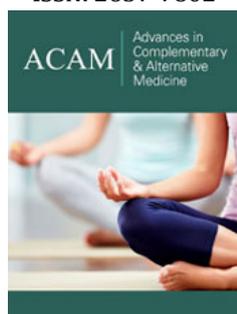


Outcomes of a Homeopathic Protocol for Allergic Respiratory Syndromes: A Retrospective Observational Study of 430 Patients at the Integrated Medicine (IM) Centre, Pitigliano Hospital-Italy

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Abstract

Introduction: Four hundred and thirty allergic patients reaching our observation in the period 2011-2015 were followed up at the IM outpatient clinics at Pitigliano Hospital Centre of Integrated Medicine. They were divided into two groups: seasonal allergies (262 patients) and year-round allergies (168 patients).

Methods: The patients were followed up at the homeopathy outpatient clinic by two homeopathic doctors for a period between one and four years. The dropouts and associated reasons have been investigated and they have been not connected to the use of homeopathic drugs. All patients were asked if they had experienced any side effects from the homeopathic treatment and none of the patients reported side effects caused by the homeopathic treatment in the follow-up phase.

Results: A strong reduction in the intensity of symptoms has been registered since the first month of homeopathic therapy for both seasonal allergies and non-seasonal allergies, along with a very marked reduction in the use of conventional drugs in 85% of patients with year-round allergies and 100% of patients with seasonal allergies. These results have been stable over the total observation period. The strength of this study is its large caseload of 430 patients, 356 of whom were followed up for more than one year and the remainder for up to four years. Furthermore, the reasons for dropping out have been ascertained.

Keywords: *Allergy; Homeopathy; Integrated medicine*

Highlights

- The "key things" to remember in this paper are:
- The use of homeopathy as an integrated non-alternative therapy;
- The use of an "extemporaneous preparation" to reduce costs and simplify the intake of homeopathic therapy;
- The patients followed up to 4 years and their high compliance;
- The disposal of conventional therapy and
- The improvement of the ESAS scale related to symptoms and SF12 items related to the impact of allergic diseases on daily activities.

Abbreviations: EFA: European Federation of Allergy; EAACI: European Academy of Allergy and Clinical Immunology; COPD: Chronic Obstructive Pulmonary Disease; IM: Integrated Medicine; PCS: Physical Component Summary; MCS: Mental Component Summary Edmonton; ESAS: Edmonton Symptom Assessment Scale; RIDIT: Relative to an Identified Distribution Integral Transformation; HIT: Homeopathic Immunotherapy

Introduction

Allergies are the third most common chronic disease in Italy (ISTAT 2015), with an incidence of 13.7% - almost a third (29.2%) higher than in the previous survey 10 years earlier (ISTAT 2005). In the same survey, the incidence of allergies in Tuscany was as follows: 10.3% in children up to 15 years of age, 19.3% of people aged 15-34 years, and 14.2% in people aged 35-64 years [1]. This is such an important issue for public health that the European Federation of Allergy and Airways Diseases Patients' Association (EFA) and the European Academy of Allergy and Clinical Immunology (EAACI) sponsored a declaration to the European Parliament in Brussels (no. 115/2016) that was signed by various members of the Council of Europe. It stated that "The Commission and the Council are encouraged to share best practices and study the possibility of a comprehensive strategy for meeting the challenges posed by chronic respiratory diseases-respiratory allergy, asthma and chronic obstructive pulmonary disease (COPD)" [2]. On this basis, a caseload of patients with allergies who had requested a consultancy at the Pitigliano Hospital Centre for Integrated Medicine (IM) [3] was investigated. The caseload consisted of patients who had attended the homeopathy outpatient clinic in the period 2011-2015 and had been followed up for up to 4 years.

The use of homeopathy in the treatment and prevention of allergies has been discussed and highlighted in a recent review by Banerjee et al. [4]. There is a limited number of studies and they do not always use the same methods as studies of conventional medicine. This does not help practitioners of conventional medicine gain confidence in the use of complementary techniques, especially homeopathy.

Materials and Methods

Design

The design of this study was used to determine if the introduction of a homeopathic "extemporaneous preparation" was useful in the reduction of allergic symptoms and if it influenced a better outcome. The study was conducted on a group of 430 chronic allergic patients, chosen randomly within those visited in our ambulatories, without a specific invitation and in conjuncture with conventional medicines. The study has been conducted retrospectively. We have examined data

on symptoms collected using an Edmonton scale symptom and the SF-12 questionnaires collected during the period of observation, to evaluate the quality of a life in these patients. The data on symptoms has been formally examined using Wilcoxon-Mann-Whitney test and a Redit analysis and the questionnaires have been evaluated comparing the answers before and after the introduction of the homeopathic protocol.

Patients

At the Pitigliano Integrated Medicine outpatient clinic, in the period between February 2011- December 2015, we visited 430 patients with allergies: 36% of the 430 patients were male and 64% were female. Their ages broke down as follows: 34.8% under 12 years of age, 26% between 13 and 30 years, 17.4% between 31 and 50 years, 17.4% between 51 and 70 years and 4.4% over 71 years (Table 1). They were divided into two groups: affected by year-round allergies (168 patients or seasonal allergies (262 patients)). At their first visit, patients were categorized by type of allergy (Table 1). The allergic diagnosis was performed prior to homeopathic examination by one of the common tests (skin or serum) routinely performed for specific diagnosis. All the patients with year-round allergies had identified their allergens: House dust mites (*Dermatophagoides farinae* or *Dermatophagoides pteronyssinus*) or flour mites (*Acarus siro*). Most patients with seasonal allergies (70%) said they were aware of the allergens to which they were sensitive, but only 30% had undergone skin prick tests and just 5% had undergone IgE blood tests; the most common seasonal allergies identified by prick tests were to grasses (70%), Parietaria, Olive tree plants, Composite (25%) and Moulds (5%). Most patients (70%) had taken symptomatic treatments (periodic or continuous) for many years, but with a poor symptom control so they decided to come to our Centre of Integrated Medicine because they wanted to know if it was possible to cure their allergy and wean themselves off the constant use of conventional medicines for the allergy season or chronic (year-round) use in the case of year-round allergies. The most commonly used conventional medicines were antihistamines (especially for seasonal allergies), while bronchodilators and cortisone were mainly used for year-round allergies. The patients were followed up at the homeopathy outpatient clinic by two homeopathic doctors for between one and four years. The dropouts and associated reasons were investigated by phone calls to patients who did not return for follow-up visits.

Table 1: Characteristics of the allergy population.

Sex	
Male	36%
Female	64%
Age	
0-12 years	34.80%
12-30 years	26%
31-50 years	17.40%
51-70 years	17.40%
>70 years	4.40%

Table 2: Prevalence of allergic syndromes (430 patients).

Prevalence of Seasonal Allergies in Patients Aged 0 to 30 Years	
Rhinitis	60%
Rhinoconjunctivitis	40%
Asthma	20%
Prevalence of Non-Seasonal Allergies in Patients Aged 30 to 70 Years	
Rhinitis	35%
Rhinoconjunctivitis	20%
Asthma	45%

Quality of life

All patients completed a questionnaire on quality of life (SF12) to evaluate the effectiveness of the integrated therapy. This enabled the investigation of two scores, the Physical Component Summary (PCS) for physical health and the Mental Component Summary (MCS) for mental health. Since Pitigliano Hospital is located in a rural area and since the questionnaire was administered predominantly to respondents with a low education level, the SF 12 was preferred over the 36-item questionnaire which many might have found longer and more complex.

Symptom assessment scale

An Edmonton Symptom Assessment Scale (ESAS) [5] was used to register each relevant symptom at each visit and to investigate any differences between the visits; the symptoms were thus taken in order of frequency, and the changes documented at each visit. This enabled the precise monitoring of the homeopathic treatment in relation to the hierarchy of symptoms. Each symptom was scored on a scale from 0-10 at the baseline (first visit) and the variation assessed at each visit thereafter.

Timing of visits

All parameters were investigated at each visit. Seasonal allergies were reviewed a second time during the period of the allergy (second visit), and the patients were then invited to return just during the following season the next year and for 3-4 years thereafter (follow-up visits), and so they returned at least once more during the year. Year-round allergies were reviewed two months after the first visit (second visit) and then every 3-4 months

for at least one year, followed by other visits every 6 months for up to 4 years (follow-up visits). In particular, the questionnaires were completed at the time of enrolment and then at subsequent checks to “take a snapshot” of the current situation; the questionnaires and the symptom scales were then processed at the time of the specific study.

Dropouts

The dropouts and associated reasons were investigated by phone calls to patients who did not return for follow-up. All patients were asked if they had experienced any side effects from the homeopathic treatment.

Comorbidities

The presence of comorbidities was also investigated (Table 3). This information is not only important for the patient’s clinical assessment but is an essential information in homeopathy to enable an all-round picture of the subject, guiding the choice above all the constitutional remedy from a holistic homeopathic perspective, and enabling consideration of what caused the patient to become allergic. In western biomedicine, the allergen (e.g. cat fur, pollen, dust mites) is thought to be the cause of the allergy, whereas from a homeopathic perspective, the person suffering the allergy has an inability to cope with a completely normal situation, namely the environment in which he or she lives. Rather than treating patients by suppressing the symptoms of their allergy or avoiding the allergen to prevent the risk of an allergic crisis, the homeopathic approach is to try to find the remedy most similar to the individual patients in their totality, to modify and adapt their response to the allergic stimulus.

Table 3: Comorbidities.

Comorbidities (present in 41% of the patient cohort)	
Gastrointestinal syndromes	35%
Chronic respiratory syndromes	33%
Dermatological syndromes	14%
Immunological syndromes (rheumatoid arthritis, lupus, thyroiditis, etc.)	18%

Homeopathic treatment

The treatment protocol was agreed by the center’s homeopaths and the homeopath responsible for the study, with the objective of treating patients in a way recognizable by all the homeopathic doctors, while taking account of their individuality. This was possible through the use of a homeopathic “extemporaneous preparations”. This is prepared on the basis of a personalized prescription comprising homeopathic remedies in relation to local and general symptoms, the habits and characteristics of each patient, and how their allergy manifests. The therapeutic remedies most frequently present in our homeopathic magistral preparations were Arsenicum album 9 or 15C; Poumone Histamine 30C; Allium cepa 9C; Euphrasia off. 9C; Nux vomica 9C; Blatta orientalis 9C; Antimonium tartaricum 9C; and Ipeca 9C. The formulation was prepared, in the form of drops, by qualified pharmacies or by Italian companies with a sector for the preparation of homeopathic “extemporaneous preparations”, purchased by the patients and used on average as 10 drops twice a day, to be taken directly on the tongue or diluted in a little water. The adoption of an integrated homeopathic “extemporaneous preparations” prescription satisfied three main requirements of the treatment provided in Pitigliano Hospital: 1) creating uniformity and reproducibility of the protocol across patients; 2) facilitating patient compliance with treatment; 3) reducing treatment costs. The average cost of the “extemporaneous preparations” was in fact just €10-15 per treatment, per patient, per month. The “extemporaneous preparations” was combined with some more “constitutional” remedies to personalize the treatment, the choice of which was influenced by any comorbidities, enabling the remedy to be customized to the individual patient. The most commonly added individualized remedies were Lycopodium 30C; Arsenicum album 30C; Silicea 30C; and Pulsatilla 30C

Seasonal allergies were most common in the 12-30 age group, breaking down as follows: 60% rhinitis, 40% rhinoconjunctivitis (of whom 20% with overlap syndromes) and 20% asthma. Year-round allergies were most common in older patients (from 31 years to >70 years), with the following prevalence: asthma 40%,

rhinitis 35%, rhinoconjunctivitis 25%. (Table 2) Compliance with treatment was very high, with 89% of patients coming back to the Integrated Medicine Centre on average twice a year. Dropouts amounted to 11%. All dropouts were contacted by phone by the centre’s nursing staff to find out the reason. Nearly half (48%) said the reason they had not returned was a significant improvement or total resolution of their symptoms, which was also the reason for stopping the treatment; the other 52% reported difficulty in reaching the Centre due to winding roads or limited public transport. In fact, the Centre can only be reached via country roads, and only by car or by the infrequent bus service; there is no railway station. We also investigated side effects: no patients reported any side effects during the homeopathic treatment period. Similarly, no patient reported side effects caused by the homeopathic treatment in the follow-up phase.

Use of conventional medicines

The patients were also asked about their use of conventional medicines during the homeopathic treatment, whether chronic or as needed to treat seasonal allergies. They mainly used bronchodilators (salbutamol, salmeterol, formoterol) and cortisones (prednisone, betamethasone, methylprednisone) or combinations of these drugs, alternating systemic administration and inhalation with a frequency of 2-3 administrations/ day. Many patients used these drugs, especially bronchodilators, at doses higher than those prescribed by their doctor. By the end of (minimum) one-year follow-up all patients with seasonal respiratory allergies had reduced their use of cortisone, bronchodilators or antihistamines to zero, while patients with year-round allergic syndromes had reduced their conventional drug use by 85-100%, as shown in (Table 4). Patients with seasonal allergies tended to use symptomatic treatments on an occasional basis, almost exclusively at times of acute flare-ups of symptoms. Monitoring of the treatment in these patients revealed that the lack of allergic symptoms in the seasonal period (associated with the presence of their allergen) coincided with the suspension of treatment (Figure 1).

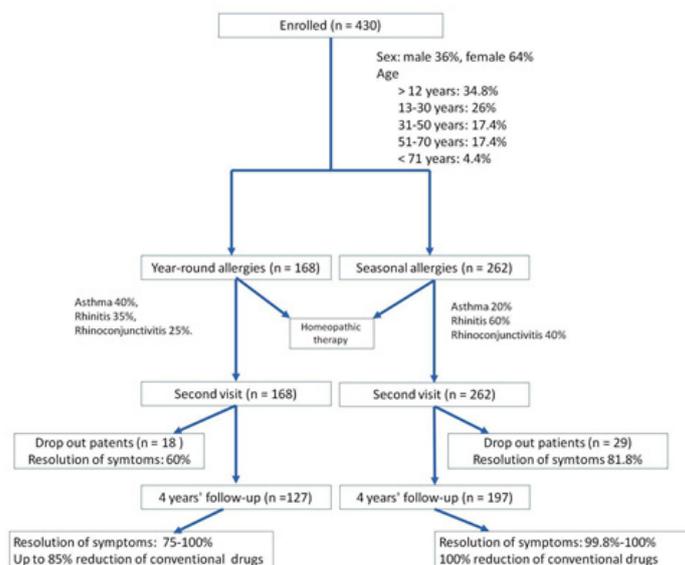


Figure 1: Outcomes flow chart.

Table 4: Conventional treatment of non-seasonal allergies (2 years' follow up).

Use of Conventional Treatment for Non-Seasonal Allergies		
	Before	After
Cortisones	90%	10%
Bronchodilators	100%	15%
Antihistamines	65%	0%

Statistical Analysis

To assess statistically significant differences in the symptoms reported at the first visit and at follow-up visits, we used the Wilcoxon-Mann-Whitney test [6]. This test is an alternative to the standard t-test, utilised to verify the hypothesis that the means of two groups are the same. The t-test assumes that the variable analysed are normally distributed in the two groups, or that the sample size in each group is very large. For the data we are analysing, this assumption is not reasonable, and we prefer to rely to the nonparametric analogue Wilcoxon-Mann-Whitney test, not requiring any distributional assumption. The test compare the null hypothesis that the allergies levels before (first visit) and after (follow-up visits) the treatment have the same distribution, versus the alternative hypothesis that the values of the Edmonton score at the first visit are generally larger than the subsequent. As usual, small value of the p-value would suggest the rejection of the null hypothesis.

As a further analysis, the mean Ridit (Relative to an Identified Distribution Integral Transformation) [7] was calculated to compare the effect of a treatment by category of responders. Ridit analysis is a statistical technique that yields a valid comparison of a treatment effect measured by ordered categorical responses. Ridit scores transform ordinal data, such as the Edmonton score,

to a probability scale, using the cumulative empirical distribution, allowing the comparison of two groups of ordinal measurements that is invariant to the category coding. In particular, the mean Ridit estimates the probability that a patient selected randomly from the first visit will have a higher Edmonton score than a patient selected randomly from the follow-up visit. Ridit test is closely related to the Wilcoxon rank sum test, as shown by Selvin [7].

While the Wilcoxon-Mann-Whitney test compares each patient's Edmonton score across the visits, the Ridit analysis compare the entire probability distribution, among all the patients or in subgroups, across the visits. In this sense, this analysis recalls a statistical model, such as a logistic regression, still avoiding inappropriate model assumptions. The results of the analysis of data from the ESAS are presented in figures. Figure 2 reports the smoothed density of the Edmonton score for patients with seasonal allergies. A strong reduction in the intensity of symptoms can already be seen at the second visit; the plot shows the Edmonton score dropping from 9-10 (mean 9.9) to 0-4 (mean 1.8), with a density that obviously shows greater variability. At the follow-up, the reduction was even greater in the entire group of patients. The range still varied from 0 to 4, but with a high concentration at 0, causing the mean to drop to 0.19. Therefore, there was a considerable reduction in the symptoms registered on the Edmonton scale, that was even more evident on follow-up. Figure 3 reports the smoothed density of the Edmonton scale for patients with non-seasonal allergies. There was a constant reduction in symptoms between the first and subsequent visits. At the first visit, the score ranged from 9-10 (mean 9.8), at the second the range was 0-7 (mean 4.3) and on follow-up it was 0-6 (mean 2.5). Therefore, there was a considerable reduction in the symptoms registered on the Edmonton scale that was even more evident on follow-up.

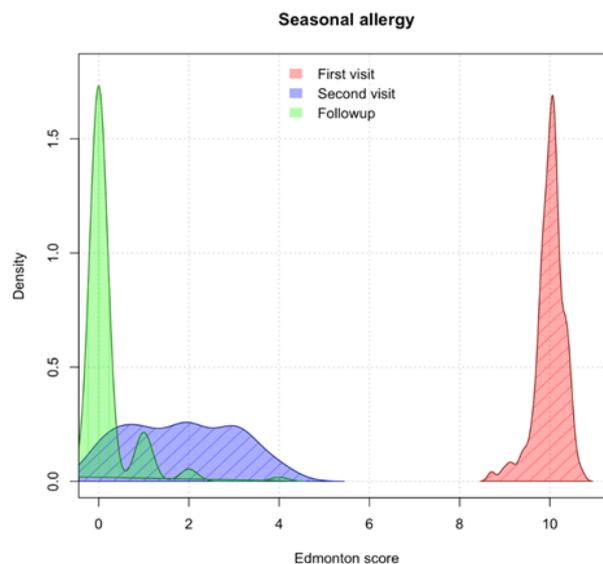


Figure 2: Observed smoothed density of the Edmonton scale at the first visit, second visit and follow-up for patients with seasonal allergies.

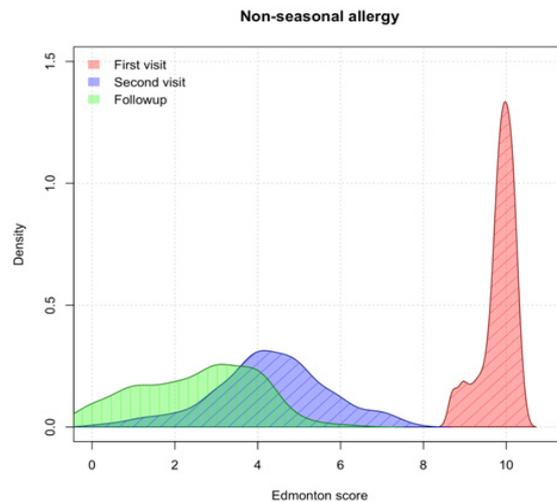


Figure 3: Observed smoothed density of the Edmonton scale at the first visit, second visit and follow-up for patients with non-seasonal allergies.

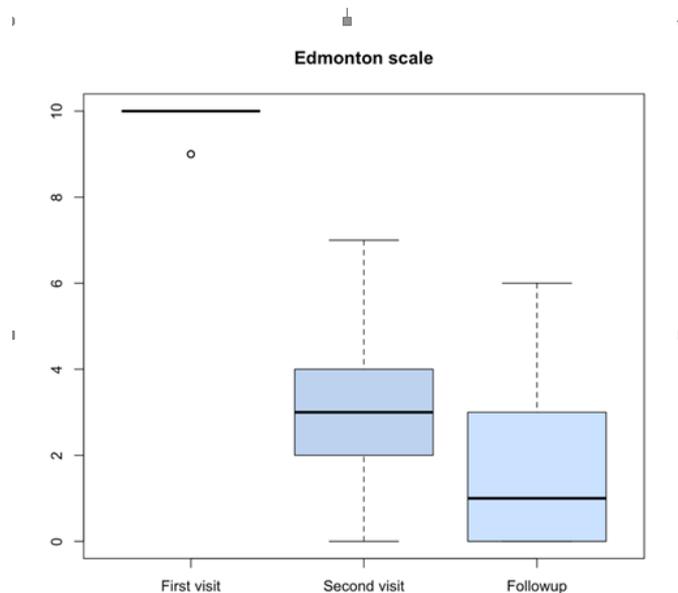


Figure 4: Boxplot for the Edmonton scale for all subjects at the first visit, second visit and follow-up.

The same analysis has been performed on seasonal allergies. Figure 4 shows the intensity of symptoms at the first, second and follow-up visits in all subjects; here too, there was a marked (60%) reduction in intensity after the first visit, followed by another, “definitive” reduction of from 75%-100% at the follow-up. This indicates that the Edmonton score, which was 10 at the first visit, had dropped to 2-4 at the second visit and 0-3 at the follow-up, calculated as the visit the longest time from the first.

The Wilcoxon-Mann-Whitney rank test for paired samples was performed to establish the significance of this reduction, evaluating if the median of the Edmonton score at the second visit and follow-up was less than the median at the first visit. As presented in Table 5, this test confirms that the difference in symptoms at the first and at subsequent visits was statistically significant. A Ridit

analysis was then performed to compare the effect of a treatment by category of responders. As seen in Table 6, the difference was statistically significant in all cases.

Quality of life questionnaire

Graphs in relation to various items of the SF12 proving significant for patients with allergies have been added to the tables. The most significant results related to the patients’ perception of health: at the first follow-up, 41.6% reported their health as good (vs. 26% on entry), 30% as very good (against 19.2%) and 15% as excellent (against 3.9%). In relation to limitation of activities of daily living as a consequence of their allergy, 50% stated that they had never or almost never experienced any limitation, against 30.7% at the baseline (Figure 5).

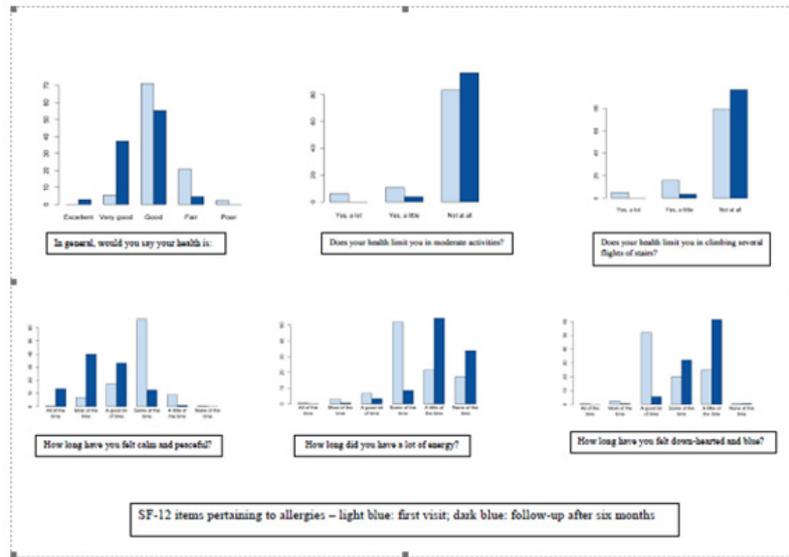


Figure 5: The most significant results related to the patients’ perception of health.

Table 5: Wilcoxon-Mann-Whitney rank test for paired samples and p-values.

Comparison	Wilcoxon-Mann-Whitney test	p-value
All patients		
First visit vs. second visit	23220	< 0.0001
Second visit vs. follow-up	15931	< 0.0001
First visit vs. follow-up	23436	< 0.0001
Non-Seasonal Allergy		
First visit vs. second visit	5356	< 0.0001
Second visit vs. follow-up	4186	< 0.0001
First visit vs. follow-up	5356	< 0.0001
Seasonal Allergy		
First visit vs. second visit	6328	< 0.0001
Second visit vs. follow-up	3828	< 0.0001
First visit vs. follow-up	6441	< 0.0001

Table 6: Ridit analysis. Mean Ridit for the first and second term of the comparison, and associated Chi-squared test.

Comparison	Mean Ridit	Mean Ridit	Chi-Squared	p-value
	First term	Second term		
All patients				
First visit vs. second visit	0.7494	0.2494	355.6489	< 0.0001
Second visit vs. follow-up	0.6305	0.3701	91.0174	< 0.0001
First visit vs. follow-up	0.75	0.25	361.3568	< 0.0001
Non-Seasonal Allergy				
First visit vs. second visit	0.75	0.25	167.7219	< 0.0001
Second visit vs. follow-up	0.655	0.345	61.5568	< 0.0001
First visit vs. follow-up	0.75	0.25	167.3944	< 0.0001
Seasonal Allergy				
First visit vs. second visit	0.7489	0.2489	189.0472	< 0.0001
Second visit vs. follow-up	0.6882	0.3134	110.6756	< 0.0001
First visit vs. follow-up	0.75	0.25	206.4036	< 0.0001

Discussion

Homeopathy has historically been associated with the treatment of allergies. However, practitioners of conventional medicine tend to be highly sceptical in relation to its use for these conditions, even though the use of microdoses of allergizing substances according to the technique of “isopathy” is a familiar technique in conventional medicine. This was the model used by Reilly [8] in the first clinical studies of the use of homeopathy in allergic syndromes. These were followed by many other studies, involving both homeopathic dilutions of allergizing substances (homeopathic immunotherapy [HIT]) and individual or mixtures of homeopathic remedies, used for respiratory and dermatological allergies. They include a double-blind study by Kim et al. [9] of the positive effects of HIT in patients with seasonal allergic rhinitis, in which the homeopathic formulation was prepared with common allergens (trees, grasses, weeds) specific to the luth- eastern United States and its effectiveness was compared against patients treated with placebo. The studies included allergy-specific symptoms using quality of life questionnaires. The conclusions were favorable to HIT ($p < 0.05$) and the subjects did not report any adverse effects Witt et al. [10] reached similar conclusions in a study using homeopathic remedies to treat patients with allergic conditions, including rhinitis and asthma. In 2010, a review by Ullmann [11], that described all published controlled clinical studies of homeopathy and allergic syndromes, reached the conclusion that homeopathy is a possible alternative to conventional treatment in allergic respiratory syndromes. However, conventional desensitizing treatment was not compared against homeopathic desensitizing treatment in any study, and the follow-up of patients treated with homeopathy was too short in many of the studies. Furthermore, most of these clinical studies did not prove to be of high quality according to the criteria of the most recent meta-analyses of homeopathic research. In Italy, Rossi et al. [12] reported the results of 13 years of outpatient experience in the integration of homeopathy with conventional treatments, finding a significant improvement in 63% of cases of allergic rhino conjunctivitis, 54% of lower airway conditions (bronchitis, asthma) and 74.1% of cases of atopic dermatitis ($p < 0.01$).

From a homeopathic perspective, although the allergen is undoubtedly part of the problem, the real problem is the terrain of the allergic individual, which needs to be rebalanced–i.e. re-adapted to the surrounding environment through the action exerted by homeopathic remedies on the individual’s defence system. To carry out this re-adaptation, complete elimination of the allergen is never advisable in homeopathy, because a true cure is tied to refamiliarization with the allergen or allergens responsible for the symptoms, given that the action of the remedy is directed towards the individual’s terrain, not the external environment. Our patients are therefore advised not to change their living environment, but to maintain only a “normal” level of cleanliness. Despite this lack of change in normal living conditions, symptoms improved considerably or even resolved completely, with a consequent improvement in quality of life. In this respect, there was an improvement in both the PCS and the MCS, as shown in the Figure

5 and in Table 1. All patients (100%) were followed up for at least one year, and 85% for up to four years. All our patients underwent homeopathic desensitization shots towards the allergen or allergens recognized as causing the allergic symptoms (isopathy). Although the principles of homeopathic and conventional desensitization are similar, they differ greatly in the dilutions used. In homeopathy, ultralow doses (30CH) are used, in which either no molecules are present or, according to the latest views, the molecules are present in the supernatant and do not change substantially in their transfer to successive dilutions [13-15]. But even in this case, the number of molecules is infinitely smaller than found in normal desensitizing compounds used in conventional preparations. A number of articles document the efficacy/effectiveness of homeopathic desensitization, including Reilly’s studies cited above and many others, such as Lewith [16]. Similar, reproducible results were achieved in patients with allergic asthma in the above-cited study by Rossi and colleagues, culminating in a study by Witt et al. [17] with a very large caseload of allergic patients and a follow-up of up to 8 years. It should be noted that in our study, given the long follow-up, the allergen was administered continuously at a dose of 3 granules in the morning for five mornings a week in the months immediately preceding and during the allergy season in patients with seasonal allergies, or continuously in the case of year-round allergies. The five-day-a-week technique was chosen empirically because in the experience of the homeopaths working at the centre, patients under long-term homeopathic desensitization treatment should be enabled to recover from the stimulus for two days a week.

In relation to the choice of constitutional homeopathic remedies, Colin [18] indicate the products used in their group of asthmatic patients. The most common constitutional remedies for paediatric patients are: *Calcarea carbonica*, *Calcarea phosphorica*, *Lycopodium*, *Pulsatilla*, and *Silicea*, while in adults, the most common are *Arsenicum album*, *Arsenicum iodatum*, *Sulfur*, *Pulsatilla*, *Natrum muriaticum* and *Sepia*. In our caseload, *Silicea* and *Pulsatilla* were used most often in children and adolescents, and *Lycopodium* and *Arsenicum album* in adults. The homeopathic “extemporaneous preparations”, used (containing, in the case of asthma, *Arsenicum album* 9 or 15C; *Poumone Histamine* 30C; *Blatta orientalis* 9C; *Antimonium tartaricum* 9C; *Ipeca* 9C, and in the case of rhinoconjunctivitis: *Poumone Histamine* 30 C; *Allium cepa* 9C; *Euphrasia off.* 9C; *Nux vomica* 9C) were combined with a constitutional remedy at a 30C dilution.

Poumone Histamine was included in the “extemporaneous preparations”, on the basis of plentiful reports in the scientific literature of the efficacy/effectiveness of homeopathic histamine, including that of Poitevln et al. [19] on the degranulation of human basophils. More recent reports also confirm the activity of homeopathic dilutions of histamine. For example, in 2004, a multi centre research group coordinated by Madeleine et al. [20] published an article in *Inflammation Research* demonstrating that the degranulation of basophils is inhibited by histamine ultra dilutions. In 2009 Bellavite et al. [21] published an article, again in *Inflammation Research*, that added important results to this argument. Their results showed that some dilutions of histamine

(namely 12CH, 14CH and 16CH) significantly inhibit basophil degranulation in comparison with the control ($p=0.001$, 0.003 and 0.009 respectively), using CD203c as a marker of cell activation. In their conclusions, the authors noted that some physical properties of the aqueous solvent could explain the results obtained with infinitesimal dilutions of histamine, referring to Demangeat [22] NMR studies of aqueous histamine dilutions.

In relation to the use of conventional drugs, we observed a very marked reduction up to 85% in patients with year-round allergies and a 100% reduction in patients with seasonal allergies over a very long total observation period. This was despite the fact that none of our patients were advised to reduce or stop taking their conventional drug/s during the homeopathic treatment: they had done this reduction independently by the first follow-up, on the basis of the progressive improvement in their symptoms. It is possible that part of this dramatic weaning off from conventional drugs seen in our caseload was due to overuse when they had not been truly necessary and/or to an excessive or excessively quick reduction due to a personal inability to carry on tolerating the side effects of these drugs. In fact, this is the primary reason that patients with allergies turn to homeopathic remedies, especially given the continuous nature of the administration of conventional drugs. It should also be borne in mind that the reduction in the use of conventional drugs, in the case of allergies, can also be attributed to variations in allergen concentrations, but it is worth noting that only 10% of patients with year-round allergies carried on using cortisone by inhalation, this important percentage of reduction cannot be attributed solely to environmental change. The limitations of this study are that it was retrospective and observational. Its strength is its large caseload of 430 patients, 356 of whom were followed up for more than one year–324 for up to four years in all. Furthermore, the reasons for dropping out were ascertained.

Conclusion

In a large caseload of patients with both year-round and seasonal allergies followed up for up to four years, homeopathy seemed to be effective in enabling them to reduce or stop their use of conventional drugs. This was not associated with a worsening of their quality of life: on the contrary, this was improved, due to the improvement in their allergy symptoms. We hope that these results help improve confidence in the much-criticized use of homeopathy to treat allergy.

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