Homotoxicological versus conventional treatment regimens in the prophylaxis and treatment of pediatric seasonal allergic rhinitis: a comparative clinical study

Dr. Antonello Arrighi, Paediatric Specialist, Teacher,
Italian Association of Homotoxicology

BACKGROUND

Allergic rhinitis is common in childhood and affects 10-20% of the pediatric population. Its prevalence is increasing due to a combination of environmental factors. This study compared the effectiveness and tolerability of a homotoxicological treatment protocol (involving treatment with Luffa comp.-Heel[1], Lymphomyosot and Euphrasia-Heel[2]), with a standard allopathic (conventional) treatment regimen.

METHODS

This was a comparative, prospective observational cohort study. Patients routinely visiting a pediatric practice with a clinical history of seasonal allergic rhinitis for at least one year were eligible. Patients were seen on 4 occasions (pre-seasonal, shortly after the onset of acute symptoms and at 3 and 6 weeks post-treatment). Nasal, ocular and general symptoms were graded on a 4-point scale and average symptom scores were calculated at each of the 4 visits.

RESULTS

In total 111 patients were included in the study (57 homotoxicology, 54 standard conventional treatment regimen). The clinical and average symptom scores were similar in both treatment groups at the various points in time. Significant improvements of acute symptoms were achieved in the first three weeks of treatment in both groups.

No adverse drug reactions were observed in patients on the homotoxicological regimen, compared to 21 adverse drug reactions in the conventionally-treated group.

CONCLUSION

In these patients, a homotoxicological treatment regimen was as effective as the standard conventional treatment regimen and was associated with substantially better tolerability. The results suggest that this homotoxicological regimen is a possible alternative to conventional treatments.

Keywords Luffa comp.-Heel (Luffeel), Lymphomyosot, Euphrasia-Heel (Oculoheel)

BACKGROUND

The prevalence of allergic rhinitis has risen significantly during the last decades, particularly in the developed countries. It is common in childhood and affects 10-20% of the pediatric population.[1] The causes for this steep rise are largely environmental (rather than genetic) and a number of hypotheses have been put forward. Although the mechanisms are not fully understood, it is increasingly clear that improved sanitary health conditions are a significant contributory factor. The "hygiene hypothesis" which states that childhood exposure to bacteria and infections are important for proper maturation of the immune system has been confirmed by recent epidemiological and immunological data.[2] Some authors have suggested that excessive vaccinations are also a contributory factor.[3] These findings are in line with the principles of homotoxicology in that bacterial infections are useful in triggering the defense system into action. Homotoxicological theory predicts that blocking, reducing or preventing such early reaction phases can lead to increasing damage of the greater defense system (progressive vicariation).

The seasonal forms of allergic rhinitis are caused mainly by pollen of, for instance, olives, birches and hazelnuts. The diagnosis of allergic rhinitis can be confirmed on the basis of the anamnesis in conjunction with various allergy tests. Local nasal and ocular symptoms are sometimes accompanied by associated general symptoms such as headache due to nasal obstruction.

Conventional treatments can be effective in treating the symptoms, but are sometimes associated with side effects. A search for alternatives is therefore justified. While conventional pharmacotherapy mainly aims to treat the symptoms, homotoxicological medicine also aims to change the patient's general constitution, in order to gradually make the patient less reactive.

This study compared the effectiveness and tolerability of a homotoxicological treatment protocol with a standard allopathic treatment regimen.

METHODS

This was a comparative, mono-centre, non-randomized, prospective observational cohort study.

Patients routinely visiting an Italian pediatric practice with a clinical history of seasonal allergic rhinitis for at least one year were eligible with the exception of those with infectious diseases of the upper respiratory tract and those with chronic diseases such as diabetes, cardiopathy, chronic renal insufficiency, etc.

Patients assigned to the homotoxicological protocol were administered the following prophylactic drugs pre-seasonally:

- Luffa comp.-Heel (tablets): 1 tablet twice a day per os
- Lymphomyosot (drops): 15 drops twice a day per os

In addition, for symptomatic treatment use was made of:

- Luffa comp.-Heel (tablets): 1 tablet, three times a day per os
- Luffa comp.-Heel (nasal spray): 1 spray per nostril, 4 times daily
- Euphrasia-Heel (eye-drops, single-dose format), 2 drops in each eye, 3 times daily

Patients assigned to the standard conventional treatment regimen were treated with the following medicines in accordance with the guidelines of the European Academy of Allergy and Clinical Immunology (EAACI) 2000 consensus statement:

- Cetirizine drops: pre-seasonally as a prophylactic treatment
- Fluticasone propionate nasal spray
- Azelastine chlorhydrate eye lotion
- Betamethasone tablets: as a brief cycle, only in severe cases if symptoms are insufficiently controlled

Outcome assessment

Nasal, ocular and general symptoms were graded on a 4 point scale ranging from 0 (no symptoms) to 3 (very severe symptoms).

The following nasal symptoms were graded: itchiness, sneezing, rhinorrhea, nasal obstruction. The ocular symptoms included were: ocular itchiness, lacrimation, photophobia, eyelid edema. The general symptoms included were: headache, sleep disorders, irritability, reduced concentration, worsening of school results and reduced play-motoric activity. On the basis of the score counts, the average nasal, ocular and general symptom score was calculated in both treatment groups, as well as an overall average score which summarized all the symptoms.

Each patient had 4 examinations in total at the following time points:

- Visit 1: preliminary, 'enrollment' examination, approximately 2 months prior to the onset of acute symptoms and a few days prior to initiation of prophylactic treatment.
- Visit 2: within 72 hours of the onset of acute symptoms, shortly prior to the start of symptomatic treatment.
- Visit 3: after 3 weeks of treatment.
- Visit 4: after 6 weeks of treatment.

The three average clinical scores as well as the average clinical score for all the symptoms were compared between treatment groups at visits 1 to 4. The safety assessment was based on the occurrence of adverse events and adverse drug reactions in both treatment groups.

RESULTS

In total 111 patients with a mean age of 12.3 years (range 6 to 16 years) were included in the study. Baseline characteristics of both groups are given in Table 1. Table 1 indicates that groups were comparable on the parameters assessed. The results for the clinical symptom scores

Table 1: Characteristics of patients in both treatment groups at baseline

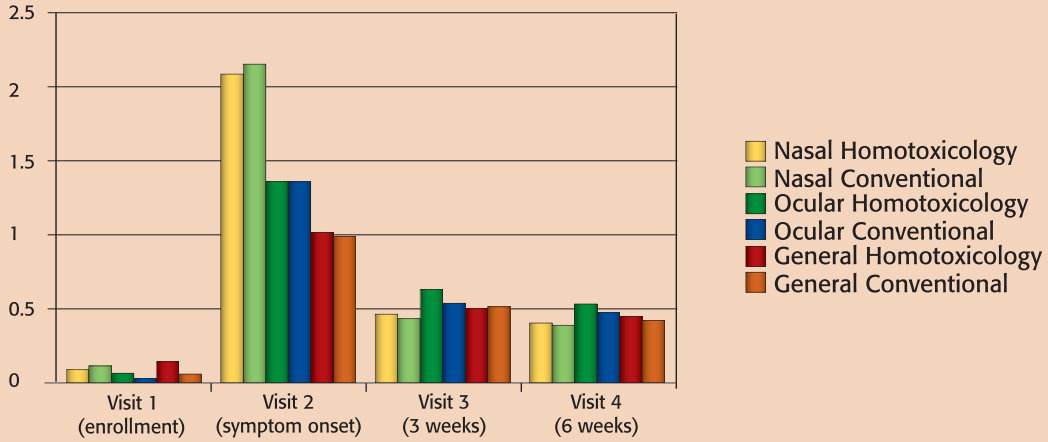
	HOMOTOXICOLOGY Group	CONVENTIONAL Group
PATIENTS GENDER (FEMALE / MALE)	57 32 / 25	54 29 / 25
Allergic Family Anamnesis		
• 1 Allergic parent	48 (84%)	46 (85%)
• 2 Allergic parents	31 (54%)	30 (56%)
• Brother and/or sister	38 (67%)	41 (76%)
• No allergic parents	9 (16%)	8 (15%)
Prick Test / Graminae (+)	56 (98%)	52 (96%)

Table 2: Summary of the nasal, ocular and general clinical symptom scores at various stages in both treatment groups

	HOMOTOXICOLOGY Group			CONVENTIONAL Group		
	TYPE OF SYMPTOM			TYPE OF SYMPTOM		
	NASAL	OCULAR	GENERAL	NASAL	OCULAR	GENERAL
Clinical Score* N						
(0:1:2:3) Visit 1	55:0:2:0	55:1:1:0	55:0:1:1	51:1:2:0	53:1:0:0	53:0:1:0
Average score	0.07	0.05	0.09	0.09	0.02	0.04
Average overall		0.07			0.05	
Clinical Score* N						
(0:1:2:3) visit 2	0:14:25:18	13:20:15:9	20:19:15:3	0:12:22:20	11:21:14:8	20:16:16:2
Average score	2.07	1.35	1.01	2.15	1.35	1.00
Average overall		1.47			1.50	
Clinical Score* N						
(0:1:2:3) visit 3	33:21:2:1	26:27:3:1	33:18:6:0	32:19:3:0	28:23:2:1	30:19:5:0
Average score	0.49	0.63	0.52	0.46	0.55	0.53
Average overall		0.54			0.51	
Clinical Score* N						
(0:1:2:3) visit 4	35:20:2:0	29:26:2:0	35:17:5:0	34:18:2:0	30:22:2:0	33:18:3:0
Average score	0.42	0.52	0.47	0.40	0.48	0.44
Average overall		0.47			0.44	

* Key to the seriousness of clinical symptoms: 0=no symptoms, 1=mildly severe, 2=moderately severe, 3=very severe

Figure 1: The average nasal, ocular and general clinical symptom severity scores at various stages in both treatment groups



in both treatment groups at visits 1 to 4 are summarized in Table 2. Table 2 indicates that the clinical and average symptom scores were similar in both treatment groups at the various points in time. The average symptom scores in both treatment groups at the various treatment stages are depicted for both groups in Figure 1. Most patients were asymptomatic at enrollment and it is clear that the great majority of symptomatic treatment effects were established after three weeks of therapy.

None of the patients in the homotoxicology group experienced an adverse drug reaction. Twenty-one patients in the conventional group reported adverse drug reactions: 9 patients (16.6%) reported drowsiness within the first 48 hours after initiation of the prophylactic treatment that was attributable to Cetirizine. (The drowsiness disappeared after 7-10 days (average 8.6 days)); 7 patients (13.0%) reported nasal burning and dryness, which was attributable to the use of fluticasone dipropionate (all these patients were able to continue treatment); 5 patients (9.25%) reported a worsening of ocular symptoms related to treatment with Azelastine chlorhydrate (drug use was discontinued in all patients).

DISCUSSION

The homotoxicological treatment regimen was effective and safe in the prevention and treatment of the acute symptoms of seasonal allergic oculorhinitis, even with regards to the rapidity of the onset of remission of acute symptoms. This was achieved without the adverse drug reactions observed in a number of patients on conventional drugs.

The rationale behind the homotoxicological treatment regimen was as follows:

- Lymphomyosot is a drainage remedy that activates the functions of the lymphatic system. It contains calcium phosphoricum, which makes it particularly useful for children with marked lymphatic reactions.[4,5] It is particularly indicated in those patients who have not completely recovered from respiratory infections contracted during the winter period.
- Luffa comp.-Heel: this homeopathic combination remedy is an effective treatment both of the constitution as well as the acute phase of allergic rhinitis. The combination of both the tablets and nasal spray (which have different, yet synergistic compositions) has proven to be effective in a multi-centre study.[6]
- Euphrasia-Heel*: this combination remedy contains euphrasia officinalis, cochlearia officinalis, pilocarpus jaborarandi and echinacea angustifolia. Based on these individual homeopathic constituents, Euphrasia-Heel is assumed to have general anti-inflammatory and detoxifying activities specifically intended for the treatment of the eyes. A prospective, controlled cohort study of 769 patients compared the efficacy of this composition and a-sympathomimetic eye drops (0.5 mg/ml tetryzoline HCl). The study included cases of mild to moderate conjunctivitis. This study revealed that efficacy of the homeopathic combination remedy was equivalent to that of tetryzoline as measured by mean symptom scores.[7]

The investigation of clinical effectiveness in routine practice is important because such studies are more representative of the "real world" of clinical practice than efficacy trials in highly selected patient populations. A limitation inherent to the chosen pragmatic approach is that it is not possible to make a statement about the effectiveness of the chosen preparations as a monotherapy.

The general aim of homotoxicological treatment of allergic rhinitis is to address the "allergy phenomenon" as a whole by treating the constitutional features as well as the acute symptoms. This, together with a good compliance profile, suggests that the chosen homotoxicological regime is a possible alternative to conventional treatments.

References

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* Euphrasia-Heel is also called Oculoheel in some countries.