Herausgeber, Druck und Verlag
Hallwag AG, CH-3000 Bern 1, Nordring 4

Schweizerische Rundschau für Medizin
Revue suisse PRAXIS de médecine

Schweiz. Rundschau Med. (PRAXIS) 69
Nr. 31, 1106–1108 (1980)

Immunobiotherapy with Broncho-Vaxom® in 20 children

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Summary

A 10-days prophylactic treatment with the immunobiological preparation, Broncho-Vaxom® in dosage for children, was undertaken during 3 successive months on 20 children before the start of winter season. On comparing the incidence of infections in the upper respiratory tract, ears, nose and throat after treatment with that of the previous winter and in the 6-month period which is preceding this therapy, a reduction was noted in 80 % of the children.

Zusammenfassung

Bei 20 Kindern erfolgte in den Vorwintermonaten eine nach vier und acht Wochen wiederholte zehntägige prophylaktische Therapie mit dem Immunobiotherapeutikum Broncho-Vaxom® Kinder. Im Vergleich zum Winter ein Jahr zuvor und im Vergleich zu sechs Monaten vor der Therapie konnte bei 80 % der Kinder eine Verminderung der Infektanfälligkeit der oberen Luftwege und des ORL-Bereiches festgestellt werden.

Résumé

Un traitement prophylactique de 10 jours avec la préparation immunobiologique Broncho-Vaxom Enfants a été effectué 3 fois, durant 3 mois, chez 20 enfants pendant les mois préhivernaux. En comparant la fréquence des infections des voies respiratoires supérieures et de la sphère ORL avec celle de l'hiver de l'année précédente et des 6 mois avant la thérapie, une réduction a été constatée chez 80 % des enfants.

Patients and Methods

Prophylactic immunotherapy against infections of the upper respiratory passages and of the ears, nose, and throat was conducted in 20 children in my pediatric practice during the winter of 1976-77, using a new immunobiotherapeutic preparation, BRONCHO-VAXOM®*. BRONCHO-VAXOM® is a bacterial lysate presented in capsules (with a special dosage form for children), whose immunostimulatory activity has been demonstrated both pharmacologically (1,2) and clinically, especially in children (3).

The 20 children, 10 boys and 10 girls, in the age range one to 12 years (mean age four years) fullfilled the following criteria: their parents were known to be reliable people, and consented to the prophylactic measures; the children had been under my care during the winter of 1975-76; their home circumstances were known to me.

The treatment was undertaken between mid-October and the end of December 1976. It consisted in a 10-day course of one capsule of BRONCHO-VAXOM® (dosage for children) daily, followed by identical courses after 4 weeks and after 8 weeks. At the beginning of treatment, and four and 12 weeks later, the children had a medical examination, which included inspection of skin, the mouth, and the ears, auscultation of the heart and lungs, and a blood picture. At each examination the parents were questioned about the occurence of any illnesses and about tolerance to the medication. All the children who began the BRONCHO-VAXOM® course completed it, under parental supervision.

* OM Laboratories, Meyrin/Geneva, Switzerland

Results

1. Tolerance

Neither difficulties in administering BRONCHO-VAXOM® nor discomfort after its ingestion were reported. In no child was there evidence of an allergic reaction, and there were no rashes. The mean values for leucocyte counts, total and differential, done before, during, and a month after the prophylactic therapy revealed no evidence of leucocytosis, eosinophilia, or other haematological abnormality (Table 1). Two children (patients 5 and 7 in Table 3) had respectively 6 and 7 % of eosinophil granulocytes a month after the third course of BRONCHO-VAXOM®; one had an attack of pseudocroup at the time and the other was suffering from recurrent tonsillitis.

2. Subjective assessment

The parents of 18 of the 20 children reported a lower susceptibility to infections during the winter of 1976-77 after the course of immunobiotherapy with BRONCHO-VAXOM® than during the winter of 1975-76 when no such course was given. No parents were disappointed with the results of the course.

3. Objective assessment

The number of upper respiratory and ear, nose and throat infections in the 20 children was 23 between January and April 1976 and 13 in the same months of 1977, and the totals of sickness days were 94 and 55 respectively (Tables 2 & 3). In the six months preceding the BRONCHO-VAXOM® prophylactic course the 20 children had 38 infections causing 148 sickness days, whereas in the six months following the course the corresponding figures were 26 and 86 (of which 26 sickness days were the lot of one single patient) (Table 2). In 16 children the number of infections after immunobiotherapy was lower in comparison both with the number in the winter of 1975-76 and with that during the six pre-immunobiotherapy months.

Details of the infections and numbers of sickness days in the individual children are shown in Table 3. Two children (Nos 6 and 7) were no better after the BRONCHO-VAXOM® course than before it: the first was suffering from recurrent spastic bronchitis since birth, and the second had tonsillar suppuration with recurrent tonsillitis and otitis which ceased after tonsillectomy in May 1977. In two other children (Nos. 11 and 12) infections were no fewer after the course than before, although their parents regarded the result of the course as satisfactory.

Table 1: Mean leucocyte counts in children given three prophylactic 10-day courses of Broncho-Vaxom® (children) at monthly intervals

		Interval after beginning BRONCHO-VAXOM®		
Blood cells counted	Beginning Broncho-Vaxom ® (19 patients)	1 month (17 patients)	2 months (16 patients)	3 months (19 patients)
Total leucocytes (per mm3)	7463	7832	7118	8416
Neutrophils (%)	39,1	38,3	35,1	39,6
Band cells (%)	1,7	0,5	0,9	1,2
Eosinophils (%)	2,7	2,6	2,3	2,4
Basophils (%)	0,3	0,4	0,2	0,1
Monocytes (%)	2,1	2,0	0,4	1,7
Lymphocytes (%)	54,0	56,1	61,2	54,9
Plasma cells (%)	0,2	0,2	0,0	0,1

Table 2: Total upper respiratory and ear, nose, and throat infections, and sickness days, in 20 children before and after prophylactic immunobiotherapy with Broncho-Vaxom® (children)

	Jan.-Apr. 1976 No treatment	Jan.-Apr. 1977 (Broncho-Vaxom®)	6 months before Broncho-Vaxom®	6 months after Broncho-Vaxom®
No. of infections	23	13	38	26
Sickness days	94	55	148	86

Table 3: Upper respiratory and ear, nose, and throat infections, and sickness days, in 20 children before and after prophylactic immunobiotherapy with Broncho-Vaxom® (children capsules). Results per child

	January-April 1976 (no treatment)		January-April 1977 (Broncho-Vaxom®)		
Patient No.	Infection	Sickness days	Infection	Sickness days	Result
1	Cough and pyrexia	3	–	–	+
2	Bronchitis (3x)	15	Bronchitis	10	+
3	–	–	–	–	+
4	Pharyngitis, Conjunctivitis	2	–	–	+
5	Bronchitis (2x)	10	Bronchitis	7	+
6	Bronchitis	3	Bronchitis (2x)	8	–
7	Bronchitis (2x), Pharyngitis	17	Bronchitis, Otitis, Sinusitis	10	–
8	–	–	–	–	–
9	–	–	–	–	+
10	Pharyngitis, Tonsillitis	7	–	–	+
11	Pharyngitis	3	Pharyngitis	3	–/+
12	Pharyngitis	3	Pharyngitis (2x)	8	–/+
13	Pharyngitis	5	–	–	–/+
14	–	–	–	–	+
15	Pharyngitis (pyrexia diarrhoea, cough)	7	–	–	+
16	–	–	–	–	+
					+
17	Pharyngitis	3	Pharyngitis	4	–/+
18	Sinusitis	5	–	–	+
19	Pharyngitis	5	Rhinitis	2	+
20	Tonsillitis, Pharyngitis	6	Bronchitis	3	+

Discussion

It was with some scepticism that I approached a trial of an immunobiotherapeutic preparation, for I have never with any conviction prescribed this type of medication in my practice.

Tolerance to BRONCHO-VAXOM® can be pronounced excellent, on both subjective and objective grounds (the parents' statements, skin inspection, differential leucocyte counts).

Frequency and duration were counted only for those infections for which the parents had brought their children to consult me, and I had therefore to rely on the parents' reports concerning the more frequently occuring mild infections. The parents of 16 children, that is, 80 % of the group studied, declared spontaneously that in the winter following the course of immunobiotherapy with BRONCHO-VAXOM® their children were less susceptible to infection than previously. This was confirmed by the 40 % lower frequency and duration of infection in the winter of 1976-77 compared with that of 1975-76. In neither of those winters was there any special prevalence of respiratory tract infections in Basle. The good result was further confirmed by the fact that the infection rate during the six months after the prophylactic course was also lower than during the six months before the course, despite the fact that the six months before the course were in summer and late summer, that is, the season during which in any year the expected infection rate is lowest.

The high effectiveness of BRONCHO-VAXOM® in reducing the incidence of infection of the upper respiratory passages and of the ears, nose and throat emerges clearly from this study. Its administration by parents, without medical supervision, presents no problems.

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