

C. Supino



THERAPEUTICS

OMEGRIPHI®(GUNA-FLU) PREVENTION OF UPPER RESPIRATORY INFECTIONS IN PAEDIATRICS

A CONTROLLED, MULTICENTRIC CLINICAL TRIAL

SUMMARY

In this clinical study on 291 children aged between 3 and 6, we compared the efficacy of a homotoxicological drug with a conventional reference treatment, in the prevention of Upper Respiratory Infections.

The protocol examined involves the use of a homeopathic complex (Omeogriphi®) while the conventional treatment involves the administration of Bacterial Lysates (Biomunil®, Bronchovaxom®, Bronchomunal®). The morbidity factor (165-day observation period) was used as the evaluation parameter.

The study illustrated the clinical effectiveness of the homeopathic treatment – in the Group treated with Lysates a 50% morbidity rate was recorded, whereas for the Group treated with the homeopathic drug, the morbidity rate was 38%.

The remedy Omeogriphi® in several countries is called Guna-Flu.

INTRODUCTION

Infections of the upper respiratory tract (URI) are the most common pathology in pediatrics; although they do not generally present serious clinical consequences, they do impair the child's quality of life and incur high medical and social costs.

The main pathogens that affect the upper airways are viruses, mycoplasmas and bacteria – they are localised at various levels, causing pathological areas that are often adjacent. The localisation can be synchronised, or it can occur in succession.

The age groups most affected are the first and second infancy, when the child attends day nursery and primary school – places where the high concentration facilitates infection and increases the possibility of transmission. A high number of siblings also predisposes to infections and increases their incidence,

particularly if they attend the same day nursery and primary school. The pathological process is the same at all levels – inflammation and oedema of the mucosa, vascular congestion, hypersecretion of mucous and changes in the structure and function of the ciliary apparatus.

After the first inflammatory phase, the immune immaturity characteristic of infancy causes compensatory reactive hypertrophy of the lymphatic structures, which conditions the gradual progression towards possible complications. For a high frequency of URI, each child needs specific courses of treatment at least 2-3 times a year, particularly in the winter months. URIs can be categorised under the New Table of Homotoxicology (*H.H. Reckeweg, modified*), and more specifically, under the **Humoral Phase**. The problems relating to the respiratory apparatus clearly lend themselves to physiopathological and homotoxicological interpretation. The re-

spiratory apparatus is one of the emunctories that the body activates in the toxin Excretion Phase. The production of mucous and the structure of the epithelium facilitate the external drainage of toxins – just think about physiological mucociliary clearance and the effectiveness of the secretion mechanism in expelling fine dust, inert toxins, bacteria, viruses etc. from the apparatus. Coughs and bronchial spasms are defensive processes aimed at preventing the penetration of toxins.

The Reactive Phase, represented by vivid inflammatory phenomena is none other than the **activation** of the aspecific and specific reactive defence systems.

Emunctory blockage, as a result of an excess of *pathogenic noxae*, together with the blocking of mucociliary activity, initiate the phenomenology of chronicisation that, when set against a chronic toxin deposit, introduces the Degeneration Phase.

The notable frequency of URIs and the subsequent continuous use of conventional drugs **inevitably alter the biorhythms of the connective tissue**.

At paediatric age, lymphatic tissue hypertrophy occurs, as the immunological immaturity in children leads to an increase in lymphatic tissue attempting to compensate for the **quality** of the response with the **quantity** of defence tissue.

However, lymphatic tissue hypertrophy, particularly in the pharyngeal and palatine tonsils, affects the quality of life of children who suffer from phonatory, olfactory, respiratory and neuro-reflexive disorders, as a result of changes in the functionality of the mucosa of the primary airways.

A retrospective study of children suffering from *Sleep Disorder Breathing* (SDB) (Nocturnal apnoea and roncopathy) illustrated how they make little

progress at school – there is a “*learning debt*” during the first few years at school (or even prior to that), which is never completely “*paid off*” (Gozal et Al., 2001). This often means that the child has to undergo an adenoidectomy and/or tonsillectomy.

The pharyngeal tonsil is linked to the development of the CNS. The latter’s period of maturity corresponds to the loss of control of thermal variations (febrile convulsions) and coincides, de facto, with adenoid atrophy. The pharyngeal tonsil, therefore, has a **protective** role towards the CNS in its maturation phase.

The patient’s neurological situation should also be taken into account when dealing with the pathology of this structure, as the damage from an adenoidectomy can alter from neurological disorders to actual changes in character.

The palatine tonsils play a very important part in the activation of the immune system, as they have privileged contact with external antigenic material. Tonsillar phlogoses are, therefore, an “*indicator*” of the immaturity of the immune system in children. The intervention of tonsillectomy should only be carried out if absolutely necessary, particularly in first infancy. From second infancy onwards, the indication for tonsillectomy is essentially based on recurring febrile tonsillitis and the presence of focal disease (Milan, 2000).

MATERIALS AND METHODS

In this study, we included children of both sexes aged between 3 and 6. Although they belonged to the appropriate age range, we excluded from the study all those subjects for whom the following were present in their case history:

1. Respiratory allergy,
2. Chronic cardiopulmonary pathology,
3. Neuropsychiatric pathology,

4. Renal pathology.

All the children included in this study attended school – we regarded this parameter as being one of the most important concausal factors for the exchange and dissemination of respiratory pathogens (*Flügge drops*).

We randomly prescribed **Omeogriphi®** (Guna, Milan) and drugs containing bacterial lysates (Biomunil®, Bronchomunal®).

Omeogriphi® was administered in a dose of one tube a week for at least 3 consecutive months; Biomunil® - 4 sachets a week for the first three weeks, then 4 sachets a month for the following three months; Bronchomunal® - 10 cps a month for three months.

-Omeogriphi® contains: *Anas barbariae* (heart and liver autolysate) 200K, *Influenzinum* 9CH, *Vincetoxicum officinalis* 5CH, *Aconitum napellus* 5CH, *Belladonna* 5CH, *Cuprum* 3CH, *Echinacea angustifolia* 3CH, *lactose* and *saccharose* q.s. 1g.

-Biomunil® contains *ribosomal fractions of Klebsiella pneumoniae*, 3.5 parts; *Streptococcus pneumoniae*, 3.0 parts; *Streptococcus pyogenes* group A, 3.0 parts; *Haemophilus influenzae*, 0.5 parts.

It also contains fractions of *Klebsiella pneumoniae membrane*, 15.0 parts, via a Lyophilisate equivalent to 0.525 mg of ribosomal RNA.

It is regarded as an immunostimulant drug as it introduces bacterial antigens into the immune system, stimulating the production of antibodies.

-Bronchomunal® (also known as **Bronchovaxom®**) contains lyophilized bacterial fractions of *Haemophilus influenzae*, *Diplococcus pneumoniae*, *Klebsiella pneumoniae* and *ozaenae*, *Staphylococcus aureus*, *Streptococcus pyogenes* and *viridans* and *Neisseria catarrhalis*. It acts by inducing an increa-

se in the T helper/T suppressor ratio (Emmerich et Al, 1990) increasing the concentrations of INF γ , IgA and IL-2 [Manuel, 1994; Keul, 1996 (a)] without altering the IgE concentrations [Weiss, 1987; Keul, 1996 (b)].

The doctors who enrolled in this multicentric study* gathered the data in the second half of February 2002 (a period with maximum incidence of URIs). We evaluated how many URIs had affected the subjects included in the study; what use was made of antibiotics and/or anti-inflammatories and/or homeopathic medicines and/or homotoxicological medicines; whether they had recovered; *negative compliances* and the reasons behind them.

* In alphabetical order: Dr.ssa G. Bianco, Paediatrician based in the commune of Formia; Dr.ssa V. Favi, Paediatrician based in the Commune of Gaeta; Dr.ssa M.A. Rainone, Paediatrician based in the Commune of San Felice Circeo; Dr. C. Supino, Paediatrician based in the Comune of Itri; Dr. A. Urbano, Paediatrician based in the Commune of Fondi. All the communes belong to the Province of Latina.

➤ 291 cases were collected, of which 142 had been treated with Omeogrifi® and 149 with bacterial lysates (FIGURE 1).

The Omeogrifi® Group comprised 142 children divided into 3 age groups (FIGURE 2):

1. between 3 and 4 years old: 59 (41.5%)
2. between 4 and 5 years old: 47 (33.1%)
3. between 5 and 6 years old: 36 (25.3%)

The Bacterial Lysates Group (Controlled) comprised 149 children divided into 3 age groups (FIGURE 3):

1. between 3 and 4 years old: 47 (31.5%)
2. between 4 and 5 years old: 55 (36.9%)

Figure 1

Distribution of patients included at random.

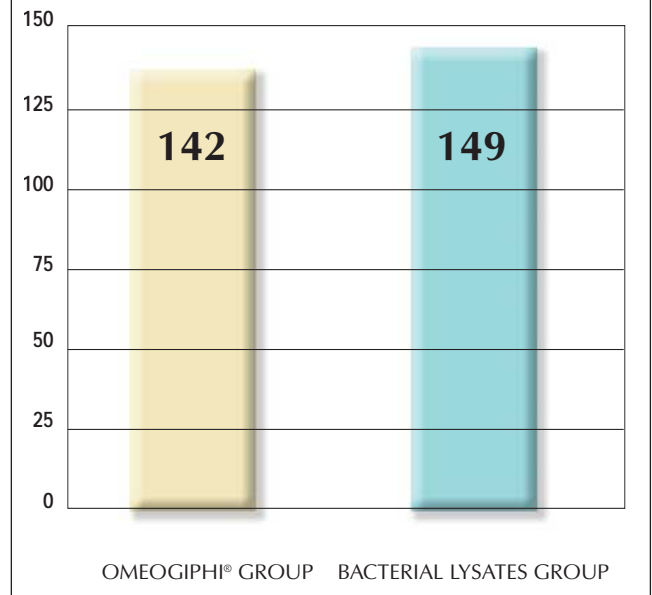


Figure 2

Distribution of subjects included in the Omeogrifi® Group according to age group and relevant percentages.

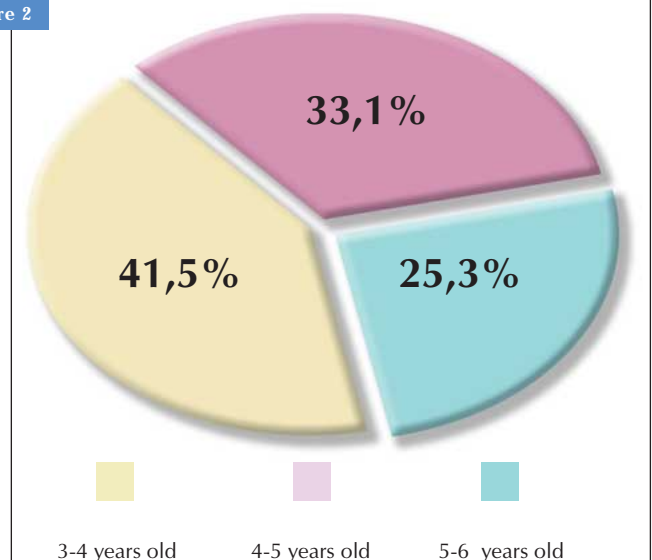
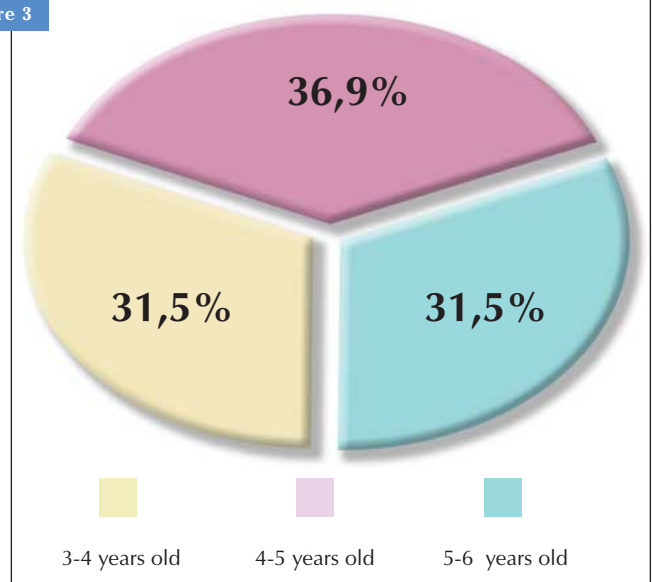


Figure 3

Distribution of subjects included in the Control Group (Bacterial Lysates) according to age group and relevant percentages.



3. between 5 and 6 years old:
47 (31.5%)

RESULTS

The aim of this study is to evaluate the **preventive efficacy** of various medicines containing bacterial lysates and a complex homeopathic medicine known as Omeogriphi® (Guna, Milan).

➤ In the Omeogriphi® Group (142 cases), 4 left the study – 1 (recurrent abdominal algia after administration of the drug); 1 (underwent an adenoidectomy); 1 (Atopy); 1 (mother’s decision).

138 children therefore continued with the trials.

During the study period, 53 (38.4%) out of the 138 cases became ill with URIs. (FIGURE 4).

Of these 53, 31 were treated using antibiotic treatment and 22 using complex homotoxicological medicines, depending on the location of the pathology and subsequent symptomology.

With regard to the age groups, out of the 53 children, 32 (60.3%) of those aged between 3 and 4, were ill; 13 (24.5%) of those aged between 4 and 5 were ill; and 8 (15%) of those aged between 5 and 6 were ill.

➤ In the group who underwent preventive treatment with bacterial lysates (149 cases), 2 left the study – 1 (abdominal algia after administration of the drug); 1 (mother was ill and this hindered administration of the drug in accordance with the indications provided).

147 children, therefore, continued with the study.

During the study period, of the 147 children, 74 (50.3%) became ill with URIs. (FIGURE 5).

Of these 74, 48 were treated using antibiotic therapy and 26 using complex homotoxicological medicines.

Figure 4

Number of cases and percentage of URIs in the Omeogriphi® Group.

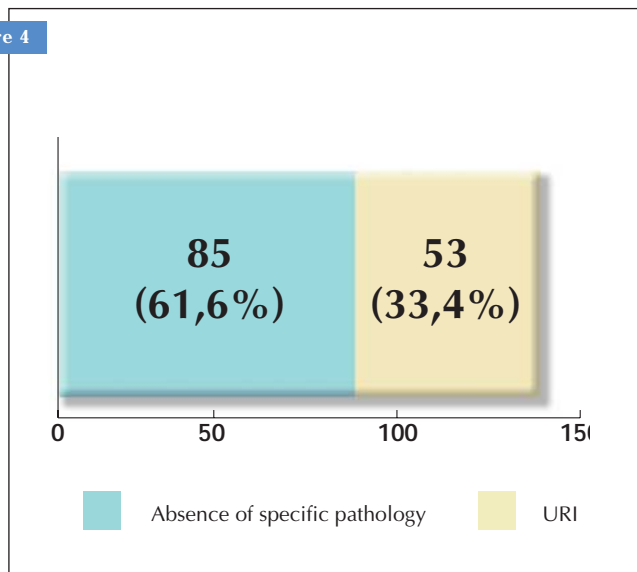
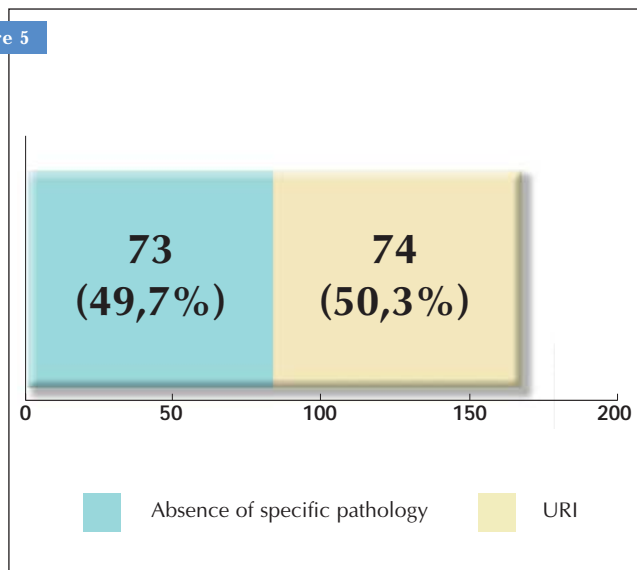


Figure 5

Number of cases and percentage of URIs in the Bacterial Lysate Group.



With regard to the age groups, out of the 74 children, 25 (33.7%) aged between 3 and 4 were ill; 31 (41.9%) of those aged between 4 and 5 were ill; and 18 (24.3%) of those aged between 5 and 6 were ill.

DISCUSSION

Upper Respiratory Infections (URIs) are extremely common at paediatric age. This leads to considerable cost to the Sistema Sanitario Nazionale and loss of working days for those parents forced to stay at home to care for a sick child.

URIs result from the combined action of several factors such as (amongst others):

- Early socialisation: the majority of studies suggest that socialisation during pre-school age and particularly in first infancy, encourages an increased number of infections, through increased risk of contagion.
- Passive inhalation of tobacco smoke: this works by altering various local defence mechanisms.
- Environmental pollution.
- Seasonal factors: URIs are usually concentrated in the period between Autumn and Winter.
- High number of cohabitants: particularly if these are at paediatric age, this can be an important cofactor similar to early socialisation.

In this study, we compared the preventive efficacy of Bacterial Lysates with a

complex homeopathic medicine (Omeogriphi®).

► From the first assessment, it emerged that the only negative collateral effect recorded after administration of the two drugs was abdominal algia (1 case in each Group). Secondly, only **38%** of the children included in the Omeogriphi® Group fell ill with URI compared with **50%** of those included in the Control Group. These percentages certainly **illustrate that Omeogriphi® has better preventive efficacy** than Bacterial Lysates (conventional reference medicines).

If we make a more detailed analysis of the data according to the age group of the children who presented URI, we can see that for the Bacterial Lysates Group, this went from 34% in the 3-4 year-olds to 24% in the 5-6 year-olds; whilst for Omeogriphi®, it went from 60% for the 3-4 year-olds to 15 % for the 5-6 year-olds. These are the values one would expect as the maturing of a child's immune systems tends to peak towards the 5th or 6th year of life.

Viruses and bacteria are "used" by a child's body to further develop their own immune system with febrile, release and blocking mechanisms, for example.

We can, therefore, hypothesise that the presentation of bacterial antigens by the lysates introduces a maturity boost to the immune system, but as this is not associated with a drainage therapy and emunctory activation, we believe that these antigens "flood" the matrix, reducing the quality of the immune response.

Omeogriphi® strengthens reactive and excretory functionality, predisposing it to lower morbidity levels and, therefore, to better preventive efficacy. ■

The Author would like to thank Prof. L. Milani for revising the manuscript, taken from the Thesis on the Improvement of the Triennial School of Clinical Homeopathy and Integrated Disciplines, discussed by the Author in Rome on 22/06/2002 (Reporter: Dott. A. Lozzi).

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