

THE HOMOEOPATHIC TREATMENT OF SEASONAL ALLERGIC RHINITIS

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I, E.C.POOLMAN, DO HEREBY DECLARE THAT THIS DISSERTATION
REPRESENTS MY OWN WORK BOTH IN CONCEPTION AND IN
EXECUTION

.....

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ABSTRACT

The purpose of this study was to evaluate the efficacy of simillimum and allergen treatment to patients allergic to mixed grass pollens in terms of patients' responses to RAST and patients' perception of the effectiveness of treatment in order to identify key issues calling for the selection of the most effective method of treatment.

Twenty patients suffering from seasonal allergic rhinitis were admitted to the study if they met the selection criteria: a positive RAST response to mixed grass pollens and a clinical history of seasonal allergic rhinitis for at least two years. Patients were recruited through advertising in the media and shopping centres.

These 20 patients were randomly allocated to one of two experimental groups. The one group received the selected simillimum treatment and the other group received the selected simillimum and the

homoeopathically prepared allergen (mixed grass pollens), for a period of three months. The remedies were prepared according to the Homoeopathic Pharmacopoeia and dispensed by a qualified pharmacist at the Department of Homoeopathy, Technikon Natal.

Before and during treatment the patients completed symptom score sheets to assess their perception of the effectiveness of the treatment. RAST tests were performed before and after treatment. Non-parametric statistical analysis of these results within the same group were performed by using the Wilcoxon test. Analysis between groups were done using the Mann-Whitney-U test.

Statistically there was a significant difference in the RAST scores of patients who received simillimum ($Z=0,045$), where $Z < 0,05$ reflects significance. There was no significant change in the RAST scores of patients receiving allergen and simillimum ($Z = 0,073$). No significant difference was noted in the RAST scores between groups before and after treatment ($Z = 0,348$ and $Z = 0,294$ respectively).

A statistically significant change occurred in the total values of both groups' symptom scores before and after treatment (Reading 0 and Reading 9). In the simillimum group $Z = 0,024$ (61,37%) and in the simillimum-allergen group $Z = 0,0043$ (74,96%). Patients in both groups thus had a significant improvement in clinical symptoms and signs, with a 13,59% greater improvement occurring in the simillimum-allergen group. There was, however, no significant difference between the two groups' symptom score sheets before and after treatment ($Z = 0,307$ and $Z = 1$ respectively).

Another significant change that occurred in both groups was between Reading 4 and Reading 5: $Z = 0,009$ in the simillimum group and $Z = 0,024$ in the simillimum -allergen group, where symptoms were also greatly reduced between Reading 7 and Reading 8 ($Z = 0,0020$).

In conclusion it can be said that all the patients benefitted from the homoeopathic treatment of seasonal allergic rhinitis, but even more so when

the homoeopathic allergen is combined with simillimum. All the patients in the simillimum-allergen group accentuated the immediate relief experienced by taking the allergen in acute hay fever attacks. This is recommended as the homoeopathic treatment of choice for seasonal allergic rhinitis, taking care of acute and chronic symptoms and signs.

UITTREKSEL

Die doel van die studie was om die uitwerking van simillimum en allergeen-behandeling vas te stel in pasiente wat allergies is vir grasstuifmeel. Dit was gemeet in terme van pasiente se reaksie op RAST-toetse en hulle waarneming van die effektiwiteit van behandeling soos weergegee in vraelyste, sodat riglyne in verband met die behandeling geïdentifiseer kon word.

Twintig pasiente wat aan hooikoors ly is tot die studie toegelaat as hulle aan onder meer die volgende vereistes voldoen het: 'n positiewe RAST-toets vir gemengde grasstuifmeel en 'n kliniese geskiedenis van hooikoors die afgelope twee jaar. Pasiente is gewerf deur middel van advertensies in die media.

Die 20 pasiente is willekeuriglik in een van twee eksperimentele groepe ingedeel. Een groep het die gekose simillimum en die ander groep het die simillimum en die homopaties-voorbereide allergeen

ontvang. Die studie het oor drie maande gestrek.

Die medisyne is voorberei volgens die Homopatiese Pharmacopoeia en is deur 'n gekwalifiseerde apteker, verbonde aan die Department van Homopatie, Technikon Natal toegedien.

Voor en gedurende die studie het die pasiente gereeld vraelyste ingevul om hulle waarneming van die medisyne se effektiwiteit te bepaal. RAST-toetse is voor en na die studie gedoen. Non-parametriese statistiese ontleding van die resultate is gedoen volgens die Wilcoxon metode in dieselfde groep en die Mann-Whitney-U-toets tussen die groepe.

Daar was 'n beduidende statistiese verskil in die RAST-toetse van die simillimum groep ($Z = 0,045$), waar $Z < 0,05$ beduidend is. Daar was geen statistiese verskil in die RAST waardes van die simillimum-allergeen groep nie ($Z = 0,073$) en ook nie in die vergelykende waardes tussen die groepe voor en na die studie nie ($Z = 0,348$ en $Z = 0,294$ respektiewelik).

'n Statisties beduidende verskil is gevind tussen die totale waardes van die vraelyste in dieselfde groep voor en na die studie (Lesing 0 en Lesing 9), as volg: simillimum-groep $Z = 0,024$ (61,37%) en in die simillimum-allergeen-groep $Z = 0,0043$ (74,96%). Pasiënte in albei groepe het dus gebaat by die behandeling, maar die groep wat die allergeen gebruik het, het 'n groter verligting van simptome ondervind (13,59%). Wanneer die groepe se vraelyste voor en na die studie vergelyk was, was geen beduidende verskil gevind nie ($Z = 0,307$ en $Z = 1$ respektiewelik).

'n Beduidende verskil wat in albei groepe na vore getree het, was tussen Lesing 4 en Lesing 5 : $Z = 0,009$ in die simillimum groep en $Z = 0,024$ in die simillimum-allergeen groep. In laasgenoemde groep is 'n beduidende verskil ook tussen Lesing 7 en 8 ($Z = 0,002$) aangeteken.

Ter opsomming het alle pasiënte dus baat gevind by die homopatiëse behandeling van hooikoors, veral die pasiënte in die simillimum-allergeen-groep. Hulle het dit ook beklemtoon dat onmiddellike

verligting ondervind was met die gebruik van die
allergeen gedurende 'n hooikoors aanval. Die
homopatiëse behandeling wat dus aanbeveel kan word
en wat verligting van akute en kroniese simptome
bring, is die daaglikse gebruik van die allergeen
en van 'n noukeurig gekose simillimum.

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DEFINITIONS

SIMILLIMUM: Latin word designating medicines whose proving includes the symptomatic group which is closest to the characteristic symptoms of a morbid condition (Demarque, 1986).

INTRODUCTION

Much research has been done on allergic rhinitis in various fields, including homoeopathy, which has been found successful in treating allergies (Poitevin,1990). Most studies, however, do not explain the factors involved in selecting the most effective method of treatment to elicit cure, nor do they demonstrate that there is a cure for this condition.

Hay fever is one of the commonest complaints of upper respiratory tract infections, debilitating many people during spring and autumn (Haus, 1987). The homoeopathic principle of "like cures like" regarding simillimum and allergen treatment was investigated in this study. The results pointed toward the most effective homoeopathic cure of the disease including the immediate relief of symptoms. Although no statistical difference existed between the before- and after trial RAST results, all the patients benefitted clinically, whether taking simillimum only or allergen and simillimum.

When it can be demonstrated repeatedly with future studies that homoeopathy cures the pathology and increases the general state of well-being of patients, it can be recommended universally as the preferred method of treatment. This will decrease the absenteeism in the labour force and will increase the production and financial gain for both employer and employee. The patient will be healthier, leading to less medical costs and increased socio-economic well-being.

Homoeopathy is accessible to most people and anyone can thus benefit from the application and use thereof. In the effect of individuality of symptoms and signs the principle of homoeopathy removed or alleviated rare symptoms, like one-sidedness of complaints, which usually were discarded in other therapeutic practices. The side-effects - sleepiness, dizziness, nausea, etc - that so often occur in allopathic treatments, were not encountered, demonstrating that Homoeopathy is a reliable, safe and cost-effective therapeutic practice.

CHAPTER ONE: THE PROBLEM AND ITS SETTING

1.1 THE STATEMENT OF THE PROBLEM

This study proposed to evaluate the efficacy of simillimum and allergen treatments to patients allergic to mixed grass pollens in terms of patient responses to radio-allergosorbent tests (RAST) and patients' perception of the effectiveness of treatment in order to identify the key issues calling for the selection of the most effective method of treatment.

1.2 THE STATEMENT OF THE SUBPROBLEMS

1.2.1 The first subproblem.

The first subproblem is to evaluate the efficacy of simillimum treatment of allergic patients in order to determine the extent of the selected treatment and its curative value.

1.2.2 The second subproblem

The second subproblem is to qualify the efficacy of simillimum and allergen treatment of allergic patients when these treatments are combined to evaluate the curative properties of the selected treatment.

1.2.3 The third subproblem

The third subproblem is to analyse and interpret the treated data in order to identify key issues calling for the selection of the most effective method of treatment.

1.3 THE HYPOTHESES

1.3.1 Hypothesis one.

It is hypothesized that simillimum treatment will have a significant effect on the patients' general state of well-being in terms of the patients' perception of the treatment, but not such an effect on the patients' responses to RAST.

1.3.2 Hypothesis two.

It is hypothesized that simillimum and allergen treatment comined will have a high correlation with the patients' responses to RAST and to their perception of the effectiveness of the treatment - thus improving the patients' general state of well-being and curing the pathology.

1.3.3 Hypothesis three.

It is hypothesized that simillimum treatment will characteristically be selected when the patients' general state of well-being is affected and a low RAST is recorded. The combination of simillimum and allergen treatment will be selected when the patiens have significantly raises IgE levels and a debilitated state of well-being.

1.4 THE DELIMITATIONS

1. The patients selected for this study had to be able to attend the clinic at least once a week.

2. This study did not attempt to identify the different potencies for different symptoms and signs, although potencies of selected remedies were stated.

3. Patients sampled for this study were older than 14 years of age.

4. This study did not attempt to explain the mechanism of action of the homoeopathic medicine.

1.5 THE ASSUMPTIONS

1.5.1. It was assumed that patients took their medication according to prescription.

1.5.2 It was assumed that patients replied to questions asked on symptom score sheets honestly

and accurately.

1.5.3 It was assumed that pollen counts during the experimental period remained between known levels (Appendix A).

1.5.4 It was assumed that the Homoeopathic remedies, because of their nature, did not cause any anaphylactic reactions.

1.5.5 It was assumed that the pathogeneses of the remedies used were correct.

1.5.6 It was assumed that the remedies were prepared as set out in the Homoeopathic Pharmacopoeia.

1.5.7 It was assumed that the participants in the trial made no lifestyle changes.

CHAPTER TWO: REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

One of the commonest complaints the general practitioner encounters daily during the hay fever season is seasonal allergic rhinitis, or hay fever. Research has shown that the incidence of atopic disease is increasing (Haus, 1987). For these reasons hay fever and its related aspects such as immunology and physiology have been the focus of much ongoing research in many disciplines, including homoeopathy (Reilly, McSharry, Taylor and Aitchinson, 1985; Kleijnen, Kniipschild and Ter Riet, 1992).

2.2 IMMUNOLOGY AND PHYSIOLOGY

Hay fever, being a Type I Immediate hypersensitivity response (Solomon, Schmidt and Adragna, 1990), elicits the release of Ig E from sensitized cells. Degranulation from mast cells occur and the inflammatory process starts.

Immuno-allergy is especially suited to homoeopathic treatment because of the large number of homoeopathic remedies used to treat acute and chronic inflammatory syndromes (Poitevin, 1990).

2.3 CLINICAL TRIALS

However, in homoeopathy few clinical trials of good quality have been recorded (Kleijnen, et al., 1992), although much has been written on the treatment of allergies (Hahnemann, 1983; Hunton, 1985; Wallace, 1986; Poitevin, 1990). Thus it appears that it is desirable for homoeopathy to be evaluated - not only will this verify experiments done, it will also demonstrate the clinical success of thousands of homoeopathic physicians (Poitevin, 1990; Kleijnen, et al., 1992).

2.4 HOMOEOPATHY

The physician who practices classical homoeopathy usually prescribes one remedy, the simillimum. This method has been used since the origination of

homoeopathy (Kent, 1961; Hahnemann, 1983). Modern life, and because of patients' impatience, however, do not allow for the remedy to be administered and the patient to wait days, weeks or sometimes months for alleviation of symptoms. The current method of treatment is the administration of one or more frequent doses of the simillimum. This method was applied in this trial.

The impracticality of true classical homoeopathy lead to the advance of combination remedies, which are often used in over the counter prescriptions. The classical homoeopath will not use these (Kleijnen, et al., 1992), nor were they used in this trial. Another method of treatment in homoeopathy is the administration of the causal agent, for example mixed pollens in hay fever, also called isopathy (Jouanny, 1980). Isopathy, in combination with the selected simillimum is the other method of treatment to be used in this study.

The writer intended to show a difference in the pathology, symptomatic and general health spheres of the patients receiving the selected treatments,

and identified key issues calling for the selection of the method of treatment.

It was already statistically demonstrated by Reilly, et al., 1985, that homoeopathy is not a placebo response. This study also reflected the high success rate of desensitization of allergic patients with the causal agent. Whether simillimum treatment has the same results was researched in this study.

2.5 INSTRUMENTS OF MEASUREMENT

In order to objectively measure the response of patients to the selected forms of treatment, RAST-assays (Toerien, 1990; Emanuel, 1992) and symptom score sheets (Andersson, Svensson, Andersson and Pipkorn, 1989) were used. RAST assays have been used extensively since the early 1970's to detect total and specific IgE respectively for the diagnosis of allergic disease (Emanuel, 1992). In this study specific IgE was used, according to the Pharmacia CAP System. This system's test results correlate closely with positive Phadebas RAST

results and permit improved discrimination especially in the very low and very high concentration ranges (Leimgruber, Peitrequin, Mosimann, Claeys, Seppey, Jaccard and Pecoud, 1989).

The grass pollen allergen, because of its binding capabilities to the solid phase, is more likely than other allergens to give a high positive result. This was to the study's advantage, because when the patient had a higher sensitivity, the readings reflected changes more readily when they occurred. Previous studies, however, found that, in most cases, RAST scores were unchanged after one year of allopathic hyposensitization and treatment (Kato, Nakai, Ohashi and Kato, 1991).

Mixed reaction is usually encountered when allergy skin tests are mentioned (Weinberg, 1990). Professional colleagues either regard the tests as very complex and difficult to carry out or as very simple to perform with no side effects (Turkeltaub, 1989; Weinberg, 1990).

There are specific guidelines for safe and correct performing of these tests, which must be followed to make this test reliable (Ramsay, 1992). For this reason skin prick tests were not selected.

When compared to in vitro tests such as the measurement of circulating serum levels of Ig E by the use of radio-allergosorbent tests (RAST), no statistical difference was found between S P T and RAST (Berman, Boggs, Lee and Leonardy, 1988; Finnerty, Summerell and Holgate, 1989).

Saha, 1993, has found that although S P T are excellent for screening, demonstration of specific IgE antibodies combined with the history of symptoms to the allergen in question is a definite proof of IgE mediated diseases.

The use of two or more methods are, however, preferred to enhance the reliability of the research.

The symptom score sheets used to assess the patients' progress measured the patients'

perception of their condition and of the effectiveness of the selected treatment. This allowed the researcher to get an overall picture of the experimental results which included objective pathological test (RAST) and subjective feedback from the patient. These selected forms of measurement allowed a better understanding of the functioning of the remedies. It also reflected the conditions where and when physiological and/or pathological intervention occurred.

In order to establish reliability and validity of clinical trials in homoeopathy, Kleijnen, et al. (1992), put forth several criteria to be met, such as the patients' characteristics adequately described; the number of patients analysed; randomisation; intervention well described; double blinding; effect measurement relevant and well described; and presentation of the results in such a manner that the analysis can be checked by the reader. Although this trial was not able to meet all the criteria, the researcher was aware of them and tried to make allowances for the enforced shortcomings such as small groups.

This study thus endeavoured to provide a better understanding of homoeopathy and to demonstrate a method of treatment for hayfever without side-effects. This is in contrast to allopathic treatment of hay fever that provides amelioration or suppression of symptoms with treatments such as anti-histamine and cortisone, which may have serious side-effects (Davidson, 1991).

2.6 ALLOPATHIC MEDICINE

The three methods that are used in allopathic medicine are the avoidance of the allergen; pharmacotherapy; and desensitization (Kay, 1992). Although avoidance of allergen has been used for decades, its disadvantage is the change in lifestyle, which is not always possible.

The second method of pharmacotherapy offers a wide range of medications that treat the acute allergic condition and offer preventative intervention. Kay (1992) named cromoglycates, nasal steroid sprays, antihistamines and decongestants as the mainstay of treatment.

The third and last method is immunotherapy, or desensitization. This may be the treatment of choice in patients who do not benefit sufficiently from anti-allergic drugs (Kay, 1992). It did not, however, show great evidence of clinical improvement or long-term cure (Ewan, et al., 1988), and is not used in the United Kingdom because of the recommendations of the Committee on Safety of Medicines in October 1986 (Kay, 1992).

2.7 CONCLUSION

In summation it can be said that a better understanding of simillimum and allergen treatments and the factors that affect these, was reached by the application of a methodological clinical trial even though all the criteria set by Kleijnen, et al. (1992), were not met.

CHAPTER THREE: MATERIALS AND METHODS

3.1 Selection of Patients

Twenty patients suffering from seasonal allergic rhinitis due to a grass pollen allergy, as evidenced by their clinical symptoms and histories, were selected from the Technikon Natal Homoeopathic clinic on the basis of the following criteria:

1. Patients aged over 14 years - because younger patients are not able to complete the symptom score sheets.
2. A clear history of seasonal allergic rhinitis for two previous years at least.
3. Currently active hay fever with or without eye symptoms, excluded if only eye symptoms were present.
4. No evidence of acute infection or acute asthma and no severe chronic illness other than hay fever.
5. Patients must not be pregnant or lactating.
6. Before entering the study patients must not

have received topical antihistamines	
	-12 hours
systemic antihistamines or steroids	-24 hours
long action antihistamines	-4 weeks
chromoglycate or any analogue	-24 hours
systemic steroids	-one week
topical steroids	-2 weeks
depo-steroids	-8 weeks

7. No such drugs are to be used during the study except selected "escape antihistamines".
8. No other homoeopathic treatment or pollen or grass-allergy therapy must be used.
9. Consent was obtained from participants.

3.2 RAST-testing.

The Rast tests were performed according to the Pharmacia CAP-system (Pharmacia Diagnostics AB Uppsala, Sweden). Patients had to test positive to the serum specific IgE test consisting of Bermuda, Rye, Timothy, Meadow, Kentucky Blue, Johnson and Bahia Grass.

3.3 Design of the study

Patients were randomly allocated to one of two experimental groups and referred to as numbers according to their chronological order of receiving the first treatment. RAST-testing was done before and after the trial - only patients who tested positive to the RAST were admitted to the trial. During the study patients' perception of the effectiveness of treatment was noted on symptom score sheets (Appendix B). Patients had to sign a consent form (Appendix C).

3.4 Symptom score sheets

During the trial the patients' severity of symptoms were recorded every two weeks on symptom score sheets (Appendix B). The patients also noted the quantity of antihistamines taken during the period.

3.5 Medication

Homoeopathic preparations of simillimum and

allergen were supplied by a recognised manufacturer and dispensed by a qualified pharmacist.

Instructions regarding the treatment differed according to the selected remedies and potencies.

3.6 Statistical analysis

Statistical analysis was done with nonparametric tests. The Wilcoxon Signed Rank test was used to determine statistical significance within each group and the Mann-Whitney U-test for assessing significance between the two groups.

CHAPTER FOUR: RESULTS

4.1 Homogeneity of groups

Table I indicates the characteristics of patients in both groups. There was no significant difference between the groups.

TABLE I: COMPARISON OF GROUPS

	MALE	FEMALE	AGE
SIMALL	4	6	32,2+/-13
SIMIL	6	4	20,4+/-6

4.2 Mixed grass-pollen serum specific IgE (RAST)

Rast scores decreased significantly ($Z = 0,045$) in the simillimum group but not in the simillimum-allergen group ($Z = 0,073$). Table II indicates the results of the RAST tests before and after treatment.

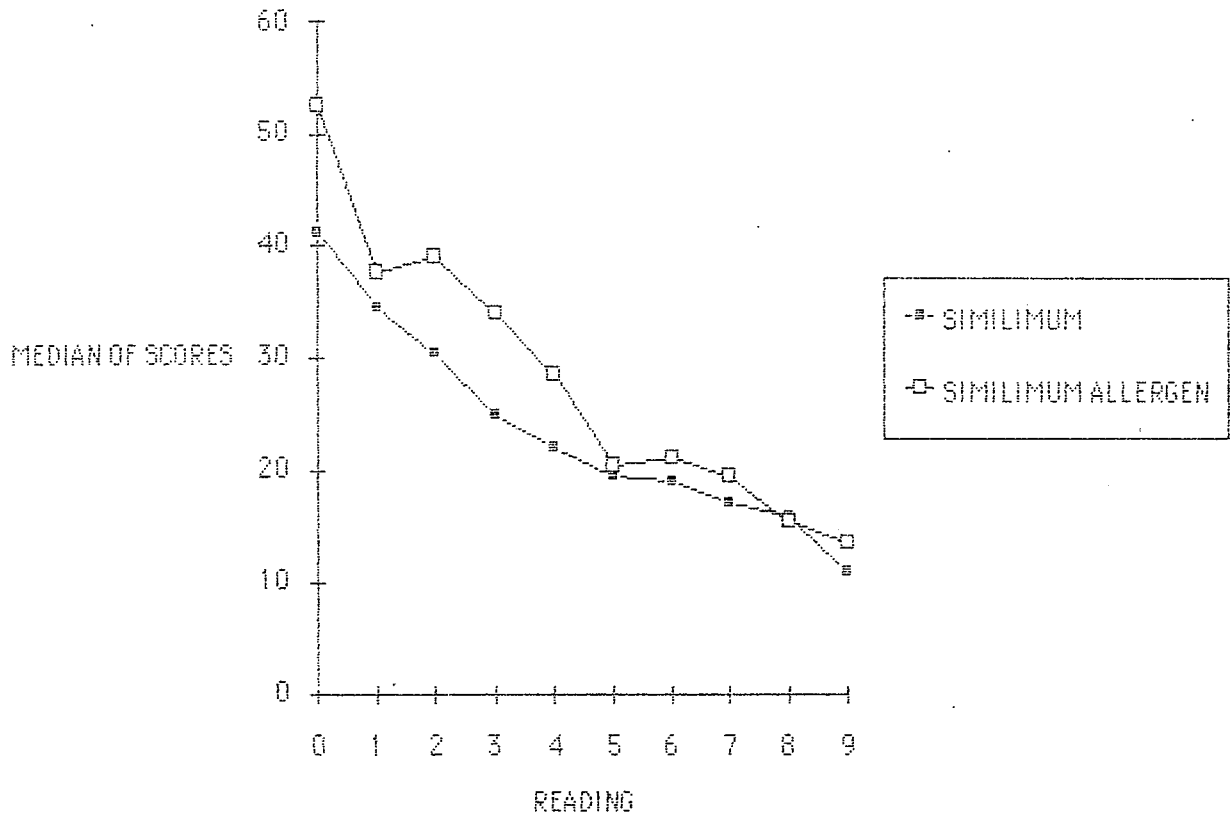
TABLE II: OVERALL OUTCOME OF RAST TESTING AT THE
END OF TREATMENT

	DECREASE	SAME	TOTAL
SIMALL	2	8	10
SIMIL	1	9	10

4.3 Symptom scores

Symptom scores were significantly ($Z = 0,024 - 61,37\%$) reduced in the simillimum group and in the simillimum-allergen group ($Z = 0,0043 - 74,96\%$). Graph I depicts these reductions.

GRAPH 1: REDUCTION IN SYMPTOM SCORES



4.4 Correlations between parameters studied

There was no significant difference between the RAST tests between groups before and after the trial ($Z = 0,348$ and $Z = 0,294$ respectively), nor between the symptom scores before and after treatment ($Z = 0,307$ and $Z = 1$ respectively). However, a similar significant reduction ($Z = 0,009$ in simillimum and $Z = 0,024$ in simillimum-allergen group) occurred between Reading 4 and Reading 5 and between Reading 7 and Reading 8 ($Z = 0,0020$) in the simillimum-allergen group (Graph 1).

4.5 Remedies prescribed

Table III depicts the remedies which were selected as simillimum and their frequency and potencies.

TABLE III: FREQUENCY OF REMEDIES PRESCRIBED

<u>REMEDIES</u>	<u>15CH</u>	<u>9CH</u>	<u>TOTAL</u>
ARSENICUM ALBUM	1		1
ARUNDO DONAX		3	3

<u>REMEDIES</u>	<u>15CH</u>	<u>9CH</u>	<u>TOTAL</u>
CALCIUM CARBONICUM	1	1	1
LACHESIS MUTUS		2	2
LYCOPODIUM CLAVATUM	6	1	7
NATRUM MURIATICUM	8	3	11
NUX VOMICA		1	1
PSORINUM	3		3
PULSATILLA	2	1	3
SEPIA OFFICINALIS	1		1

CHAPTER FIVE: DISCUSSION

The patients who took part in this study were recruited from advertisements in the regional daily newspapers, in shopping centres and libraries. Those who met the selection criteria were randomly allocated, according to a predesignated method to one of two treatment groups. Various patients who had the required symptoms and signs had to be excluded from the study because of the extreme sensitivity of the RAST tests. The disks used tested for sensitivity to Bermuda, Rye, Timothy, Meadow, Kentucky Blue, Johnson and Bahia grass pollens, but not for sensitivity to the very common grasses like Kikuyu. No patients dropped out of the study. There were two periods of intake - July/August and October because of the poor response to advertising in June. Thus all patients were exposed to at least one month of high grass pollens presence (Appendix A). There was no correlation between the high pollen count and the symptom scores - symptom scores in both groups in both periods show the same tendency (Graph I).

This study demonstrated that the Homoeopathic management of seasonal allergic rhinitis is effective and offers an improvement of symptoms of at least 50 % for all patients. It is also able to alleviate an acute attack immediately.

This improvement was demonstrated by the statistical significance between the initial and final questionnaires of both groups. Patients who received simillimum had a 61,37% improvement of symptoms ($Z = 0,024$), whereas patients in the simillimum-allergen group had a 74,96% improvement ($Z = 0,0043$). This indicates a 13,59% greater improvement in the simillimum-allergen group although no statistical significance existed between the initial and final symptom scores of both the groups.

Clinically all patients reported an increased sense of well-being and a reduction in sensitivity to grass pollens. These changes occurred progressively, but in both groups a marked improvement occurred after 6 to 8 weeks of treatment

(Reading 4 and Reading 5). These changes were statistically significant: $Z = 0,009$ in the simillimum group and $Z = 0,024$ in the simillimum-allergen group. A possible explanation for this is that the simillimum, which was prescribed to both groups, reached its maximum effect after 6 weeks.

The significant improvement that occurred between Reading 7 and Reading 8 in the simillimum-allergen group had no correlation with grass pollen counts (Appendix A) and can be ascribed to the effect of the homoeopathic prepared allergen.

The objective method used to diagnose the condition, Pharmacia CAP System, permits an increased sensitivity to specific IgE (Leimgruber, et al, 1989). This method is widely used as a diagnostic tool (Bousquet et al, 1988) but did not reflect many changes in the groups. Only 3 out of the 20 patients had decreased RAST scores. This correlates with previous studies (Kato et al, 1991) that found that, in most cases, RAST scores were unchanged after one year of allopathic

hyposensitization and treatment. In those cases where a change occurred, the treatment was clinically rated as unsuccessful. It is interesting to note that the patient in the simillimum group (Patient 4), who had a reduction in RAST score, had no significant improvement of symptoms. He was also the youngest patient (14) in the study. This can be reflected in the study of Kato et al, 1991, that found that RAST positivity was directly proportional to an increase in the age of the patients and the duration of the disease.

The patients in the simillimum-allergen group who had a reduction in their RAST scores (Patients 9 and 10) were those whose prescriptions were repeated more often than the other patients'. Patients in this group also commented on the immediate relief experienced when the homoeopathic allergen was taken during hay fever attacks. They compared this with the effect of antihistamines / cortisone and found that the homoeopathic allergen worked just as effectively, even when they were

exposed to direct contact with the allergen, for example on golf courses.

Patients in the simillimum group did not complain of a postnasal drip or sinusitis, whereas in the other group three patients (Patients 5,6 and 10) reported aggravations of these symptoms after the second and third weeks of treatment. These symptoms were progressively ameliorated toward the end of the study.

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

CONCLUSION:

The purpose of this study was to identify the key issues calling for the selection of the most effective homoeopathic treatment of seasonal allergic rhinitis.

Issues that were identified to be important in the choice of treatment were the presence of chronic symptoms like chronic sinusitis, headaches and a post nasal drip. When these symptoms were present the likelihood of aggravations were increased, especially in the group that also received the allergen. Those patients took longer to react to the treatment. It was thus imperative for those patients to receive a remedy other than the allergen -simillimum - to experience an increased sense of well-being.

In the same respect, people who often had severe acute hay fever attacks, expressed their concern in

finding some treatment that alleviates the acute symptoms. The patients in the simillimum-allergen group found that the homoeopathically prepared allergen had that effect. The patients in the simillimum group had an increased sense of well-being, but not the immediate relief during an attack.

The most effective treatment for seasonal allergic rhinitis thus was found to be the homoeopathically prepared allergen, prescribed on a daily basis and when necessary, in conjunction with the simillimum on a weekly/chronic basis to cure or prevent symptoms like chronic sinusitis and headaches.

RECOMMENDATIONS

In order to establish reliability and validity of clinical trials in homoeopathy, trials have to meet several criteria (Kleijnen, et al, 1992). One of the shortcomings of this trial was the limited number of patients. It is recommended that future trials be done with at least 30 patients in each

group in order to extrapolate the results to the general population. This will also establish the reliability and validity of the study. A treatment period of at least one year and continued monitoring of the patients after conclusion of the study is also recommended.

The objective diagnostic tool, RAST, that determines specific IgE sensitivity, was used as a basis for statistical analysis, but was found lacking in respect of quantitative monitoring of sensitivity of patients. It is also extremely specific and did not include all the grass pollens found in the Natal region. This must thus rather be used as one of many screening methods in combination with tests like nasal provocation and skin prick tests.

If the RAST-tests are used, it is recommended that the disks used are modified to include common grass pollens like Kikuyu, which presently is not included on the disks.

Clinical analyses like symptom score sheets were better reflections of the patients' sense of well-being; of the quantitative improvement of symptoms experienced and where these changes occurred.

Another recommendation is an extended study involving groups that receive placebo, allergen only, simillimum only and allergen and simillimum combined. This will more accurately point towards the most effective homoeopathic treatment of seasonal allergic rhinitis.

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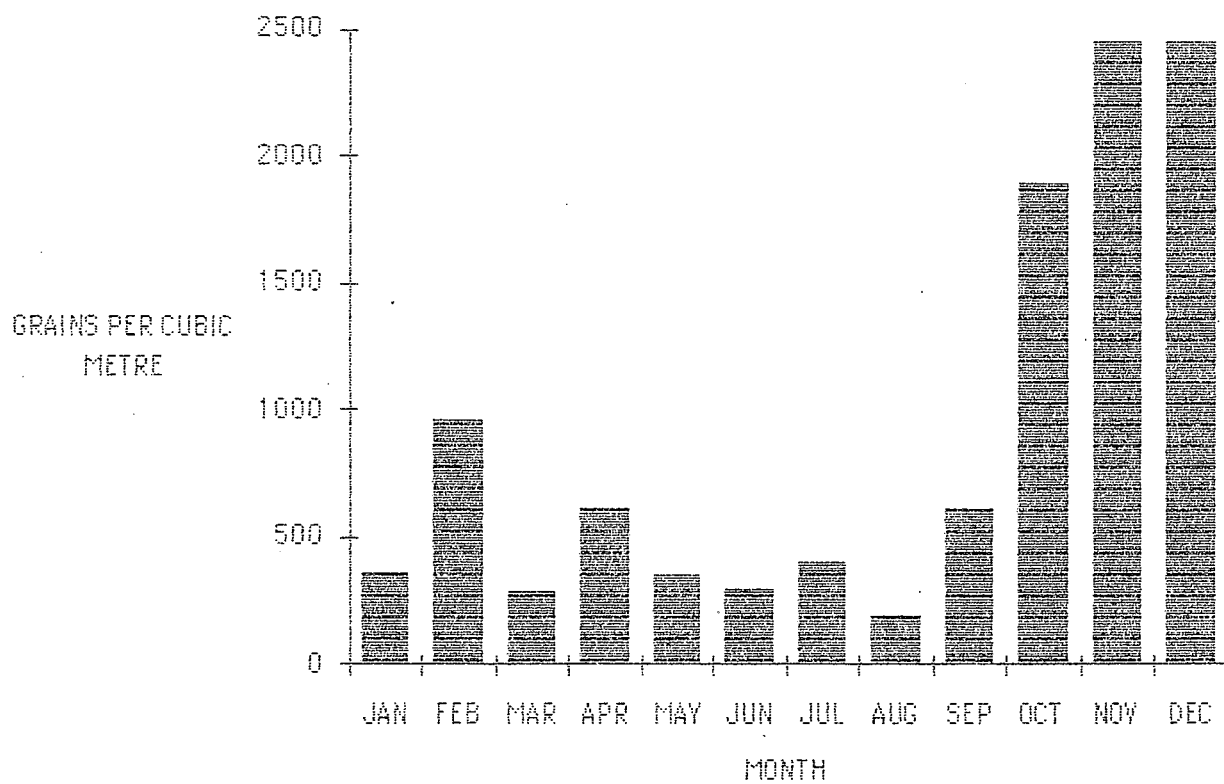
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APPENDIX A

GRAPH 2: MEAN GRASS POLLEN COUNT



Symptom score sheet

Patient's name:.....

Date:.....

Instructions: Grade the severity of the following symptoms on a scale of one to ten by circling the appropriate number next to each question.

- 0 = no symptoms
- 1 = mild symptoms
- 10 = very severe

For question (9) rate the overall severity of your symptoms on the scale provided by making a mark at the appropriate level of severity on the line provided.

1. Sneezing

0....1....2....3....4....5....6....7....8....9....10

2. Blocked nose

0....1....2....3....4....5....6....7....8....9....10

3. Runny nose.

0....1....2....3....4....5....6....7....8....9....10

4. Watery eyes

0....1....2....3....4....5....6....7....8....9....10

5. Irritated or itching eyes

0....1....2....3....4....5....6....7....8....9....10

6. Itching palate

0....1....2....3....4....5....6....7....8....9....10

7. Itching ears

0....1....2....3....4....5....6....7....8....9....10

8. Itching nose

0....1....2....3....4....5....6....7....8....9....10

9. Overall severity of symptoms

0....1....2....3....4....5....6....7....8....9....10

1 = very mild

10 = very severe

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PATIENT CONSENT FORM

TITLE:

File number:

I,..... on this day of1993, agree to participate in the above mentioned research project at the Homoeopathic Day Clinic, Technikon Natal in Durban.

I hereby declare that I understand and agree to abide the patient instructions and research conditions attached.

I am aware that any research document or questionnaire responses will be identified by file number and the name of the patient and that I shall not have access to any files, so that objectivity of results is assured.

Name:

Signature.....

Witness :.....

Signature.....