of rye bread, she found 701 grains of pollen, or 70 grains per gram, of which 25 were grains of cereal pollen (table B).

Now individuals who suffer from typical pollen allergy eat bread without thereby aggravating their symptoms.

It is therefore justifiable to expect that pollen that is ingested and therefore digested, undergoes such a degree of chemical breakdown that it loses all capacity of provoking allergic reactions on the digestive mucosa.

This hypothesis, in the particular case of STHENOREX, has been completely confirmed by the clinical trial carried out by Dr. Garcelon.

We have made a search for clinical sensitivity to STHENOREX in patients consulting us for spasmodic coryza, conjunctivitis or seasonal asthma (in May, June or July), provoked by allergy to a variety of pollens.

These symptoms were present individually or in various combinations, in a total of 28 patients.

A gelule of STHENOREX contains:

- Water-soluble pollen extract 120mg
- Lipid-soluble pollen extract 6mg
- Base: Q.S.P. one gelule
- Sulphurous anhydride 1g p. 1000

The composition of pollens contained in STHENOREX is as follows:

- PINE (Pinus montana)
- ALDER (Alnus glutinosa)
- RYE (Secale oereale)
- MAIZE (Zea mais)
- TIMOTHY (Phleum pratense)
- COCKSFOOT (Dactylis glomerata)

The 28 patients studied were distributed as follows:

- 18 males, mean age 26 (range 9 to 51),
- 10 females, mean age 25 years (range 9 to 40).

This confirms that pollen allergy is most commonly found amongst young people.

Pollen allergy can be objectively demonstrated by skin tests carried out with a control solution and concentrated extracts prepared by the Stallergenes laboratory:

- Trees (particularly group II).
- Grasses (12 fodder grasses and 3 cereals),
- Weeds.

A number of observations were carried out using a test based on a concentrated rye-pollen extract prepared by the Pasteur Institute. In addition, one test was systematically carried out using STHENOREX powder diluted in one drop of 0.1 N sodium bicarbonate.

EXPERIMENTAL PROTOCOL

Once the diagnosis of pollen allergy had been made and skin sensitivity to one or more groups of pollens (including the dry extract of STHENOREX) had been demonstrated, the first stage of the clinical trial comprised the oral administration of one gelule of STHENOREX. The patient remained under medical supervision for three hours, so that any immediate-type allergic reaction could be demonstrated.

Once this stage had been passed uneventfully, the patient took a further four gelules daily for one week, this being the usual dosage of the drug. If no reaction was noted, treatment was re-started 15 or 30 days later, at the same dosage, so as to investigate any possible antigenicity of the product.

Finally, when the preceding stages of the trial had passed without incident, STHENOREX was administered to sensitized subjects during the pollen season.

RESULTS

In 20 subjects tested, we made the following observations:

POSITIVE TESTS:

Fodder grasses: 27
(One subject being sensitized only to rye pollens),
Trees……..9
Cereals…….24
STHENOREX…..9

In 20 subjects who ingested STHENOREX as described above, no reaction was seen. Treatment was perfectly tolerated, even during the pollen season (June). However, patients who had been prescribed the drug for therapeutic purposes during this period (there were 5 of these) showed no improvement in their allergic symptoms from its use.

DISCUSSION

Apart from the sensitivity to rye pollens alone, seen in one of the subjects we studied, it is not surprising to note that allergy to grass pollens, which is a feature of most pollen allergy in the Paris region, was the predominant pattern, and was most commonly accompanied by sensitivity to cereal pollens, while the importance of tree pollens, though not negligible, was of minor degree.

The fact that one third of tests with STHENOREX powder gave a positive result demonstrates that despite the various modifications under-gone by the product in the course of manufacture (during which the allergenic polypeptide fractions are broken down to amino acids), the product retains its specific antigenic properties.

The degree of hypersensitivity varies from one individual to another, and it is worthy of note that seven of the eight patients who reacted to STHENOREX were those with the greatest number of positive reactions to the various groups of pollens studied.

Finally, even though cases of 'ultra-specificity' may be rare, (1 out of 28), certain patients may be sensitized to a single specific pollen, e.g. rye pollen, which is in fact contained in STHENOREX.

Other clinical and immunobiological investigations carried out in various hospitals have also shown analogous instances of cross-antigenicity between STHENOREX and various types of pollen.

CONCLUSION

At all events, clinical tolerance of STHENOREX is excellent. Its oral administration to a group of patients with pollen allergy did not give rise to any allergic reactions. The product is not itself a sensitizer, and while it contains amino acids of vegetable origin that are capable of giving rise to positive skin tests in certain subjects, it is likely that it rapidly loses all antigenic specificity during its absorption by the digestive tract.

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