

A NEW APPETITE STIMULANT DRUG BASED ON POLLEN EXTRACTS, WITH
NO HORMONAL OR ANTIHISTAMINE ACTION, IN A PAEDIATRIC PRACTICE

Report on 100 observations

G. Lepercq*

* - Paediatric service,
Hôpital Léon-Bernard,
91 - Limeil-Brévannes

The trial covered 101 children.

The overall indication for admission to the trial was low weight due either to chronic malnutrition or to recent weight loss.

The children's ages ranged from 4 months to 12 years and 3 months, with a mean of 3 years 7 months.

The sex distribution was approximately even: 53 boys and 48 girls.

Results were assessed on the basis of weight gain, with correction of any concomitant anorexia or asthenia.

In the absence of precisely known aetiologies such as malabsorption due to intestinal villous atrophy or pancreatic insufficiency, we are not able to give a precise metabolic cause for most of our cases of chronic malnutrition, nor for any weight gain registered (save that no cases of oedema were noted at any time).

Sthénorex** (** - Ozothine Laboratories) was given in one of two forms:
- gelules containing only 6 mg of lipid-soluble pollen extract and 120 mg of water-soluble extract;
- sachets (not yet marketed) containing a one-third greater dose of the active principles, with a flavoured vehicle.

The dose was one gelule morning and night for all ages, or of one sachet (above the age of 5) or half a sachet (below this age), morning and night; the duration of treatment in all cases was one month.

No clinical or laboratory evidence of intolerance was seen. 10 of the 101 children had a soft stool at some stage of treatment. This digestive disturbance was always slight, and recovered without any need for stopping treatment with Sthénorex or for giving symptomatic treatment.

Overall Results

Expressing results as follows: +++ = very good; ++ = good; + = average; 0 = negative, we can draw up the following table:

- Weight gain:

| | |
|-----|----|
| +++ | 28 |
| ++ | 42 |
| + | 14 |
| 0 | 17 |

The addendum to this paper gives a more detailed appreciation of the weight study.

- Anorexia: 87 anorexic children:

+++ 23
++ 41
+ 5
0 10

- Asthenia: 77 asthenic children:

+++ 13
++ 41
+ 5
0 18

Results in relation to clinical indications

When weight gain is related to clinical indication, a number of points can be noted:

- Chronic patients: 24 cases:

+++ 6
++ 7
+ 5
0 6

But a limited number of conditions account for almost all the very good and good results: malformations of the urinary tract, compensated chronic neurological disease, chronic blood disorders, nonspecific intestinal disease. These were present in 15 children, who showed the following results:

+++ 6
++ 6
+ 1
0 2

In contrast, children with cardiac disease, well-defined metabolic disorders (Lesch-Nyhan syndrome, mucoviscidosis, Schwochwan syndrome), numbering 9 in all, showed the following results:

+++ 1
++ 4
0 4

- Children convalescing from acute illness: 40 cases:

The overall results appear very good:

+++ 15
++ 20
+ 1
0 4

The nature of the infectious illness does not appear to play a part: there were 5 cases of measles, 3 of varicella, 11 of acute respiratory infection and 6 of viral hepatitis.

Results in viral hepatitis were as follows:

+++ 4
++ 1
0 1

- Malnutrition of unknown aetiology

This group comprised 37 children, characterised by the absence of any precisely known cause for their low weight.

Results in this group were:

+++ 7
++ 15
+ 8
0 7

These results appear relatively less good than in the preceding group, but the way in which cases were collected divides the children (37 in number) into two groups:

- cases of isolated low weight, noted in hospital: 18 cases
- cases of low weight noted at consultations in a child psychiatry clinic (i.e. with coexistent psychiatric or personality disorder): 19 cases.

The first group showed:

+++ 6
++ 7

The second group showed:

+++ 1
++ 8

General conclusions

The general conclusions relating to weight gain show that this highly acceptable and well-tolerated product has a very high degree of overall effectiveness, with over 74% of positive results.

The absence of any side-effects is particularly worthy of note, in comparison to other appetite stimulant drugs.

It is regrettable that no weight gain was seen in infants with cardiac disease (in whom weight gain is of vital importance), in our limited series of four children.

The efficacy of the product appears to be slightly less in low weight of unknown cause associated with personality disorder.

Observations

Serum proteins were measured before and after treatment in 40 children. Total serum protein rose by 3 g/l in 27 children (no account was taken of smaller increases).

We cannot offer any precise explanation for this observation.

In this context we must point out that a double-blind trial on 6 children receiving Sthénorex and 6 receiving placebo showed a rise in serum protein of 4.30 g/l (mean) in the treatment group, as compared to 0 in the controls.

The other results of the double-blind trial were as follows:

| | | |
|-----------------------------|----------------------|------------|
| Weight gain over one month: | treatment group..... | 0.561 kg |
| | controls..... | 0.080 kg |
| Appetite gain (+++) | treatment group..... | 4 out of 6 |
| by end of treatment: | controls..... | 0 |

Conclusion

Although the mode of action of the product cannot yet be rigorously explained in pharmacological terms, it appears to us to be widely effective, and - let us repeat - entirely free from side-effects, a point worth stressing in the context of appetite stimulant drugs.

The absence of side-effects and allergic reactions appears to us to eliminate any contra-indication to its use.

Addendum

Wherever possible, body weight was recorded during the month preceding or following the treatment month, or in all three. This depended on the duration of admission.

- 8 children showed a weight gain during the preceding month of 85 g (mean); during the treatment month their mean gain was 510 g.

- 8 children weighed during and after treatment showed:

mean weight gain during treatment: 450 g
mean weight gain after treatment: 220 g

- 15 children observed over 3 months showed:

mean weight gain during pre-treatment month: 190 g
mean weight gain during treatment month: 450 g
mean weight gain during post-treatment month: 190 g.

Naturally, in the case of infectious illnesses, the weighings of the pre-treatment month did not include the period of the acute illness itself.

All these figures, particularly the last set, suggest that the drug has a direct action, rather than that weight gain was due to convalescence or a change in diet alone.