



CLINICAL

A. Arrighi

SUMMARY

Acute respiratory infections, better known as ARTI (Acute Respiratory Tract Infections), are a major concern in pediatric age from both the epidemiological and the economic and social standpoints, given the considerable related costs.

- This clinical trial was carried out on 213 children (112 F; 101 M) between 3 and 8 years of age to assess the effectiveness of a PRM + Homotoxicological therapy (not precluding the use of allopathic medicines *a priori*) vs a conventional therapy for the prevention and treatment of ARTI. During the year prior to the trial, all patients had a positive history of RRI. The families were asked to choose between two therapeutic options (either the PRM - Homotoxicological or the conventional treatment) on the strength of their personal convictions; we thus conducted a prospective trial to evaluate outcome in which any placebo effect was balanced by the family's preference. Group A (PRM - Homotoxicological treatment) followed a protocol for RRI prevention using CITOMIX™ and homotoxicological treatments for any episodes of ARTI, plus antipyretics and antibiotics where necessary. - Group B (conventional treatment) followed a protocol for RRI prevention based on the immunostimulant IMMUCYTAL® (purified ribosomal vaccine) and treatment for acute episodes with synthetic molecules belonging to various classes of drugs. The patients were followed up for 8 months.

In evaluating the results we considered the number of ARTI episodes in the 2 Groups during the follow-up, indicative of the efficacy of the two prevention protocols, and a series of indicators.

All patients underwent blood sampling at the time of enrolment to establish their baseline IgA levels, then again 4 months later, and the percentage increase was calculated for the 2 Groups.

Any recourse to surgery (adeno- or tonsillectomy) was investigated among the patients in the two Groups, quantifying any differences using percentages.

- Our results demonstrated the superiority of the PRM-Homotoxicological treatment over the conventional treatment for every indicator considered. All the factors analyzed support the validity of the PRM-Homotoxicological treatment, justifying its application on a wide scale, given its lack of side effects and sustainable social costs.

KEY WORDS

ACUTE RESPIRATORY INFECTIONS, PHYSIOLOGICAL REGULATING MEDICINE, PEDIATRICS, PREVENTION, THERAPY, HOMOTOXICOLOGY, CITOMIX™, IMMUCYTAL®

CITOMIX™ VS IMMUCYTAL® IN THE PREVENTION AND THERAPY OF ACUTE RESPIRATORY INFECTIONS IN PEDIATRIC AGE.

- A CONTROLLED PROSPECTIVE CLINICAL TRIAL

INTRODUCTION

Recurrent respiratory infections (RRI) are considered a problem of "marginal interest" in the international medical literature, probably because of the innocent nature of these infections, which are the expression of an Immune System immaturity destined to regress spontaneously with time, and of the young patients' early socialization ("the experience of contagion") (1, 2).

While some school-age children become ill a mean 6 times a year, others become ill as often as **2-3 times** a month during the autumn and winter, and this poses unacceptable problems for both the children and their families, as well as incurring considerable socio-sanitary costs (3).

De Martino *et al.* claimed that at least 6% of Italian children suffer from RRI (4).

For these children, conventional medicine generally recommends the so-called immunostimulants (IS), drugs with various different compositions that have been the object of numerous clinical trials (5, 6) and much contradictory and often controversial debate (7)

on their real efficacy, with the academic world often adopting a rather haughty attitude, and the food and drug administrations sometimes even taking a drastic stance (France has approved the elimination of these drugs from the market).

In recent times, several clinical studies have nonetheless confirmed the efficacy and safety of these IS, the proper use of which was found to reduce the incidence of cases of RRI by 40% with respect to a placebo (8, 9).

The identification of the TLR (Toll-Like Receptors) has also provided rational grounds for the use of these drugs. TLR are an essential constituent of inborn immunity. They are sensors on the surface of numerous myelomonocytic, endothelial and epithelial cells, and on the cells of various organs. Structurally, they are transmembrane proteins with an extracellular and a cytoplasmic domain. Their stimulation by molecular structures occurring on the surface of various micro-organisms (bacteria, viruses, fungi) determines the expansion of the memory B lymphocytes, the reinforcement of the antibody responses and the activation of the complement cascade.

TAB.1

PATIENTS DIVIDED BY TYPE OF TREATMENT	
Type of treatment	No. of patients
Group A PRM-Homotoxicological treatment	113 (51 M, 62 F)
Group B Conventional treatment	100 (50 M, 50 F)

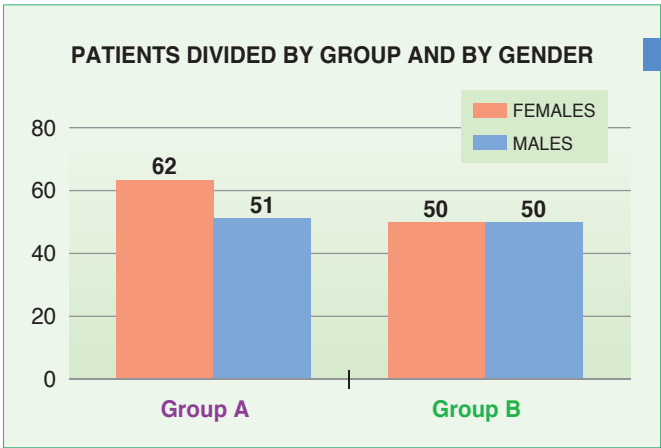


FIG. 1

A meta-analysis conducted by the Cochrane Library (2006), that took into consideration 759 clinical trials, concluded that all the IS considered (bacterial extracts, pidotimod, herbal extracts) reduce the number of respiratory infections by 40% by comparison with a placebo, and there is no difference, again with respect to the placebo, in terms of side effects (10). It is nonetheless recommended that they only be used in the case of children contracting airway infections more often than the mean incidence in the pediatric population; in other words, children should **not** be treated if they suffer from **less than 6 infec-**

tions a year. This is the cutoff that emerges from the majority of the epidemiological studies conducted on the general population. In clinical practice, the decision whether or not to treat a child is based on an assessment of the incidence of ARTI (*Acute Respiratory Tract Infections*) during the period in which they recur most often, i.e. between November and April. The reasonable lower limit, which represents the cutoff for the definition of RRI, amounts to more than one infection a month. On the other hand, the recommendation to treat “*all overexposed children (in day care, kindergarten and primary school)*”

appears excessively broad, because that would mean treating nearly all the children in the corresponding age bracket.

- The non-conventional approach to this type of problem is of considerable interest because it relies on medicines designed to modulate immune response, exploit the single individual's strengths and specific reactivity. It is an approach that is not in antagonism with that of academic medicine, but seeks instead to chart a new course, no longer based on therapeutic individualisms that can have little or no scientific value, but on clinical trials conducted according to international standards (11, 12, 13).

This is the only way to stand the test *versus* conventional medicine, by proposing protocols that can serve as guidelines, as in conventional medicine, but that still leave the expert physician the necessary freedom of action to customize the treatment for a given individual, without forgetting that the physician has to treat the person, not just to deal with disease and a related set of unpleasant symptoms that need to be speedily eradicated.

I have personally already dealt with the topic of recurrent respiratory infections (RRI) in pediatric age (14, 15) and the results have always been better than expected from every point of view: patients had a lower incidence of ARTI, with a more physiological and rapidly-resolved clinical course of the single episodes, enabling a more limited use of antibiotics and meeting with the greater satisfaction of the parents of the children in the group treated with homotoxicological medicines instead of the standard allopathic drugs. The same results also emerged from clinical studies conducted by other Authors, who confirmed the effective prevention and treatment of RRI using non-conventional medicines (16, 17).

- The present study represents a further challenge, concerning the use of just one drug, **CITOMIX™**, which represents the new frontier for the integration between Homoeopathy, Immunology and

CITOMIX™: therapeutic regimen

FIG. 2

- RRI PREVENTION:
10 pellets once a week from September to April
- TREATMENT OF SINGLE EPISODES:
10 pellets 3 times a day for 5 consecutive days
- PREVENTION OF RECURRENCES:
2 pellets morning and evening for 1 week

TREATMENT OF SINGLE EPISODES OF ARTI

Remedies used:

SIMPLE COMPOUNDS

Mercurius-Heel® S, Phytolacca-Heel®, Cistus-Heel®, Bryaconeel®, Aconitum-Heel®, Cuprum-Heel®, Engystol®, Droperteel®, Husteel®, Tartepheerel®, Tartarus-Heel®, Viburcol®, Lymphomyosol®, Galium-Heel®, Omeotox®, Omeogriphi®

-HOMACCORD®

Apis-Homaccord®, Aconitum-Homaccord®, Belladonna-Homaccord®, Drosera-Homaccord®, Natrium-Homaccord®, Dulcamara-Homaccord®, Phosphor-Homaccord®

TISSUE COMPOUNDS AND ASPECIFIC GENERAL STIMULANTS

Echinacea compositum S® e forte, Arnica compositum®, Pulsatilla compositum®, Vis-Heel®, Mucosa compositum®, Euphorbium compositum®, Coenzyme compositum

NOSODES

Grippe-Nosode-Injeel®, Otitis media-Nosode-Injeel®, Streptococcus-Haemol.-Nosode-Injeel®

FIG. 3

Molecular Biology - only one drug for use in prophylaxis and in association with the therapies used for treating single acute episodes of respiratory infections (ARTI).

CHILDREN WITH RRI

Children are defined as suffering from **Recurrent Respiratory Infections (RRI)** if they develop **more than one episode** a month of ARTI during the period of maximum exposure (November to April). We speak of RRI providing there is no underlying pathological condition that might justify the recurrence of such infections. RRI are common in the pediatric setting, although - by definition - the condition is benign and tends to regress spontaneously as the child grows up.

In RRI we can distinguish a number of different clinical entities:

- NONSPECIFIC UPPER AIRWAY INFECTION, or *Upper Respiratory Infections* (URI) or undifferentiated infection
- ACUTE OR RECURRENT PHARYNGO-TONSILLITIS
- RHINITIS OR RHINO-SINUSITIS
- ACUTE AND RECURRENT OTITIS MEDIA (AOM, ROM)

- LARYNGITIS
- TRACHEOBRONCHITIS
- ASTHMATIC BRONCHITIS, i.e. atopic and non-atopic children, and children with hyperactive cough recep-

tors that tend to develop paroxysmal cough of no known cause; individuals that develop a lower lung involvement, characterized by cough, dyspnea and wheezing on auscultation, when they acquire respiratory infections

- BRONCHIAL PNEUMONIA.

PATIENTS AND METHODS

In this study, we assessed the efficacy of the PRM drug **CITOMIX™** by comparison with conventional therapy in the prevention and treatment of pediatric ARTI.

• Inclusion criteria

Children presenting to the group's pediatric office, either under the public health service (the Local Public Health Unit ASL-8 Arezzo) or as private patients, between **01.09.2007** and **31.10.2007**, who met the following requirements: **age between 3 and 8 years**, a positive clinical history of

IMMUCYTAL® preventive regimen

1 sachet a day for 4 days a week for 3 consecutive weeks in the first month, then 1 sachet a day for 4 days a month in subsequent months

FIG. 4

TREATMENT OF SINGLE EPISODES OF ARTI

Classes of drugs used:

NONSTEROIDAL ANTIINFLAMMATORY DRUGS (NSAID)
AND STEROIDAL ANTIINFLAMMATORY DRUGS

ANTIPYRETICS

ANTIBIOTICS

ANTIHISTAMINES

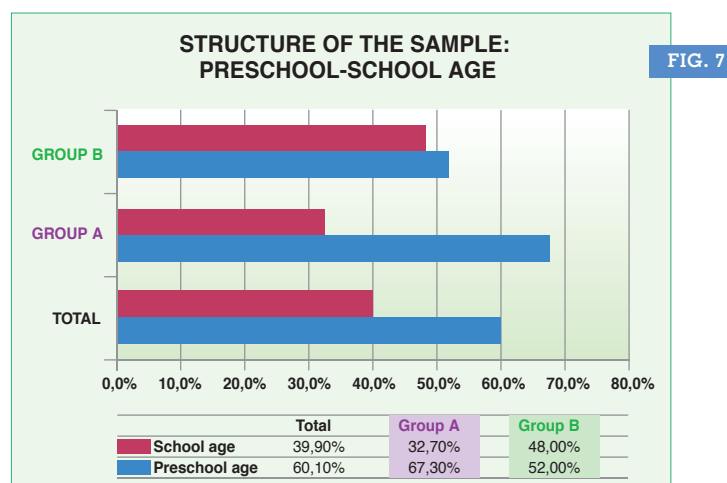
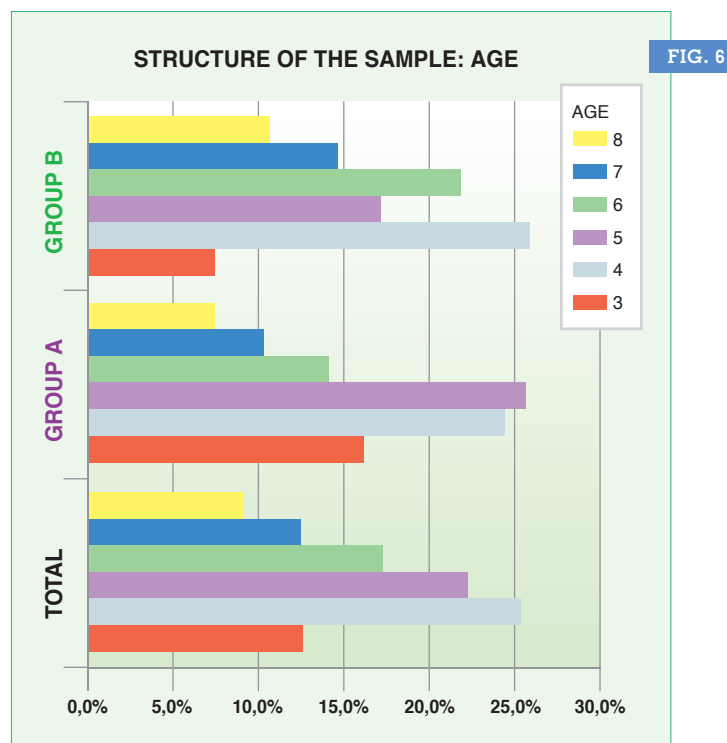
β₂-AGONISTS

COUGH SEDATIVES

MUCOLYTICS

NASAL DECONGESTANTS AND OTOLOGICAL PREPARATIONS

FIG. 5



TAB.2

Structure of the sample: DISTINGUISHED BY GENDER AND BY GENDER AND AGE

		Total		Group A		Group B	
		n.	%	n.	%	n.	%
Gender	Total	213	100,0%	113	100,0%	100	100,0%
	F	112	52,6%	62	54,9%	50	50,0%
	M	101	47,4%	51	45,1%	50	50,0%

TAB.3

		Total		Group A		Group B	
		n.	%	n.	%	n.	%
Total	F	112	52,6%	62	54,9%	50	50,0%
	M	101	47,4%	51	45,1%	50	50,0%
Preschool age	F	67	52,3%	40	52,6%	27	51,9%
	M	61	47,7%	36	47,4%	25	48,1%
School age	F	45	52,9%	22	59,5%	23	47,9%
	M	40	47,1%	15	40,5%	25	52,1%

RRI (i.e. children who had developed more than 6 episodes of ARTI between November 2006 and April 2007).

• Exclusion criteria

Children suffering from chronic diseases (diabetes, cardiopathies, chronic renal insufficiency), or receiving immunosuppressant or cortisone treatment, or given antibiotic therapy for lengthy periods of time, or suffering from allergies.

► The patients included in the study were divided into two groups:

- **Group A: 113** (62 F, 51 M) - PRM-Homotoxicological treatment
- **Group B: 100** (50 F, 50 M) - Conventional therapy.

In all, the study involved **213 children** (112 F, 101 M) with a mean age of five years and seven months (TAB. 1; FIG. 1).

PROTOCOL FOR THE PREVENTION OF RRI AND THE TREATMENT OF ARTI

• **GROUP A** was treated with **CITOMIX™** (Guna Laboratories, Milano - Italy) according to the following regimen (FIG. 2):

- **RRI prevention:** 10 pellets once a week from September to April
- **treatment of single acute episodes:** 10 pellets 3 times a day for 5 consecutive days
- **prevention of recurrences:** 2 granules morning and evening for a week.

For the treatment of single episodes of ARTI, Group A used CITOMIX™ in association with other homotoxicological medicines and PRM, without ruling out the use, where necessary, of antibiotics and antipyretics, all recorded in detail in the patients' clinical records (FIG. 3).

• **GROUP B** adopted the following regimen:

- **RRI prevention** using the immunostimulant drug IMMUCYTAL, a purified ribosomal vaccine (Pierre Fabre Pharma), according to a regimen commonly used in medical practice
- **treatment of single episodes of ARTI** with molecules belonging to various pharmacological classes.

TAB.4

**Structure of the sample:
PARENTS' FORMAL EDUCATION**

		Total		Group A		Group B	
		n.	%	n.	%	n.	%
Mother's schooling	Total	213	100,0%	113	100,0%	100	100,0%
	Middle school	74	34,7%	18	15,9%	56	56,0%
	High school	99	46,5%	64	56,6%	35	35,0%
	University	40	18,8%	31	27,4%	9	9,0%

TAB.5

		Total		Group A		Group B	
		n.	%	n.	%	n.	%
Father's schooling	Total	213	100,0%	113	100,0%	100	100,0%
	Middle school	73	34,3%	34	30,1%	39	39,0%
	High school	94	44,1%	51	45,1%	43	43,0%
	University	46	21,6%	28	24,8%	18	18,0%

The prophylactic protocol using conventional medicines was implemented from September to April and involved using IMMUCYTAL sachets according to the following dosage: 1 sachet a day 4 times a week for 3 consecutive weeks in the first month, then 1 sachet a day for 4 days a month thereafter (FIG. 4).

The following classes of drugs were used in the treatment of the single episodes of ARTI (FIG. 5): nonsteroidal anti-inflammatory drugs (NSAIDs) and steroids; antibiotics; mucolytics, cough sedatives; β 2-agonists; antihistamines; nasal decongestants, and otological preparations for topical use. The two prophylactic protocols are analyzed in detail below.

► Group A

CITOMIX™ represents the new frontier in the integration between Homoeopathy, Immunology and Molecular Biology. The particular association between a pool of cytokines and the homoeopathic remedies makes this compound a powerful non-specific Immune System stimulant and regulator. In particular, the presence of IFN- γ and IL 2 characterizes the product in the antiviral sense, while the presence of IL 4 (which activates the B lymphocytes) and GCSF (which stimulates and differentiates the progenitors of the granulocytes) identifies it as an antibacterial medication. IL 4 also determines an increase in the IgA levels, which are fundamental in defending against pathogenic germs at respiratory mucosa level. The presence of IL 1 β ,

is of considerable importance too, because of its action in triggering the “defensive” inflammatory response, and so is IL 6, which sustains the activity of the IL 1 β , in addition to determining an increase in the IgA. The Suis organ preparations contained in this compound also have an immunostimulant function; *Vasa lymphatica suis*, *Medulla ossis suis*, *Glandula thymi suis* gently stimulate the immunocompetent tissues. The immunostimulant action and triggering of the inflammatory defensive response by its various constituents thus make CITOMIX™ a remedy that can be used in all the various phases of the therapeutic strategy, i.e.

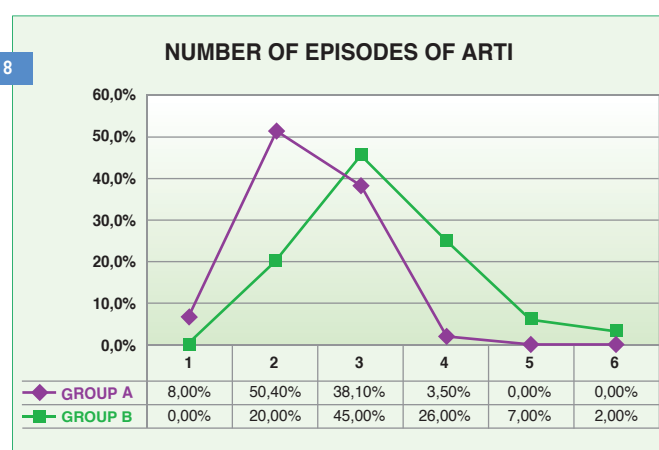
- **PREVENTION:** to non-specifically reinforce the immune defenses on both the bacterial and the viral fronts;
- **IN THE ACUTE PHASE OF EPISODES OF ARTI:** it induces a more rapid resolution of the inflammatory processes, improving the prognosis, and achieving a more rapid recovery of the patient;
- **PREVENTION OF RECURRENCES:** its administration after the acute episode prevents recurrences, rapidly inducing a return to normal of the patients' own immune balance, accelerating what used to be called their “convalescence”.

► Group B

IMMUCYTAL® belongs to the class of purified ribosomal vaccines. According to the medical Literature, it is considered an ideal immunostimulant because it comprises a natural vector, represented by ribosomal fractions obtained from the principal bacteria responsible for respiratory infections (*K. pneumoniae*, *H. influenzae*, *S. pneumoniae*, the *S. pyogenes* group A) and an adjuvant, consisting of fractions of *K. pneumoniae* membrane.

The effect of IMMUCYTAL® is to reinforce the immune defenses thanks to the specific response (the production of antibodies) and the non-specific response (phagocytosis) in children who are more ex-

FIG. 8



TAB.6

		Total		Group A		Group B	
		Mean	SEM	Mean	SEM	Mean	SEM
Total	N° ARTI episodes	2,79	,06	2,37	,06	3,26	,09
F	N° ARTI episodes	2,72	,09	2,37	,09	3,16	,13
M	N° ARTI episodes	2,86	,09	2,37	,09	3,36	,13

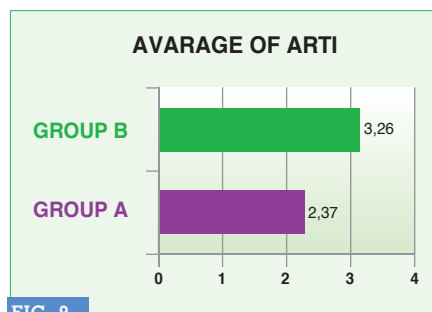


FIG. 9

posed to RRI, due to environmental factors and their own immune system's immaturity. A randomized, double-blind, placebo-controlled study conducted by Mora *et al.* (18) found a 50% reduction in the episodes of ARTI, and a 50% reduction in the duration of the single episodes of ARTI, with 62% of the treated patients versus 21% of the untreated patients showing an improvement in the audiometric tests, and less use of antibiotics. In particular, IMMUCYTAL® would appear to be particularly effective in children with recurrent otitis media (ROM).

FOLLOW-UP

The patients were studied from 01.09.2007 to 30.04.2008 (8 months = 240 days). At the time of the first encounter, the aims of the study were explained to the children's parents, who gave their informed consent.

They were offered two alternative therapies: either a PRM-homotoxicological therapy or a conventional therapy.

This prospective, outcome evaluation modality has an undeniable advantage in that the placebo effect is balanced by the fact that the choice of treatment is made by the family, on the strength of their own personal convictions, with no outside interference that might affect the reliability of the results.

RESULTS

The structure of the sample was analyzed to highlight any imbalance that might influence the interpretation of the results.

- AGE

When the children's ages were considered in detail, there were no statistically significant differences between the two Groups (FIG. 6).

- PRESCHOOL-SCHOOL AGE

In consideration of the differences existing between school-age children (6 years old or more) children of preschool age (from 3 to 5 years old), the sample was statistically unbalanced. This was undeniably to the advantage of Group B, which contained a larger proportion of school-age children, who generally become ill less often than those of preschool age, because the latter are more immature in terms of their Immune System (FIG. 7).

- GENDER, AND GENDER BY AGE

The distinction by gender in absolute terms, and within the two age brackets, revealed no statistically significant difference between the two Groups (TABLES 2, 3).

- PARENTS' FORMAL EDUCATION

The data on the mothers' level of formal education showed a marked difference between the two Groups: the mothers of children in Group A had a higher mean level of education than those of children in Group B. The differences in the fathers' level of formal education were not statistically significant (TABLES. 4, 5).

- EPISODES OF ARTI IN THE PREVIOUS YEAR

The analysis of the number of ARTI episodes in the previous year identified no statistically significant differences between the two Groups, neither for the mean figures, nor for the point distribution.

- IGA AT ENROLLMENT

According to our data, the females in Group B had higher IgA levels than those in Group A.

The following indicators were considered:

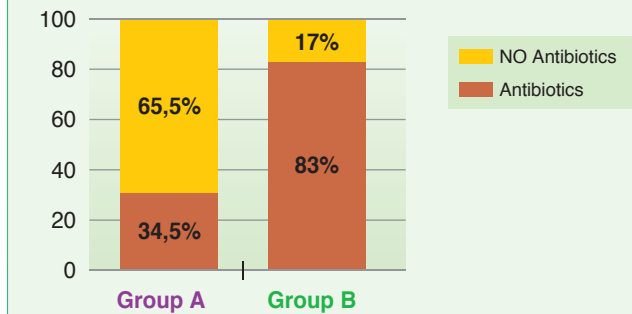
TAB.7		DAYS OF FEVER					
		Total		Group A		Group B	
		Mean	SEM	Mean	SEM	Mean	SEM
Total	Days of fever	6,64	,22	4,96	,16	8,54	,35
F	Days of fever	6,39	,26	4,97	,20	8,16	,42
M	Days of fever	6,92	,36	4,96	,24	8,92	,56

TAB.8		CYCLES OF ANTIBIOTICS					
		Total		Group A		Group B	
		Mean	SEM	Mean	SEM	Mean	SEM
Total	Cycles of antibiotics	,88	,06	,39	,05	1,43	,09
F	Cycles of antibiotics	,82	,09	,37	,07	1,38	,13
M	Cycles of antibiotics	,94	,09	,41	,08	1,48	,13

TAB.9		Total		Group A		Group B	
		Mean	SEM	Mean	SEM	Mean	SEM
Total	Cycles of antibiotics vs ARTI episodes	0,28	0,02	0,15	0,02	0,42	0,02
F	Cycles of antibiotics vs ARTI episodes	0,27	0,03	0,14	0,03	0,42	0,04
M	Cycles of antibiotics vs ARTI episodes	0,28	0,03	0,16	0,03	0,42	0,03

USE OF AT LEAST ONE CYCLE OF ANTIBIOTICS

FIG. 10



TAB.10		Total		Group A		Group B	
At least one cycle of antibiotics	Total	n.	%	n.	%	n.	%
	No, none	91	42,7%	74	65,5%	17	17,0%
	Yes, at least one	122	57,3%	39	34,5%	83	83,0%

1.a different **prophylactic efficacy** of the two protocols adopted, taking into account the number of episodes of ARTI in the two Groups during the follow-up;

2.a different **efficacy in the treatment of single episodes of ARTI** evaluating a number of items, i.e.

- days of fever
- cycles of antibiotics used
- days of absence from school;

3.a different frequency in the recourse to surgery (adeno- and/or tonsillectomy) between the two Groups;

4.all patients involved in the study had a blood test at the time of their enrollment to determine their IgA levels; this test was repeated 4 months later, calculating the difference in the percentage increment between the two Groups.

NUMBER OF EPISODES OF ARTI

TAB. 6 shows that the difference of at least one episode between the two Groups was statistically significant. In FIG. 8, the curve for Group A has peak percentage values that are further to the left than in the corresponding curve for Group B, which goes to show that the homotoxicological prevention protocol is more effective than the conventional prophylactic regimen. In short, there were globally 37% fewer

episodes ARTI in Group A than in Group B (FIG. 9).

DAYS OF FEVER

On average, the children in the Group on the PRM-homotoxicological treatment had just under 5 days of fever, while those in the group given conventional treatments had more than 8.5 (TAB. 7).

Globally, therefore, the children in Group B had to cope with 72% more days of fever than those in Group A and, in a given

episode of ARTI, fever lasted a mean 2.1 days in Group A as opposed to 2.6 days in Group B.

CYCLES OF ANTIBIOTICS

When the cycles of antibiotics administered to the children were considered, it emerged, here again, that the children in Group B resorted to the use of antibiotics statistically more often than those treated with Citomix (TAB. 8). Moreover, the ratio of antibiotics cycles to ARTI episodes was three times higher in Group B than in the PRM-homotoxicological treatment Group (TAB. 9). Only 34% of the children in Group A were given at least one cycle of antibiotics, as opposed to 83% in Group B (FIG. 10 - TAB. 10).

DAYS OF ABSENCE FROM SCHOOL

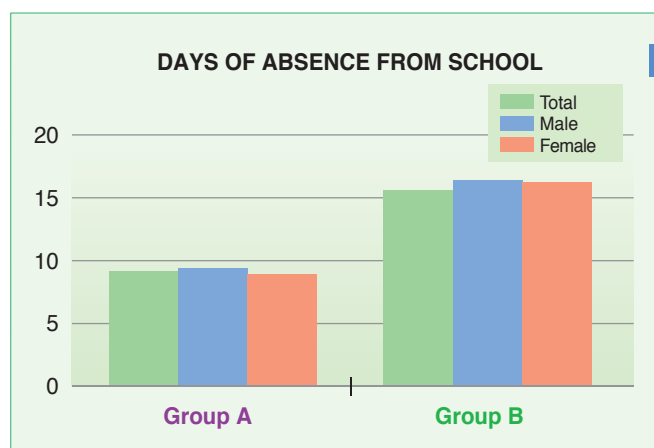
The clearly more frequent absence from school (nearly 6 days more) for the children in Group B than for those in Group A coincides with a major social cost (TAB. 11 - FIG. 11).

VARIATION IN IGA 4 MONTHS AFTER ENROLLMENT

The analysis of the absolute values revealed no statistically significant differences

DAYS OF ABSENCE FROM SCHOOL

FIG. 11



TAB.11		Total		Group A		Group B	
		Mean	SEM	Mean	SEM	Mean	SEM
		12,23	,37	9,65	,35	15,14	,54
F	Days off school	11,76	,47	9,61	,50	14,42	,69
M	Days off school	12,74	,57	9,69	,50	15,86	,82

TAB.12

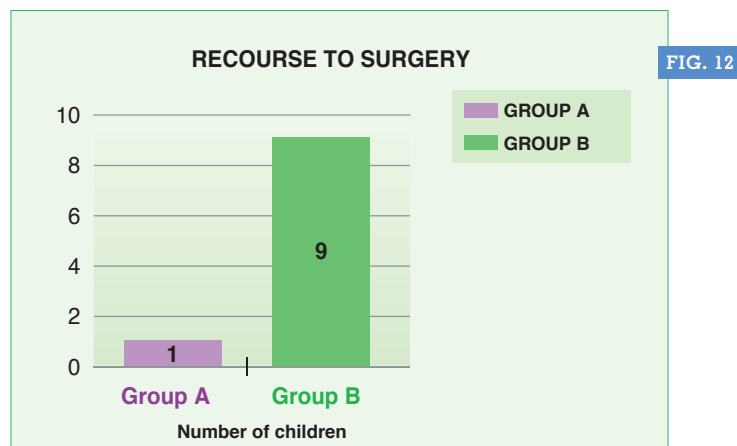
IGA CHANGES AFTER 4 MONTHS OF TREATMENT: absolute values

		Total		Group A		Group B	
		Mean	SEM	Mean	SEM	Mean	SEM
Total	IgA after 4 mths	129,92	3,10	124,09	3,68	136,52	5,06
F	IgA after 4 mths	125,56	4,08	117,74	4,51	135,26	7,03
M	IgA after 4 mths	134,76	4,69	131,80	5,91	137,78	7,33

TAB.13

IGA CHANGES AFTER 4 MONTHS OF TREATMENT: percentage differences

		Total		Group A		Group B	
		Mean	SEM	Mean	SEM	Mean	SEM
Total	difference %	21,24	,88	25,17	1,51	16,80	,45
F	difference %	22,88	1,56	28,40	2,56	16,03	,74
M	difference %	19,42	,61	21,25	1,04	17,56	,51



between the two Groups (TAB. 12), unlike the situation when we analyzed the percentage differences *vis-à-vis* the values recorded at the time of enrollment: the percentage increase in IgA in Group A was a mean 25.17% as opposed to 16.80% in Group B (TAB. 13). This finding is of interest, given the importance of IgA from the point of view of protecting the mucosa in general, and for the respiratory mucosa in particular.

RECOURSE TO SURGERY

Only 1% of the children in Group A underwent adeno- and/or tonsillectomy, as opposed to 9% of the children in Group B (FIG. 12).

DISCUSSION

This prospective study demonstrated the superiority of the **PRM-homotoxicological therapy** over conventional therapy in relation to various aspects:

-the former was superior in **RRI prevention**, in terms of fewer episodes of ARTI during the follow-up;

-it was more effective as concerns the **single episode of ARTI**, coinciding with fewer days of fever, fewer absences from school, less recourse to antibiotics;

-**recourse to surgery** was more limited among the children taking the PRM-homotoxicological therapy;

-moreover, there was evidence of a **greater percentage increase in the level of IgA** from the baseline recording (at patient en-

rollment) to the second assay 4 months later. This is an expression of the immunostimulant effect of CITOMIX™.

► An important aspect that it is worth emphasizing is that this result was achieved using only one medicine, with a straightforward therapeutic regimen that was readily acceptable and inexpensive.

- **CITOMIX™** is the pivotal element in the prophylaxis, the treatment of acute episodes and the prevention of recurrences; it has a synergic effect, reinforcing the effects of other specific homotoxicological medicines for dealing with individual clinical pictures, determining the patient's prompt and speedy recovery.

- The absence of any side effects, good compliance, and the results documented amply justify its use, and it can be recommended for use on a large scale. ■

Acknowledgements

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Author's address

Dr. Antonello Arrighi, MD

– Specialist in Pediatrics
 – Lecturer on the School of
 Homeopathy, Homotoxicology
 and Integrated Disciplines
 - Accademy of Biological Medicine.
 Via G. Puccini, 19
 I - 52025 Montevarchi (AR)