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The treatment of chronic- obstructive bronchitis in children

**Prospan® Syrup for children: a tried and tested
product in a new form of administration -
results of a clinical test**

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The treatment of chronic-obstructive bronchitis in children

Prospan® Syrup for children: a tried and tested product in a new form of administration - results of a clinical test

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Prospan®, a bronchospasmolytic preparation based on extract of ivy, has been used for several decades in the treatment of inflammatory and obstructive infections of the airways - primarily because of its high degree of effectiveness, but also because of its excellent tolerance. It has been administered in the form of drops and suppositories. Wishing to find the optimum method of administering this popular medicine to children, the Engelhard company has developed a liquid form free of alcohol, sugar additives and colouring agents.

Important: high patient compliance in children

When selecting a suitable bronchospasmolytic preparation for the treatment of chronic-obstructive bronchitis, besides its effectiveness and tolerance, ease of administration is of special importance for children. The liquid form is particularly effective in improving patient compliance.

The objective of the present study was to test the effectiveness and tolerance of this new form of administration in children suffering from chronic-obstructive bronchitis. Patient compliance was also covered.

Patient selection and methods

In this single-centre clinical test 26 children - 13 girls, 13 boys - aged between 4 and 10 years were treated for four weeks with 1-2 teaspoonfuls of Prospan® Syrup four times a day.

Spirometric tests were carried out on the children at weekly intervals, and auscultatory findings noted on each occasion. Throughout the study the children or the persons looking after them were asked to keep a daily patient diary noting dyspnoea, frequency of coughing attacks and expectoration.

Age and body weight. The average age of the children was 6.4 years. The average height of the girls was 122 cm, that of the boys 126 cm. Average weight for both sexes was 24 kg. The nutritional condition of 80% of the patients was normal; three were described as obese, two as cachectic.

Clinical findings. In most cases the children had been suffering from chronic-obstructive bronchitis for about three years, but had been diagnosed as such only about a year earlier. As was to be expected, symptoms were concentrated in autumn and winter. When examined at the start of the test, most of the patients suffered 10 to 20 coughing fits per day, the intensity of coughing being predominantly described as moderate. Most

patients did not expectorate, the sputum of the 8 who did being described as glassy, clear or light in colour.

Previous treatment. 10 of the 26 patients (38.5%) had already received some form of treatment. Three had taken Spasmomucosolvan liquid, while Ambroxol liquid, Bricanyl elixier, Bronchoretard mite, Ditec aerosol, Fluimucil 200 in conjunction with Paediathrecin forte, Intal powder in inhalation capsules and Volmac 4 mg had each been given to one patient.

Physical examination and a study of case histories identified allergic diathesis in 5 children. No other children were suffering from any other illness, nor had they suffered from any serious illnesses in the past.

Results

Control examinations were carried out strictly as planned after each of the four weeks of treatment. The regime of 1-2 teaspoonfuls of Prospan® four times daily was also strictly adhered to. There were no problems of patient compliance. All 26 children completed the test as intended. Although 6 children contracted other illnesses during the study, none had to be withdrawn from it. It is particularly worthy of note that neither at the start of the study nor during it were any of the criteria for inclusion or exclusion breached. Where patients had been previously treated with other medicines, 14 days were allowed to ensure their complete elimination.

Swift alleviation of symptoms

Dyspnoea, coughing fits and expectoration, which are noted daily in the patients' diaries, were perceptibly alleviated. In most cases they either disappeared entirely during the course of the study or were significantly alleviated. In the overwhelming majority of patients the symptoms were either completely absent at the conclusion of

treatment or present only in an extremely mild form.

Dyspnoea: between days 1 and 28 of the study the Wilcoxon test gave a descriptive p-value of $p=0.028$.

Coughing frequency: this was so sharply reduced that the change was statistically significant ($p<0.01$).

Expectoration: there was an initial aggravation in the 8 patients who complained of it at the start of the study, but by the end of the study this symptom was present in only 3 of them. The explorative Wilcoxon test gave a descriptive p-value for this symptom of $p=0.091$.

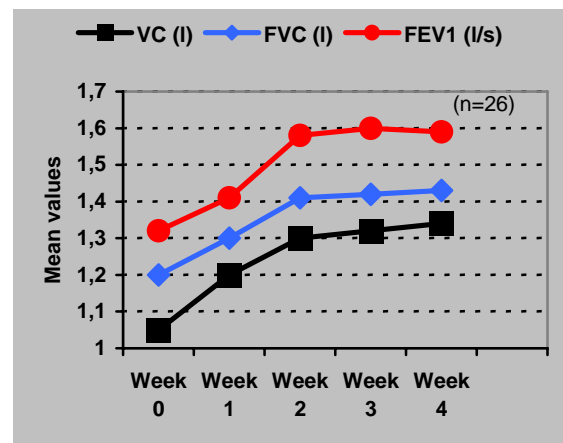


Fig. 1: Results of Spirometry

The **alleviation of all symptoms** was also reflected in both spirometric examinations and auscultatory findings. All spirometric examination parameters (vital capacity, forced vital capacity, one-second capacity, second capacity as a percentage of vital capacity, peak flow) identified significant improvements on the initial values after only one week (fig. 1). In auscultation the McNemar test identified significant differences in dry rale between the start of the study and its end (fig. 2). Moist rale declined, but without statistical significance.

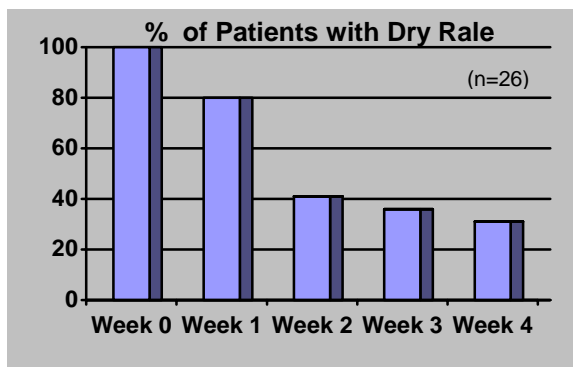


Fig. 2: Auscultation Results: Dry Rale

Global effectiveness

At each control examination the medical supervisor was asked to assess the effectiveness and tolerance of Prospan® Syrup on a scale of 1 to 4. At the end of the four-week study the doctor found its global effectiveness to be much better than after the first week. At the end of the study Prospan® Syrup was judged to be ineffective in two patients and excellent in the majority of children (15 out of 28) (fig. 3).

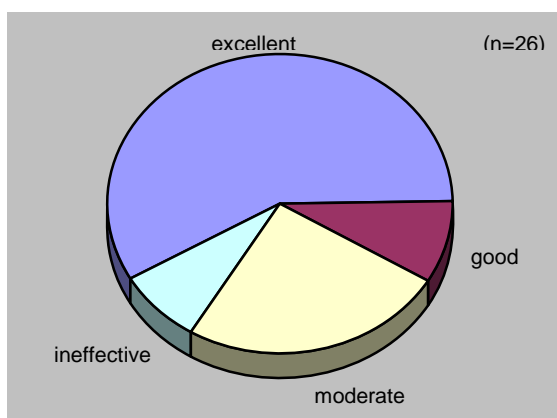


Fig. 3: Assessment of Effectiveness at the Conclusion of the Study

Tolerance

Tolerance was assessed as excellent at all control examinations except two. This is supported by the fact that no patient reported any adverse reactions.

Discussion

Active ingredient and its effect

Ivy (*hedera helix*), which is contained in Prospan® in the form of a standardised extract, is a medicinal herb which has been used as an effective treatment for several hundred years (Mayer et al; Madaus).

The drug is in wide use today because of its bronchospasmolytic and bronchosecretolytic properties, in the treatment of inflammatory and obstructive infections of the airways (Berger; Mayer et al). Prospan® in drop and suppository form has been proved in numerous clinical studies (Arch; Böhlau; Düchtel-Brühl; Friede; Hamacher et al; Huber; Leskow; Loos; Rath; Rudkowski et al; Schmengler; Schmid; Stöcklin) to be an effective treatment for bronchitic syndrome, inducing expectoration and spasmolysis and relieving coughing and dyspnoea. Prospan® enjoys the particular advantage that it has no contraindications, adverse reactions or interactions with other preparations (Data Sheet). As well as adults, Prospan® is thus particularly suitable for children.

A new form of administration for children

Previously available only as drops and suppositories, Prospan® has been developed by Karl Engelhard & Co. in liquid form - which is much liked by children.

A further advantage of this form, which is of particular appeal to parents, is that it is free of alcohol, sugar additives and colouring agents.

Study of effectiveness and tolerance

The study involved 26 children of both sexes aged between 4 and 10 years, who were treated for four weeks with Prospan® Syrup for children. Its effectiveness was judged on the basis of

spirometric examinations, auscultatory findings and symptom documentation.

A statistical evaluation of the results after four weeks of treatment gave a performance of *good* or *excellent* in 65.4% of cases and *moderate* in 26.9%, the condition being unchanged in only 7.7%. Tolerance was assessed as *excellent* in 92.3% of cases.

Patient compliance and adverse reactions

Only a qualified assessment of the effectiveness of Prospan® Syrup could be reached in the case of 6 children who contracted other illness during the study (scarlet fever, otitis media, streptococcal angina, acute episode of chronic bronchitis). An especially favourable point is that despite these 6 additional illnesses and the relatively lengthy of the study, none of the patients was compelled to withdraw from it.

It is worthy of note that Prospan® was tolerated extremely well throughout the study, no adverse reactions being observed.

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Conclusion

Owing to its high degree of effectiveness and its particularly good tolerance, Prospan® Syrup for children constitutes a valuable addition to the forms already available (drops and suppositories) for the treatment of children with chronic-obstructive bronchitis.

Summary:

In a single-centre clinical test 26 children were treated for four weeks with 1-2 teaspoonfuls of Prospan® Syrup four times daily. Most of the children showed an improvement as early as week 1, as evidenced by spirometric examination, symptoms (coughing, expectoration and dyspnoea) and auscultatory findings. In more than two-thirds of cases, effectiveness was assessed as *good* or *excellent*. Its high tolerance is reflected in the global judgment of the medical supervisor who marked it as *excellent* in 92.3% of cases and *good* in 7.7%: not in a single case was it marked as *moderate* or *poor*.

No child suffered any adverse reactions. Patient compliance may be described as outstanding: even though 6 children contracted other illnesses during the study, no child had to be withdrawn from it.

Keywords: Prospan® Syrup for children, chronic-obstructive bronchitis.

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