THE EFFICACY OF HOMOEOPATHIC MIGRAINE COMPLEX ON MIGRAINE HEADACHES

BY

Claudia Aleotti

Dissertation submitted in partial compliance with the requirements for the Master's Diploma in Technology in the Department of Homoeopathy at the Technikon Natal.

I, Claudia Aleotti, declare that this study represents my own work in both concept and execution.

..... 28/11/1997
date

Approved for final submission

..... 28/11/1997
date

Dr BH Cawood M.B. B. Ch.(Rand)
SUPERVISOR

Place of submission: Durban Date: November 1997

DEDICATION

To my parents and my grandfather for their patience, love and support given to me during the past five years.

ACKNOWLEDGMENTS

I would like to offer my sincere appreciation and thanks to the following people:

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ABSTRACT

The purpose of this investigation was to evaluate the efficacy of a Homoeopathic Migraine complex, consisting of Iris Versicolor, Spigelia Anthelmia and Sanguinaria Canadensis, in the treatment of migraine headaches, in terms of the patients perception with respect to the frequency, severity and duration of the migraine attacks, to determine what role the Homoeopathic Migraine complex plays in the management of migraine headaches.

It was hypothesized that the use of the Homoeopathic Migraine complex would reduce the frequency, severity and duration of migraine attacks in known migraine sufferers.

In this placebo-controlled clinical trial, a sample of thirty-four patients complying with the International Headache Society criteria for migraine, and experiencing two or more migraine attacks per month, was selected from the greater Durban area in response to advertisements, that had been placed in various advertising media. They were asked to sign a patient consent form and were then randomly divided into two equal groups. The treatment group received the Homoeopathic complex, while the control group received placebo treatment. The study was double blind and the medicine was dispensed by an independent party.

Questionnaires in the form of a case history and a Pain Disability Index, were completed. These were done before commencement of the treatment and every four weeks thereafter for a period of three months, to note the patients perception of the treatment. Emphasis was placed on frequency, duration and severity of migraine headaches, regarding the pain, nausea, vomiting, phono- and photophobia, limitation of motion, and effect on quality of life.

By the end of the study, four patients had dropped out. All data obtained from the questionnaires, of the remaining thirty patients was depicted on spreadsheets. Statistical analysis was conducted using non-parametric tests. The Wilcoxon signed rank test was used to determine statistical significance within each group, and Mann-Whitney U test for assessing significance between the two groups. Graphs and tables were then drawn up to aid in the analysis of the results.

The results showed that at the end of the study, there was a statistically significant reduction ($P = 0.0007$) in the frequency of migraine headaches experienced by the treatment group (Graph 4.1). Initially, 9 patients suffered from 1 or more migraines a week, while the remaining 6, had 2 or more migraines a month. During the last month of the study, only 6 patients reported having 2 or 3 migraines, 4 patients reported having 1 migraine, and 5 patients experienced no migraines. The severity of migraines experienced by the treatment group, was also significantly reduced ($P = 0.0004$). Initially, all 15

patients suffered moderate to severe migraines (Graph 4.3). At the end of the study, only 6 patients fell into this category.

The treatment group had also showed statistically significant improvements with regard to duration of migraine headaches (P =0.007), and associated symptoms such as nausea (P =0.0007), vomiting (P = 0.002), photo- (P = 0.0004) and phonophobia (P = 0.0004), and aggravation by movement (P = 0.0004).

Those patients who were still experiencing occasional migraines, and where the severity and duration of the migraine had not improved, may have benefited from the use of a more individualised Homoeopathic remedy.

In conclusion this study showed that the use of the Migraine complex was successful in reducing the frequency, duration and severity of migraine headaches, in the majority of patients treated, as well as alleviating the symptoms related to migraine, such as nausea, vomiting, photophobia, phonophobia, visual disturbances and aggravation by motion. As a result, patients reported reduced consumption of allopathic medication, and an improved quality of life.

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LIST OF ABBREVIATIONS

IHS - International Headache Society

5-HT - 5-Hydroxytryptamine or Serotonin

CH - Centissimal Hahnemanian

NSAID - Non-steroidal anti-inflammatory drugs

DEFINITION OF TERMS

Placebo:- For the purpose of this study, the placebo was in the form of lactose pills, which had not been impregnated with Iris Versicolor 9CH, Sanguinaria Canadensis 9CH, Spigelia anthelmia 9CH, or any other substance.

Migraine:- a symptom complex characterised by periodic headaches, sensory and, or gastric disturbances.
According to IHS classification, migraine is when a patient has experienced at least 5 headaches lasting 2-72 hours with at least 2 of the following: unilateral, pulsating, moderate/ severe pain, aggravated by movement; and at least 1 of the following: nausea, vomiting, photophobia, phonophobia.
Migraine with aura:- at least 2 attacks fulfilling 3 of the following criteria: 1 or more reversible aura symptom;
1 aura symptom lasting for more that 4 minutes or 2 or more successive symptoms; 1 aura symptom never lasting more than 60 minutes; Free interval of less than 60 minutes of headache before or with aura.

Migraine complex:- Consists of Iris Versicolor 9CH, Spigelia anthelmia 9CH, and Sanguinaria canadensis 9CH.

Polypharmacy:- This method encompasses any prescribing technique in which two or more remedies are prescribed *simultaneously*, either in alternation with each other or as a combined formula.

CHAPTER ONE

INTRODUCTION

Migraine is a burden to the individual as well as to society. It is an ancient disease which occurs commonly and sufferers alternate between periods of being completely symptom-free and enduring periods of pain, suffering, and disability. (Holms 1992.) It is poorly diagnosed and only a minority of migraine sufferers seek medical attention. (Stewart and Lipton 1993.)

Migraine is an episodic headache that lasts between 2 - 72 hours. The pain may be moderate to severe, and may be accompanied by any combination of the following symptoms: throbbing, unilateral pain, aggravation by motion, nausea, vomiting, phonophobia and photophobia. Visual or sensory disturbances may precede or accompany the headache.
The severity of all these symptoms prevent a migraine sufferer from going about their normal daily schedule for the duration of the migraine. (Edward and Bouchier 1991: 851.)

Epidemiological studies report that about 10% of the global population suffer migraine headaches. In South Africa, the prevalence of migraine is between 10 - 15% irrespective of race. (Stang 1993.)

An analysis of data from the 1989 National Health Interview Survey, concerning migraine occurrence and impairment, revealed that nearly 10 million individuals in the United States, had migraine. Migraineurs were bedridden for about three million days per month and had an estimated 74,2 million days per year of restricted activity. This resulted with a productivity loss of $1.4 billion per year. (Stang and Osterhaus 1993.)

The cost to migraine sufferers is further increased with costs of consultations to doctors, drugs, tests and hospital admissions. Pain is the most important symptom for the individual patient, but disability may be the most important consequence of migraine for an increasingly cost-conscious society. (Lipton et al. 1994.)

For the migraine patient, the threat of attacks and the severity of the symptoms damage personal relationships, family life and career advancement. They are associated with an increased prevalence of depression and panic attacks (Breslau and Davis 1992), and so far migraine treatment is elusive and patients are becoming increasingly frustrated and dissatisfied with treatment outcomes (Sheftell 1993).

Current allopathic management of migraine includes the use of beta-blockers, calcium channel blockers, antidepressants, anticonvulsants, nonsteroidal anti-inflammatory agents and sumatriptan (Baumel 1994). This treatment can be very expensive, and have negative side effects such as drug dependence (Worz 1994).

There is much literature about the Homoeopathic remedies used to treat headaches and migraines, but very few controlled studies on the subject exist. Investigations have been conducted into the use of bowel nosodes as an extension of Homoeopathic treatment for migraine (Mount 1973), and the effect of diet and a constitutional Homoeopathic remedy on migraines (Fox 1990).

Maximizing the quality of life for migraine sufferers through more effective management is vital (Holms 1992). Homoeopathic treatment is non-toxic due to the successive dilutions and thereby eliminates the risk of overdose. It is a highly individualized process which looks at the patient as a whole in his reaction to disease or environmental stress. (Jouanny 1991: 17.) Although polypharmacy or complex prescribing should not be the first line of treatment, there is a high degree of similarity between the symptom pictures of the remedies in the complex and those displayed by a migraine sufferer. It could thus be used as an emergency remedy, or when the simillimum is uncertain. This complex is relatively inexpensive and will, therefore, be within the economic reach of most migraine sufferers. Should the complex prove to be remedial during this investigation, it may be extremely useful as a symptomatic Homoeopathic remedy for migraineurs. Further benefits would include an enhanced output in the work place yielding higher profits; as well as improved psychological states which will reflect on the patients' physical performance, and their relationships with colleagues and family members.

The purpose of this investigation was to evaluate the efficacy of a Homoeopathic Migraine complex in the treatment of migraine headaches, in terms of the patient's perception with respect to the frequency, severity and duration of the migraine attacks, in order to determine what role the Homoeopathic Migraine complex plays in the management of migraine headaches.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 Introduction:

Data from the 1989 National Health Interview Survey concerning migraine occurrence and impairment was analyzed to assess the impact of migraine on the US population. About four in every one hundred persons in the United States were found to have migraine, accounting for nearly 10 million individuals. Migraine was most prevalent in those aged 25 - 44 years and was about 2.5 times more frequent in females than males. Migraineurs were bedridden for about three million days per month and had an estimated 74,2 million days per year of restricted activity due to migraine. The cost of lost productivity was estimated at $1.4 billion per year for the estimated 6,196,378 migraineurs who worked outside the home. (Stang and Osterhaus 1993.)

2.2 Clinical features:

Migraine is characterised by episodic headache, which is typically unilateral and often associated with vomiting and visual disturbance. In many patients, however, the headache is bitemporal and generalised and there may be no associated focal, visual or neurological disturbance.

The condition usually starts after puberty, although it is common in children as well, and continues until late middle life. Migraine attacks occur at intervals which vary from a few days to several months, and last for about 2 - 72 hours. Premonitory symptoms in the form of zig-zag lines, flashing coloured lights, or defects in the visual field occur in some patients, and in others dysphasia, hemiparesis or hemianaesthesias may develop in association with the headache, and begin several hours before the aura or the headache. The headache is usually localised to the frontal region and spreads to affect the whole of one side of the head, but may become generalised. The pain is severe and throbbing and may be associated with nausea, vomiting, photophobia, pallor, and prostration. The two types of migraines include:

* Migraine with an aura: visual or sensory symptoms precede or accompany the headache eg. basilar artery migraine;
* Migraine without an aura: there are no visual or sensory features, only headache, nausea, vomiting and photophobia. (Edwards and Bouchier 1991: 851.)

Prodromal symptoms usually last about 2 days, and are followed by an aura which can last up to an hour. The headache begins soon after the aura and can last up to 3 days. It is followed by the resolution phase and then the recovery phase in which the patient feels tired and has a limited food tolerance. This can last for 2 days after which the patient returns to what is normal for him. (Blau 1987: 4.)

Migraine is associated with increased lifetime rates of major depression, anxiety disorders, illicit drug use disorders, nicotine dependence, and suicide attempts. Migraine suffers are more likely to report job absenteeism, use mental health services and assess their general health as fair, or poor. (Breslau and Davis 1993.)

2.3 Pathogenesis:

Migraine has a well-recognized clinical picture but a poorly understood pathogenesis. It can be described as being a neurovascular reaction to sudden changes in the internal or external environment. (Lance 1993.)

There is a decrease in cerebral blood flow at the onset of an attack and relative oligemia may result in focal disturbance of cortical function, particulary in the occipital and parietal lobes. During the phase of headache, there is dilation of the extracranial arteries, which may be related to fluctuations in blood 5-hydroxytryptamine (5-HT) levels. (Edwards and Bouchier 1991: 851.) Platelet 5-HT decreases during an attack, and increased levels of metabolites are found (Silberstein 1994).

The mechanism of migraine has been presented as an unstable trigeminovascular reflex with a segmental defect in the pain control pathway. This defect permits excess discharge of part of the spinal nucleus of the trigeminal nerve and its thalamic connections in response to excessive afferent input or corticobulbar drive. The end result is the interaction of

brain stem and cranial blood vessels, with the afferent impulses from the latter creating the throbbing character of the headache. Diffuse projections from the locus ceruleus to the cerebral cortex possibly initiates cortical oligemia and spreading depression. Activity in this system could account for the migrainous aura that may occur quite independently of the headache. (Lance 1993.)

It is believed that disruption of central sensory processing mechanisms during a migraine episode increases sensitivity to quiet sounds, and contribute to phono- and photophobia. (Woodhouse and Drumond 1993.)

2.4 Causes:

It has been shown that migraine with and without aura are genetically determined by chromosome 19 (Ophoff et al. 1994). Approximately half of the patients who suffer from migraine each have an affected relative, thus strongly suggesting a genetic predisposition. Triggers or dietary factors, including chocolate, cheese, and alcohol may precipitate attacks, and episodes may occur more frequently peri-menstrually or in patients taking oral contraceptives. (Edwards and Bouchier 1991: 851.) Prolonged emotion or tension is the most common precipitant of migrainours attacks (Raskin 1988: 51).

2.5 Management:

According to Baumel 1994, current management of migraine usually centres on two approaches: preventive (prophylactic) and abortive (acute) therapy. Preventive therapy, designed to reduce the frequency, duration, and intensity of attacks, can be accomplished through a wide variety of medications. The most commonly used are:

Beta-blockers: eg. propranolol. Not all beta-blockers are effective. Drowsiness, lethargy and cold extremities are common side-effects, and the potential to bronchospasm limits their use in patients with respiratory disease. (Findley et al. 1992.) A side-effect of prolonged use of Beta-blockers is depression. Migraineurs are already at risk (Breslau et al 1994) and do not need added risk.

Calcium channel blockers: Have an effective response but the effect is slow to develop and side-effects such as dizziness, headache and flushing are common (Findley et al. 1992.)

5-HT antagonists eg. pizotifen, methysergide. 25% - 50% of patients respond to treatment. It can cause nausea and vomiting,dizziness and weight gain (Findley et al. 1992.)

Commonly used are also *Anti-depressants* eg. Prozac, Aropax. *Anti-convulsants* eg. Rivotril and *Nonsteroidal anti-inflammatories*. Long term use of these therapies have side-effects such as dependence and gastric ulcers. Agents used in

abortive migraine therapy treat the intensity and duration of pain, as well as the associated symptoms. (Baumel 1994.)

Simple analgesics: eg. aspirin, paracetamol etc, are often combined with anti-emetics to improve absorption of simple analgesics. In practice many migraine patients find simple analgesics inadequate. Frequent administration is necessary to control symptoms, thereby running the risk of analgesic abuse or dependence, as well as progressive deterioration of pain control and renal impairment. (Findley et al. 1992.)

Non-steroidal anti-inflammatory drugs (NSAID): eg. naproxen, ibuprofen. These have limitations similar to those of analgesics. Nausea and vomiting may be compounded by NSAIDs due to their gastric irritant effects. (Findley et al. 1992.)

Erogotamine: This is limited by contra-indications, particularly in migraineurs with concomitant cardiovascular conditions, and by intolerance. Nausea and vomiting are common side-effects as well as rebound headache or toxicity. (Findley et al. 1992.)

Sumatriptan: Very effective agent, but extremely costly. (Baumel 1994.)

2.6 Homoeopathic treatment

Homoeopathic treatment was formulated by Samuel Hahnemann and is based on the principle "similia similibus curentur" - let like be cured by like. This law formulates the parallel action between the toxicological power of a given substance and

it's therapeutic action, i.e. administering a patient a weak or infinitesimal dose of a substance which, when administered to a healthy person, causes symptoms similar to those exhibited by the ill patient. Dilution and potentisation enhances the curative properties of a substance and looses all poisonous side effects. (Jouanny 1991: 12-14.)

There is a definite gap in the homoeopathic studies on migraines. There is much literature about the remedies used to treat headaches and migraines however, very few controlled studies on the subject exist. Investigations have been conducted into the use of bowel nosodes, such as Bacillus Morgan, Proteus, Morgan Gaertner, Dys Co., Sycotic Co, as an extension of Homoeopathic treatment for migraines (Mount 1973), but these are not frequently indicated. Other studies relate to the treatment of migraine by diet and a constitutional Homoeopathic remedy (Fox 1990). The remedies used included Aconitum napellus, Arnica montana, Apis mellifica, Argentum nitricum, Arsenicum Album, Belladonna, Bryonia alba, Calcarea carbonica, Dulcamara, Hepar Sulphuris, Iris Versicolor, Kalium carbonica, Kalium phosphoricun, Lachesis mutus, Lycopodium clavatum, Medorrhinum, Natrum muriaticum, Natrum sulphuricum, Nux vomica, Pulsatilla praetensis, Rhus toxicodendron, Sanguinaria canadensis, Silicea, Sepia, Sulphur and Thuja. This study demonstrated 81% improvement, but was conducted in private practice, and was not double blind.

The complex used in this study, is an example of disease-based polypharmacy, whereby multiple remedies are prescribed solely on the basis that they all have a degree of similarity to a particular disease process, without due regard for individual peculiarities. Low potencies are more frequently employed and the prescription is repeated usually on a daily basis. (Watson 1992: 71.)

It is important to understand the symptom pictures (relating to migraines) of the 3 remedies used in the migraine complex.

IRIS VERSICOLOR

Sick headache in forehead and eyes beginning with a blur before the eyes, especially after relaxing from a mental strain; intense noises in the ear; constriction around forehead, dull throbbing; constant nausea and vomiting; deficient appetite; constipation; weakness; symptoms worse on the right and in the evenings; periodical. (Hering 1991: 266; Boericke 1992: 365.)

SANGUINARIA CANADENSIS

Congestive headaches with throbbing pain; hurting as if eyes would be pressed out; begins in the occipital region and spreads upwards, settling over the right eye; veins and temples are distended; periodical; begins in the morning, increases during the day, and lasts until evening; aggravated by noise, smells, motion and light. Relieved by sleep, pressure, perfect quiet in a dark room, passing gastric or intestinal gas; nausea with salivation; burning vomiting; tired headache from

mental or physical exertion. Pain in the back of head "like a flash of lightning." (Mathur 1989: 798; Jouanny 1984: 357; Boericke 1992: 542.)

SPIGELIA ANTHELMIA

Throbbing pains in the head beginning in the occiput and radiating to the vertex and frontal region, finally coming to rest above the left eye; Vertigo; Aggravated by noise, motion, jolts; photophobia; periodical; redness and lachrymation of eye on affected side. Comes on at sunrise worse at noon and better at sunset; Painful stiffness of neck and shoulders. (Mathur 1989: 838; Jouanny 1984: 380.)

The symptom pictures of the remedies in the migraine complex correspond closely to all the signs and symptoms experienced by a migraine sufferer during a migraine attack, which is the reason for choosing these remedies.

The theoretical advantage of disease based polypharmacy, is that by combining the most commonly prescribed remedies, the practitioner is able to bypass the necessity to individualise each case and give every migraine sufferer the same prescription. The assumption is either that whichever remedy in the combination is most similar to the migraine of the person being treated will act and the other, non-indicated remedies will do nothing, OR that a group of remedies known to bear similarity to the typical symptoms of migraine will, collectively, bring about a response. (Watson 1992: 72.)

The ultimate aim of all treatment is to alleviate the patients discomfort, and thereby improve their quality of life.

CHAPTER THREE

MATERIALS AND METHODS

3.1 STUDY DESIGN AND PROTOCOL

Advertisements requesting participation in a clinical trial involving homoeopathic treatment of migraines were placed on notice boards at the Technikon Natal, as well as in the local newspapers. Those individuals responding to the advertisements were screened. If they complied with the diagnostic criteria for migraine, either with aura or without aura, as determined by the Headache Classification Committee of the International Headache Society (IHS) 1988, and experienced two or more migraine attacks per month, they were accepted into the study, and required to sign a patient consent form. (Appendix A.)

A minimum number of 30 participants were obtained by convenience sampling. This study followed a double-blind protocol with an independent party dividing the sample into a control and treatment group. The treatment group was instructed to dissolve 5 pills of the migraine complex (consisting of Iris Versicolor 9CH, Spigelia Anthelmia 9CH and Sanguinaria Canadensis 9CH) twice a day on waking and at bedtime, when they were between attacks, and hourly during attacks, for a period of three months. The control group was instructed to follow the same instructions, but were given a

placebo in the form of lactose pills.

Both groups were required to complete a questionnaire constructed by the researcher, and the Pain disability Index developed by Pollard (1984) [Appendix B], before commencement of the treatment, and every 4 weeks thereafter for a period of three months, to note their perception of the effectiveness of the treatment.

The participants were requested not to change their lifestyle (eg exercise, smoking) and eating habits for the duration of the trial in order to minimise sources of variation.

All questionnaires were administered and analyzed by the researcher, to ensure consistency.

3.2 SUBJECTS

Patients of any age, sex or race, who were diagnosed as migraine sufferers and experienced at least two migraine attacks per month, were admitted to the study.

The diagnostic criteria for migraine according to the International Headache Society (1988) was used:

MIGRAINE WITHOUT AURA:

* at least 5 attacks lasting 2-72 hours
* at least 2 of the following:
    - Unilateral
    - Pulsating
    - Moderate or severe; affecting daily activity.
    - Aggravated by physical activity

* at least 1 of the following:
    - Nausea
    - Vomiting
    - Photophobia
    - Phonophobia

MIGRAINE WITH AURA:

* At least 2 attacks fulfilling 3 of the 4 criteria below:

- One or more reversible aura symptoms
- At least 1 aura symptom lasting for more than 4 minutes or 2 or more successive symptoms
- One aura symptom never lasting more than 60 minutes
- Free interval of less than 60 minutes of headache before or with aura.

3.3 ETHICS

Patients accepted into the study were asked to continue taking any allopathic medication that they were on, and not to change their lifestyle in any way. Medication taken by patients was noted and any change in amount of consumption was taken into consideration. With-holding the Homoeopathic treatment from patients in the placebo group did not, in any way, further decrease the quality of life of these patients. At the end of the study, the patients in the placebo group were given 3 months free supply of the Homoeopathic Migraine complex, so that they too, could benefit from the effects of the study.

3.4 INTERVENTIONS

The migraine complex containing Iris Versicolor 9CH, Spigelia anthelmia 9CH and Sanguinaria canadensis 9CH was prepared by a qualified Homoeopathic pharmacist in terms of the criteria laid down by the British Pharmacopoeia (Bhattacharyya 1980: 10). It was dispensed in the form of lactose pills not larger than 2,5 mm in diameter, which were triple impregnated at 1% volume/volume with the migraine complex.

The placebo was in the form of unimpregnated lactose pills not larger than 2,5mm in diameter. Both the treatment group and the control group were instructed to dissolve five pills of their respective medication under their tongue twice a day, on waking and at bedtime, when they were between attacks, and hourly during attacks, for a period of three months.

3.5 MEASUREMENT AND OTHER OBSERVATIONS

Information regarding the patients' perception of the treatment, was gathered from the patient in the form of a case history questionnaire constructed by the researcher, and the Pain Disability Index developed by Pollard (1984) [Appendix B]. This was done on initial consultation i.e. before commencement of the treatment, and every four weeks thereafter for a period of three months. All information was gathered by the researcher. The IHS criteria for migraine was in written form

on the questionnaires and checked by Dr Cawood for consistency of diagnosis.

3.6 STATISTICAL ANALYSIS

Each month all data obtained from the questionnaires was depicted on spreadsheets. Each group in the study had only 15 members, thus statistical analysis had to be done using non-parametric tests. The Wilcoxon signed rank test was used to determine statistical significance within each group, and Mann-Whitney U test for assessing significance between the two groups. These tests were selected due to the less restrictive assumptions and near equivalence in sensitivity to the T-test (Siegal 1956). Graphs and tables were then drawn up to aid in the analysis of the results. All this was done with the necessary guidance of the statistician.

CHAPTER FOUR

THE RESULTS

CRITERIA GOVERNING THE ADMISSIBILITY OF THE DATA

Only that primary data collected in the case history questionnaire and Pain Disability Index, completed under the researcher's personal supervision, and the secondary data obtained by the researcher from various literary sources, was used.

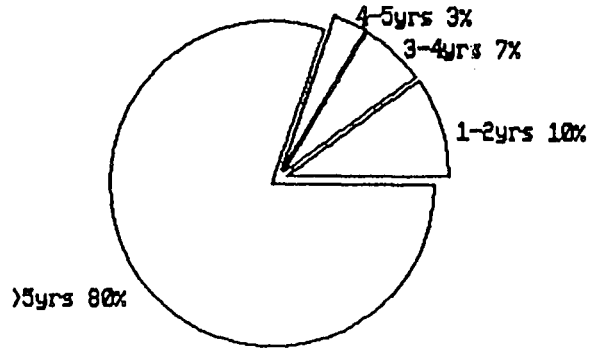
Only patients who were classified as migraine sufferers according to the International Headache Society's diagnostic criteria for migraines (1988), were admitted to the study.

Only patients who experienced at least two migraine headaches a month, were admitted to the study.

This chapter will demonstrate data obtained from patients at the initial consultation (before treatment had commenced), and the final consultation (after 3 months). More detailed data is set out in appendix C.

* The age of the sample group ranged from 19 - 64 years.
* The sample group comprised of 24 females, and 6 males.

* **The amount of years suffering from migraines:**

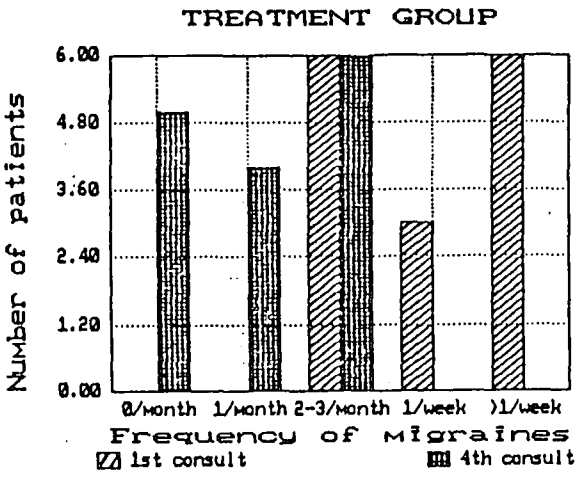


Graph 4.0

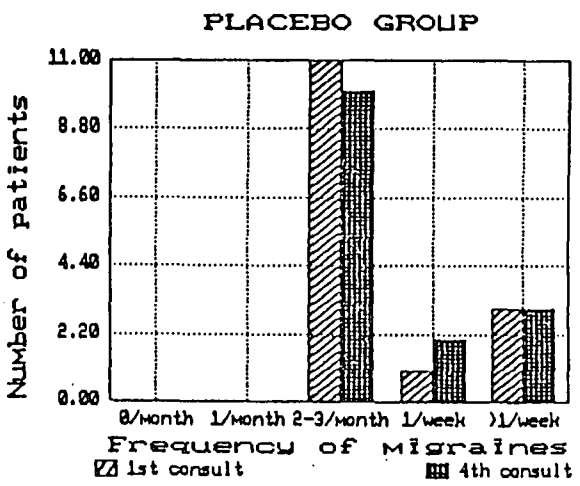
The sample group was well chosen, as 80% had suffered from migraines for longer that 5 years.

* 29 patients stated that there was at least one other member in their family who suffered from migraine headaches.

* **Frequency of migraines:**



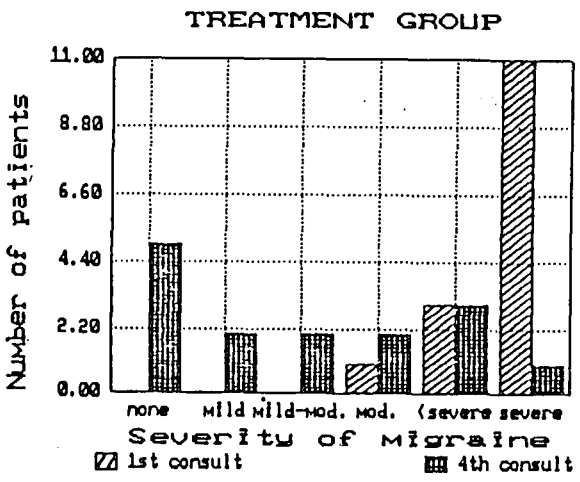
Graph 4.1



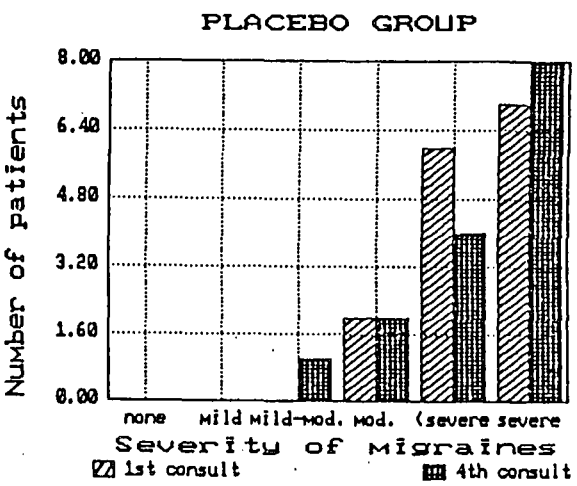
Graph 4.2

On preforming the Wilcoxon signed rank test between the initial and final consultation, it was found that the treatment group showed a statistically significant reduction in frequency of migraine attacks at the 5% level of significance (P = 0.0007), while the placebo group showed no change (P = 0.31). According to the Mann-Whitney U test, there was a statistically significant difference between the treatment and placebo groups for the duration of the study.

* **Severity of the migraines:**



Graph 4.3

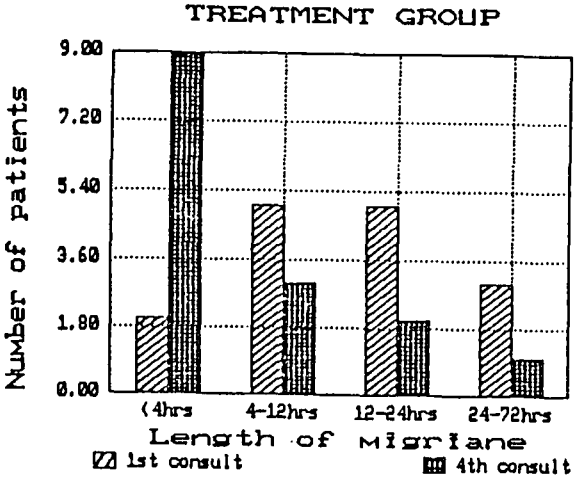


Graph 4.4

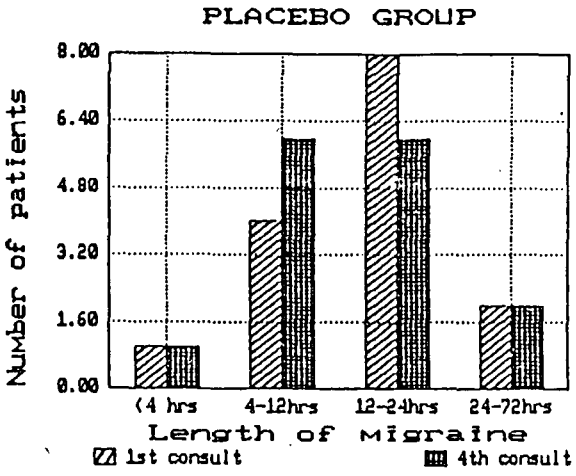
The severity of migraines experienced by the patients in the treatment group showed a statistically significant improvement (P =0.0004), while those in the placebo group showed no significant change (P =0.24). This is at the 5% level of significance, using the Wilcoxon Signed Rank Test.

According to the Mann-Whitney U test, there was no significant difference between the treatment and placebo groups at the initial consultation (P =0.08), however, after the final consultation there was a significant difference between the groups (P= 0.0003).

* **Duration of migraines:**



Graph 4.5

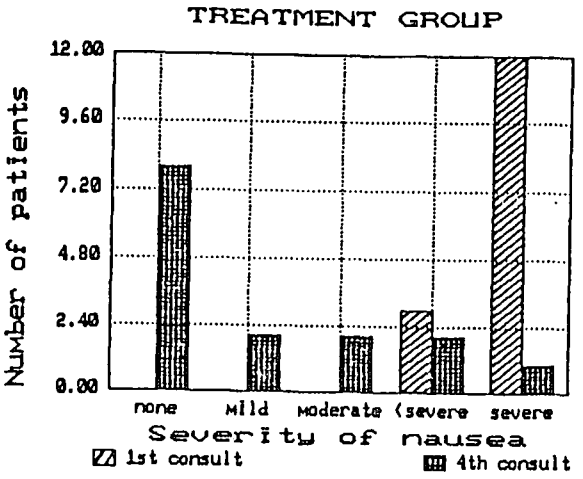


Graph 4.6

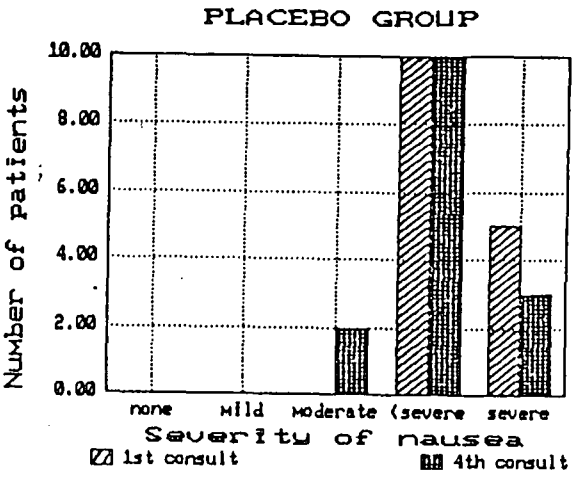
According to the Wilcoxon Signed Rank Test, there was a statistically significant improvement (P =0.007) in the duration of migraine attacks of the treatment group, between the initial and final consultation. The placebo group showed no significant change. This was at the 5% level of significance.

The Mann-Whitney U test showed that there was no significant difference between the two groups at the initial consultation (P =0.35), but a significant difference existed after the second, third and final consultations (P =0.004).

* **Severity of nausea during migraines:**



Graph 4.7

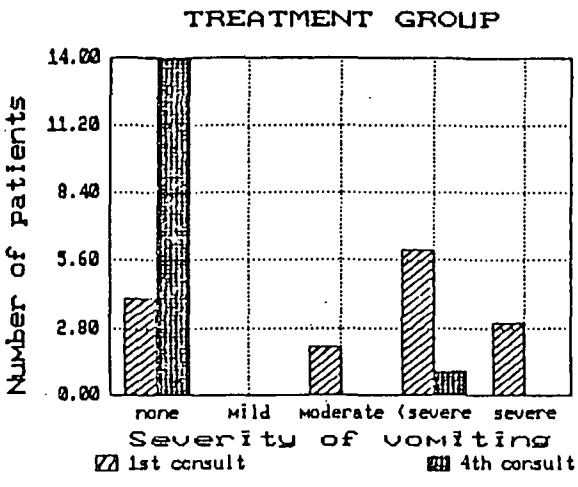


Graph 4.8

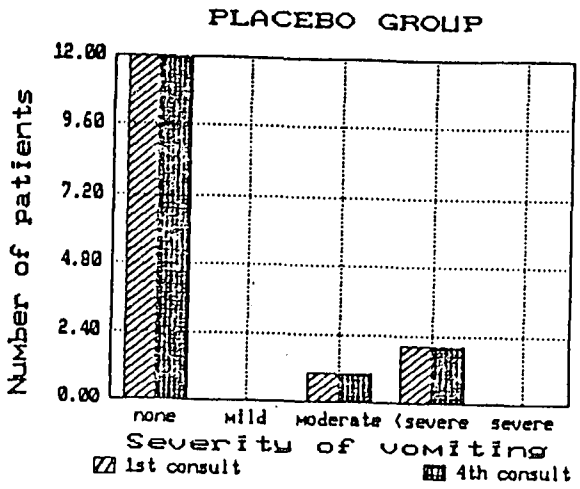
On preforming the Wilcoxon Signed Rank test, between the initial and final consultation, it was found that the treatment group showed a statistically significant improvement of the severity of nausea (P =0.0007) at the 5% level of significance, while the placebo group remained unchanged (P =0.5).

The Mann-Whitney U Test showed that there was a statistically significant difference between the treatment and placebo groups, for the duration of the study.

* **Severity of vomiting during migraines:**



Graph 4.9

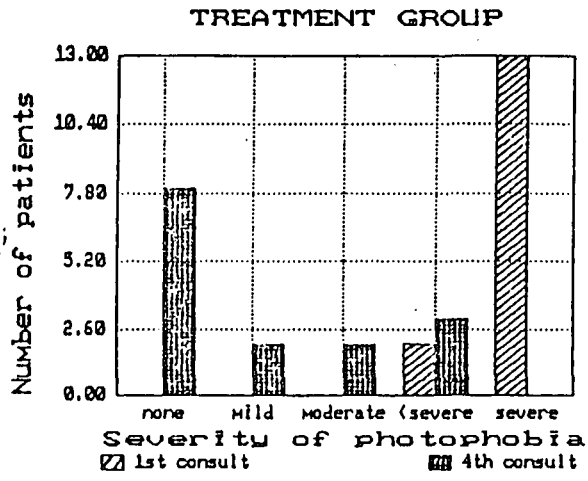


Graph 4.10

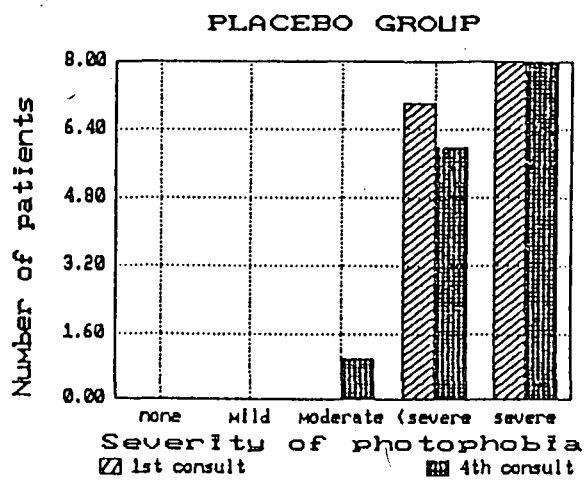
According to the Wilcoxon Signed Rank Test, there was a statistically significant improvement in the severity of vomiting in the treatment group (P =0.002) at the 5% level of significance, while the placebo group exhibited no change.

The Mann-Whitney U Test showed that although there was statistically significant difference between the two groups at the initial consultation (P =0.0015), there was no difference between them after the second consultation.

* **Photophobia during migraines:**



Graph 4.11



Graph 4.12

On preforming the Wilcoxon Signed Rank Test, it was evident that there was a statistically significant improvement of sensitivity to light in the treatment group (P =0.0004) after the final consultation. There was no significant change in the placebo group (P =0.24). This was at the 5% level of significance.

According to the Mann-Whitney U Test, there was a statistically significant difference between the treatment and placebo groups throughout the study.

Table 4.1: **Visual disturbances experienced BEFORE the headache ie. during the aura.**

	BEFORE TREATMENT		AFTER TREATMENT	
	TREATMENT	PLACEBO	TREATMENT	PLACEBO
PRESENT	5	5	0	5
ABSENT	10	10	15	10
TOTAL	15	15	15	15

On preforming the Wilcoxon Signed Rank test it was found that the treatment group had a statistically significant improvement of visual disturbances experienced before the headache (P =0.04) at the 5% level of significance. The placebo group remained unchanged.

The Mann-Whitney U Test showed that there was no statistically significance between the two groups throughout the study.

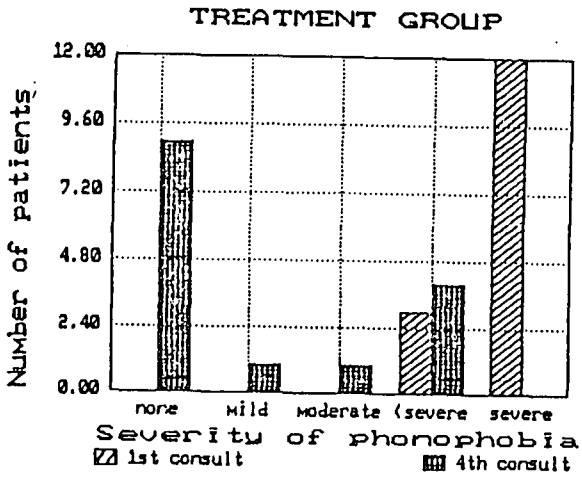
Table 4.2: **Visual disturbances DURING the headache only.**

	BEFORE TREATMENT		AFTER TREATMENT	
	TREATMENT	PLACEBO	TREATMENT	PLACEBO
PRESENT	10	9	2	9
ABSENT	5	6	13	6
TOTAL PATIENTS	15	15	15	15

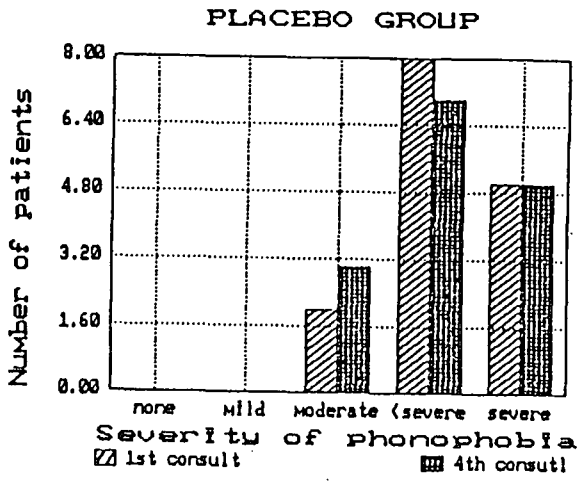
There was a statistically significant improvement of visual disturbances experienced during the headache, in the treatment group (P =0.01). This was obtained using the Wilcoxon Signed Rank Test at the 5% level of significance.

The Mann-Whitney U Test showed that although there was no significant difference between the two groups for the initial three consultations, there was a significant difference after the final consultation (P =0.03).

* **Phonophobia during migraines:**



Graph 4.13

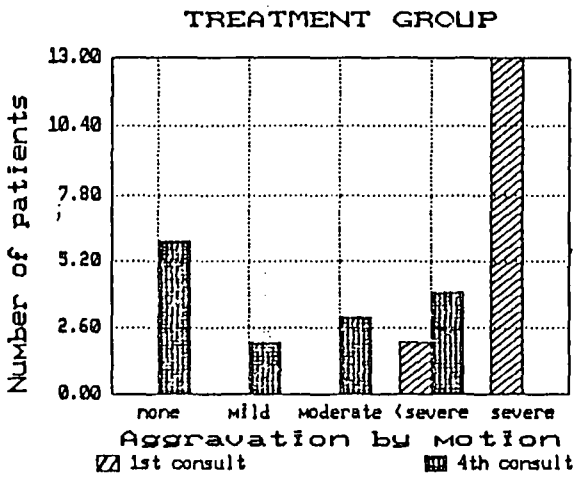


Graph 4.14

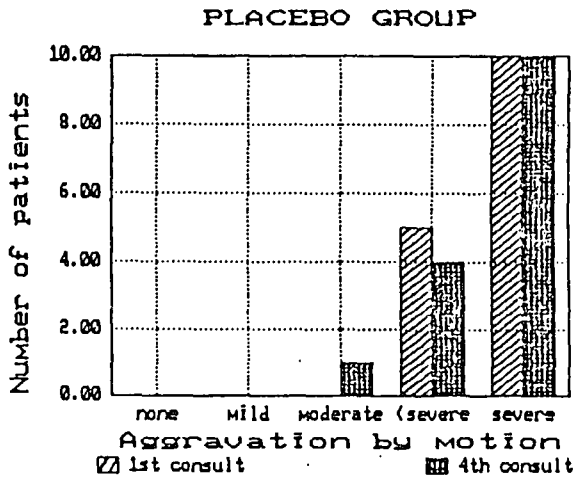
According to the Wilcoxon Signed Rank test, there was a statistically significant improvement in the treatment group with respect to noise sensitivity (P =0.0004) at the 5% level of significance. There was no significant difference in the placebo group.

The Mann-Whitney U Test showed that there was a statistically significant difference between the treatment and placebo groups throughout the study.

* **Aggravation by motion during migraines:**



Graph 4.15



Graph 4.16

On preforming the Wilcoxon Signed Rank Test, it was evident that there was a statistically significant improvement in the treatment group with reference to aggravation by motion (P =0.0004) at the 5% level of significance. The placebo group showed no significant change (P =0.31).

The Mann-Whitney U Test showed that although there was no significant difference between the two groups at the initial consultation (P =0.11), there was a significant difference between them at the following 3 consultations.

Table 4.3: **Change in amount of consumption of allopathic medication.**

	NO. OF PATIENTS WHOSE MEDICATION INCREASED	NO.OF PATIENTS WHOSE MEDICATION DECREASED	NO. OF PATIENTS WHOSE MEDICATION WAS UNCHANGED
TREATMENT GROUP	0	12	3
PLACEBO GROUP	2	0	13

SUMMARY STATISTICS AT THE INITIAL CONSULTATION

(BEFORE TREATMENT)

TREATMENT GROUP -Table 4.4

	Average	Median	Mode	Standard error	Coeff. of Variation
Frequency	3	3	2	0.239046	30.86067
Severity	4.67	5	5	0.159364	13.226001
Duration	2.6	3	2	0.254484	37.908106
Nausea	3.8	4	4	0.106904	10.895772
Vomiting	2.267	3	3	0.396012	67.665325
Photophobia	3.867	4	4	0.090851	9.099977
< Motion	3.867	4	4	0.090851	9.099977
Phonophobia	3.8	4	4	0.106904	10.895772

PLACEBO GROUP - Table 4.5

	Average	Median	Mode	Standard error	Coeff. of variation
Frequency	2.467	2	2	0.215289	33.803083
Severity	4.33	4	5	0.186871	16.701851
Duration	2.73	3	3	0.206252	29.224706
Nausea	2.67	3	2	0.251976	36.596253
Vomiting	0.53	0	0	0.290593	211.02429
Photophobia	3.53	4	4	1.333333	14.615031
< Motion	3.67	4	4	0.125988	13.307728
Phonophobia	3.2	3	3	0.174574	21.128856

SUMMARY STATISTICS AT THE FINAL CONSULTATION

(AFTER TREATMENT)

TREATMENT GROUP – Table 4.6

	Average	Median	Mode	Standard error	Coeff. of variation
Frequency	1.067	1	2	0.228174	82.848291
Severity	1.93	2	0	0.462567	92.664537
Duration	1.67	1	1	0.251976	58.554004
Nausea	1.267	1	0	0.371184	113.49399
Vomiting	0.2	0	0	0.2	387.29833
Photophobia	0.867	0	0	0.336178	150.23228
< Motion	1.267	1	0	0.344572	105.35710
Phonophobia	1.13	0	0	0.350057	119.62621

PLACEBO – Table 4.7

	Average	Median	Mode	Standard error	Coeff. of variation
Frequency	2.467	2	2	0.215289	33.803083
Severity	4.267	5	5	0.248168	22.526956
Duration	2.67	3	2	0.251976	36.596253
Nausea	3.2	3	3	0.165232	20.423632
Vomiting	0.53	0	0	0.290593	211.02428
Photophobia	3.4	3	4	0.213809	24.355255
< Motion	3.467	4	4	0.273716	30.579774
Phonophobia	3.13	3	3	0.273716	33.832941

CHAPTER FIVE

GENERAL DISCUSSION

The aim of this study was to determine the effectiveness of the Homoeopathic migraine complex on migraine headaches. This was achieved by analyzing the patient perception to the treatment with respect to the frequency, severity and duration of their migraine attacks (headaches and other symptoms), over a period of three months.

Of the initial 34 patients accepted into the study, 30 remained. One patient passed away, another immigrated oversees, and the other two dropped out for various reasons. The sample group was well chosen, as 80% had suffered from recurrent migraine attacks for longer than 5 years (Graph 4.0).

As can be seen in Graph 4.1, there was a statistically significant reduction in the frequency of migraine headaches experienced by the treatment group at the end of the study ($P=0.0007$). The most noticeable improvement appeared after one month, when 8 of the 9 patients who had been experiencing 1 or more migraine headaches a week, reported having only 2 or 3 migraine headaches during the past month. This rapid improvement is possibly due to a high degree of similarity between the patients' symptoms and the symptom pictures of the remedies used. At the end of the study, 6 patients reported

having 2 or 3 migraines, 4 patients reported having 1 migraine, and 5 patients had no migraines during the last month. The 10 patients still experiencing occasional migraines, reacted palliatively, not curatively, and may further benefit with the use of their constitutional homoeopathic remedy. There was a statistically significant difference between the treatment and placebo groups on commencement of the study (P = 0.05). As a result, patients in the treatment group experienced migraines more frequently than those in the placebo group. In the latter, 1 patient experienced an increase in frequency of migraine headaches. This could be due to increased fatigue, stress or anxiety levels interfering with the coping mechanisms (Broome 1989: 26-31). There was no noticeable reduction in the frequency of migraine headaches experienced by the patients in the placebo group. This supports the hypothesis that the migraine complex reduces the frequency of migraine headaches.

Graph 4.3 shows that patients in the treatment group reported much less severe migraines by the end of the study (P = 0.0004). Of the 15 patients who were experiencing moderate to severe migraines, 6 classified their migraine as being mild to moderate, while 5 experienced no migraines during the last month of the study. 4 Patients were still suffering severe migraines. This may be due to a lesser degree of similarity between the remedy symptom picture and the picture presented by the patients.

In the placebo group, 1 patient reported a reduced severity of migraine. This could be attributed to the placebo effect. A

placebo has been defined as any therapy or component of therapy that is deliberately used for its non-specific, psychological, or psycho-physiological effect, but is without specific activity for the condition being treated (Broome 1989: 34). The proportion of placebo respondents in particular samples may vary from 0% - 100%, although the number commonly falls in the 30 -50% range (Broome 1989: 36). In this study, 1 patient in the placebo group complained of more severe migraines, but the remaining 13 patients noticed no change. There was no significant difference between the treatment and placebo groups, thus supporting the hypothesis that the migraine complex reduces the severity of migraine headaches. The subjectivity of this question should be considered.

There was a statistically significant reduction (P =0.007) in the duration of migraine headaches experienced by the treatment group (Graph 4.5). After one month of treatment, 13 patients were still experiencing migraines lasting longer than 4 hours. This figure was reduced to 6 patients at the end of the study, thus indicating an improvement. A longer treatment time and the use of a chronic homoeopathic remedy, may have reduced this figure further. The placebo group showed a 13.33% improvement, when 2 patients reported having shorter migraines. This could be attributed to the placebo effect. There was no statistical difference between the treatment and placebo groups at the beginning of the study.

Migraine is frequently associated with a feeling of nausea,

which may be accompanied by vomiting (Edwards and Bouchier 1991: 851). In this study, all patients described their nausea as being less severe to severe. By the end of the study, only 3 patients in the treatment group fell into this category. Of the remaining 12 patients in this group, 8 suffered no nausea, while the other 4 described it as being mild to moderate (Graph 4.7). In the placebo group, 2 patients who initially complained of severe nausea, reported that their nausea had become moderate (Graph 4.8). This may be attributed to the placebo effect. The severity of vomiting, however, remained unchanged in the placebo group, throughout the study (Graph 4.10). Of the 11 patients in the treatment group who initially vomited with their migraine, 10 reported no longer vomiting with their migraine during the last month of the study (Graph 4.9). The improvement of nausea and vomiting in the treatment group may be because two of the remedies in the migraine complex, ie. Iris Versicolor and Sanguinaria canadensis, have these symptoms in their symptom picture (Boericke 1991: 365,542).

Photophobia, phonophobia and aggravation by motion commonly accompanies migraine, compelling the patient to lie still in a quiet, dark room (Raskin 1988: 45). The treatment group initially reported these symptoms to be less severe to severe. At the end of the study, 8, 9 and 6 patients respectively, no longer suffered these symptoms. The remaining patients reported the severity from being mild to less severe (Graphs 4.11, 4.13 and 4.15). Sanguinaria canadensis and Spigelia

anthelmia both have these symptoms in their materia medica, and may be responsible for the improvement. The majority of the placebo group remained unchanged. Only 1 patient reported an improvement in these three symptoms. This may be due to the placebo effect or the possibility of filling in the questionnaires incorrectly.

The effect of the migraine complex on visual disturbances before the migraine, can be attributed to the Iris Versicolor in the complex, who has this symptom in its materia medica. All 5 patients in the treatment group, who experienced visual disturbances before their migraine, ie. migraine with an aura, did no longer experience them at the end of the study, whereas the placebo group did (Table 4.1). Visual disturbances during the migraine also improved by 80% in the treatment group, whereas the placebo group remained unchanged (Table 4.2). This symptom is not found in the materia medica of any of the remedies used in the complex, but may be as a result of an overall improvement of the migraine syndrome.

When the amount of allopathic medication consumed by each group in a month was analyzed, it was found that 12 patients in the treatment group reduced their acute drug intake, while 3 patients still consumed the same amount of medication. The palliation of symptoms demonstrated by the migraine complex may be due to a high degree of similarity between the symptom pictures of the remedy and the patient, resulting in shorter, less frequent, and less severe migraines. The symptom picture

of the 3 patients whose drug intake remained the same, may not have been similar enough to those of the remedies in the migraine complex, for a noticeable change to occur.

When the effect of migraine on the quality of life was assessed, all patients remarked that migraine interfered with their family/home responsibilities, recreation, social activities, occupation, as well as self care, eg. eating, showering and getting dressed. Those patients who benefited from the study, remarked on the improved quality of their life. They found that the headaches they had, were much easier to deal with, and not as restrictive on their lifestyle.

There are many diverse ways in which the principle of similars may be applied in practice. Disease-based polypharmacy or complex prescribing has a high degree of similarity with the symptoms of a particular disease process, and not the individual being treated. (Watson 1992: 71.) This study shows that the symptom pictures of the remedies used in the migraine complex is similar enough to those symptoms displayed by the migraine patient, to have a palliative effect.

The concern and confidence with which the therapist administers a type of medication, including a placebo, appears to have an effect on its strength of action (Broome 1989: 40).
This study was double blind so the researcher did not know which patients were in the treatment group, or which patients were in the placebo group. The two groups were therefore

treated with the same amount of concern and confidence. According to Lawson and Richards (1992: 161), the double blind is the most valuable tool for assessing the merits of a form of treatment.

All data collected in this study was obtained from information supplied by the patient. There were times during the study that patients were uncertain as to the symptoms, or the severity of symptoms, they experienced before or during the migraine. I feel it would have been useful to ask them to keep a "migraine diary" reporting the symptoms they were experiencing and to rate the severity of these symptoms on a scale.

Patients in the placebo group were becoming increasingly frustrated during the study, because the majority of them were not noticing any change. An alternative study design, for example, comparing the migraine complex to Homoeopathic simillimum treatment, may have avoided this.

It would be interesting to do a follow up of patients in the treatment group, in 3 months time. This would give us information as to whether the migraine complex was successful in alleviating the symptoms of migraine in the long term, or only while it was being administered.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The study proposed to determine the impact of a homoeopathic migraine complex on migraine headaches, with reference to the patient's perception to the treatment with regard to frequency, severity and duration of the migraine headaches, in order to determine how effective the homoeopathic migraine complex was in the treatment of migraine headaches.

When the homoeopathic treatment was compared to the placebo group with regard to the frequency, duration and severity of migraine headaches, statistically significant changes were observed between the two groups. It can be said that the treatment group, as a whole, experienced less frequent, shorter and less severe migraine headaches, whereas the placebo group generally remained unchanged. The symptoms accompanying migraine, such as nausea, vomiting, photophobia, phonophobia and aggravation by motion were also alleviated to a large extent. This allowed these patients to reduce their consumption of allopathic medication, and improved their quality of life. In this group, 5 patients experienced no migraines during the last month of the study, however, the treatment time of this study was too short to note the long lasting effects of the migraine complex.

It should be remembered that there are many diverse ways in which the principle of similars may be applied in practice. The first line of treatment should be based on the similarity between the Homoeopathic remedy and the individuality of the patient. Disease-based polypharmacy or complex prescribing, has a high degree of similarity with the symptoms of the disease process, and not the individual.

However, this study has shown that the remedies used in the migraine complex, are similar enough to the symptom picture of migraine, to have a palliative effect. It could thus be used as an emergency remedy, or when the simillimum is uncertain.

RECOMMENDATIONS

* It is recommended that a larger sample group be obtained in order to make the study more statistically valid and reliable. This study was limited to a sample group of thirty due to geographical and financial restraints.

* For future studies, it is recommend that a migraine diary is given to the patients to enable them to record their symptoms, and the severity of the symptoms, during the actual migraine. This would ensure a higher degree of accuracy of information received from the patients.

* The treatment time of the study should be increased, to determine whether or not the migraine complex maintains the results obtained during the first three months.

REFERENCES

Baumel, B. 1994. Migraine: a pharmacologic review with newer options and delivery modalities. Neurology, 44(5 Suppl 3): S13-7.

Bhattacharyya, M. 1980. Homoeopathic Pharmacopoeia, 14th edition, Calcutta: M. Bhattacharyya & Co. Private Ltd. 524p.

Blau, J.N. 1987. Migraine - Clinical, Therapeutic, Conceptual and Research Aspects, London: Chapman and Hall. 695p. ISBN 0-412-27890-1.

Boericke. 1992. Materia Medica with Repertory, Augmented Indian edition. New Delhi: B. Jain Publishers. 1083p.

Breslau, N. & Davis, GC. 1992. Migraine, major depression and panic disorder: a prospective epidemiologic study of young adults. Cephalgia, 12(2): 85-90.

Breslau, N. & Davis, GC. 1993. Migraine, physical health and psychiatric disorder: a prospective epidemiologic study in young adults. Journal of Psychiatric Research, 27(2): 211-21.

Breslau, N., Davis G.C., Schultz L.R. & Peterson E.L. 1994. Joint 1994 Wolff Award Presentation. Migraine and Major Depression: a Longitudinal Study. Headache, 34(7): 387-93.

Broome, A.K. 1989. Health Psychology, London: Chapman and Hall. 498p. ISBN 0-412-33210-8.

Edwards, C.R.W. & Bouchier, I.A.D. 1991. Davidson's Principles and Practise of Medicine, 16th ed. Edinburgh: Churchill Livingstone. 1032p. ISBN 0-443-04092-3.

Findley, L., Henry, P. & Diener, H.C. 1992. Are Today's Therapies Good Enough? A Panel Debate. Glaxo Pty Ltd, pp 10 - 11.

Fox, A.D. 1990. An assessment of treatment of migraine/headache syndrome in patients seen in private practice. British Homoeopathic Journal, 79(10): 221-223.

Headache Classification Committee of the International Headache Society. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. Cephalalgia, 1988; 8 (suppl 7):1-96

Hering, C. 1991. The guiding symptoms of our Materia Medica, Chuna Mandi Paharganj, New Delhi: B. Jain Publishers Pvt.Ltd. 650p. ISBN 81-7021-090-9.

Holms, B. 1992. Quality of life matters. Glaxo Research Institute. 6-7.

Jouanny, J. 1991. The essentials of Homoeopathic Therapeutics, France: Editions Boiron. 417p. ISBN 2-85742-014-5.

Jouanny, J. 1984. The essentials of Homoeopathic Materia Medica, France Editions Boiron. 454p. ISBN 2-85742-010-2.

Lance, J.W. 1993. Current concepts of migraine pathogenesis. Neurology, 43(6 Suppl 3): 211-5.

Lawson, D.H. & Richards, R.M.E. 1982. Clinical Pharmacy and Hospital Drug Management, London, Chapman and Hall. 384p. ISBN 0-412-22760-6.

Lipton, R.B., Amatniek, J.C., Ferrare, M.D., & Gross, M. 1994. Migraine. Identifying and removing barriers to care. Neurology, 44(6 Suppl 4): S63-8.

Mathur, K.N. 1989. Systematic Materia Medica, New Dehli: B. Jain Publishers Pvt.Ltd. 953p. BM-2368.

Mount, S.J.L. 1973. On the genesis, nature and control of migraine with particular reference to the bowel nosodes as expounded by Dr. John Paterson. British Homoeopathic Journal, 62(3): 133-175.

Ophoff, R.A. & van Eijk, R. 1994. Genetic heterogeneity of familial hemiplegic migraine. Genomics, 22(7):21-6

Pollard, C.A. 1984. Preliminary validity study of the pain disability index. Percept Motor Skills, 59:974.

Raskin, N.H. 1988. Headache, 2nd edition. New York, Edinburgh, London, Melbourne: Churchill Livingstone. 396p. ISBN 0-443-08547-1.

Sheftell, F.D. 1993. Pharmacologic therapy, non-drug therapy, and counselling are keys to effective migraine management. Archives of Family Medicine, 2(8): 847-9.

Siegal, S. 1956. Non-parametric Statistics for the Behavioral Sciences, McGran-Hill Book Company, Inc, New York.

Silberstein, S.D. 1994. Serotonin (5-HT) and migraine. Headache, 34(7): 408-17.

Stang, P.E. & Osterhaus, J.T. 1993. Impact of migraine in the United States: data from the National Health interview Survey. Headache, 33(1): 29-35.

Stewart, W.F. & Lipton, R.B. 1993. Migraine headache: epidemiology and health care utilization. Cephalgia, 4(13 Suppl 12): 41-6.

Watson, I. 1992. A Guide to the Methodologies of Homoeopathy, Cutting Edge Publications, Spark Bridge, Cumbria, England. 108p. ISBN 0-951765-70-1.

Woodhouse, A. & Drummond, P.D. 1993. Mechanisms of increased sensitivity to noise and light in migraine headache. Cephalalgia, 13(6): 417-21.

Worz, R. 1994. Drug dependence and withdrawal in chronic pain patients. Fortschritte der Medicine, 1994 Jun 10; 112(16): 229-31.

APPENDIX A

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject*)
*Delete whichever is not applicable.

TILE OF RESEARCH PROJECT

NAME OF SUPERVISOR: _____

NAME OF RESEARCH STUDENT:_____

PLEASE CIRCLE THE APPROPRIATE ANSWER:

1. Have you read the research information sheet? YES/NO
2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken to?_____
7. Do you understand the implications of your involvement in this study? YES/NO
8. Do you understand that you are free to withdraw from this study: YES/NO
   a) at any time
   b) without having to give a reason for withdrawing, and
   c) without affecting your future health care.
9. Do you agree to voluntarily participate in this study? YES/NO

PATIENT/SUBJECT* NAME _____
(in block letters)

SIGNATURE _____

PARENT/GUARDIAN* NAME _____
(in block letters)

SIGNATURE _____

WITNESS NAME _____
(in block letters)

SIGNATURE _____

RESEARCH STUDENT NAME _____
(in block letters)

SIGNATURE _____

APPENDIX B

DEPARTMENT OF HOMOEOPATHY.

CASE-HISTORY QUESTIONNAIRE.

INSTRUCTIONS:

1. Section A is to be answered by the patient under the supervision of the researcher.

2. Section B is to be completed by the researcher following a physical examination of the patient.

3. The Pain Disability Index is to be completed by the patient as honestly as possible.

NAME: ADDRESS:

DATE OF BIRTH:

AGE:

SEX:

OCCUPATION:

TEL: (H): DATE:

(W):

PERSONAL HISTORY

Section A

Q1: How long have you suffered from migraine headaches?

6 months - 1 year	1
1 - 2 years	2
2 - 3 years	3
3 - 4 years	4
4 - 5 years	5
longer than 5 years	6

Q1.1: If you answered 6 months - 1 year, how many migraine headaches have you had in that time? _____

Q2: How often do you get a migraine headache?

about once a month	1
several times a month	2
about once a week	3
several times a week	4

How often in the last month have you had a migraine headache?

_____

Q3: Please rate the severity of your migraine headache

0 1 2 3 4 5

mild moderate severe

Q4: How long do your headaches usually last? _____

Q5: Are your headaches on one side only?

never	1
sometimes	2
usually	3
always	4

Q5.1: If so, which side is more common?

left	right

Q6: Before getting a headache, do you know that one is coming on?

yes	no

If the answer to Q6 was yes, please describe what you notice:

_____

_____

_____

Q7: How would you describe the character of your headache?

pressure	1
steady ache	2
throbbing	3
stabbing	4

Q8: During your headache, do you:

8.1 feel nauseous?

0 1 2 3 4

not at all severely

8.2 vomit?

0 1 2 3 4

not at all severely

8.3 feel dizzy?

yes	no

8.4 feel sleepy?

yes	no

8.5 lose your appetite?

yes	no

8.6 hear ringing in your ears?

yes	no

8.7 find that light hurts your eyes?

0 1 2 3 4

not at all severely

8.8 notice tingling, or any strange sensations in any part of your body?

yes	no

Q9: When you have a headache, do you notice any changes in your sight?

yes	no

If your answer to Q9 was yes, please describe what you notice.

_____

_____

_____

Q10: When do your headaches usually occur?

wakes you up at night	1
morning	2
afternoon	3
evening	4
all day	5
variable	6

Q11: Do any of the following bring on a migraine headache?

11.1 hunger

yes	no

11.2 tension/stress

yes	no

11.3 fatigue

yes	no

11.4 weather changes

yes	no

11.5 head movements

yes	no

11.6 certain foods

yes	no

Q12: Do any of the following aggravate your migraine?

12.1 menstruation

yes	no

12.2 sneeze/cough

yes	no

12.3 exertion

yes	no

12.4 head movements

yes	no

12.5 motion 0 1 2 3 4
not at all severely

12.6 noise 0 1 2 3 4
not at all severely

12.7 lights 0 1 2 3 4
not at all severely

Q13: Do any of the following improve your migraine?

13.1 medication

yes	no

13.2 lying down

yes	no

13.3 massage

yes	no

13.4 heat

yes	no

13.5 cold

yes	no

13.6 food

yes	no

Q14: Have you ever seen a doctor about the headaches?

yes	no

Q15: Are you on medication? (for any reason)

yes	no

If yes, please state which ones, and for what.

_____

_____

Q16: Does anyone in your family suffer from migraines?

mother	1
father	2
grandparent	3
sibling	4
children	5

Q17: Are you married?

yes	no

Q18: Do you have any children? _____

Q19: Do you smoke?

yes	no

How much?_____

Q20: How would you rate your job stress?

0 1 2 3 4 5

mild moderate severe

Q21: Have you had any illnesses or operations?

yes	no

If yes, please state what:_____

_____

Q22: Do you suffer from any allergies?

yes	no

If yes, to what?_____

Q23: Does anyone in your family suffer from the following?

high blood pressure	1
vascular disease	2
neurological disease	3
diabetes	4
gout	5

Q24: Do you have any of the following?:

high blood pressure	1
vascular disease	2
neurological disease	3
diabetes	4
gout	5

Answer the following questions only after the first, second and third month of treatment.

Q25: Do you perceive the treatment to be working in a curative way?

yes	no

Q26: If you have been taking other medication, has your intake of this medication

increased	1
decreased	2
remained unchanged	3

Section B

1. Blood Pressure:

2. Pulse:

3. Temperature:

4. Respiration Rate:

5. Ears:

6. Eyes:

7. Lymph nodes:

8. Palpate neck for tenderness/abnormalities

PAIN DISABILITY INDEX

The rating scales below are designed to measure the degree to which several aspects of your life are presently disrupted by migraine headaches. In other words, I would like to know how much your headache is preventing you from doing what you would normally do, or from doing it as well as you normally would.

For each of the six categories of life activity listed, please circle the number on the scale which describes the level of disability you typically experience. A score of zero (0) means no disability at all, and a score of five (5) signifies that all of the activities in which you would normally be involved have been totally disrupted or prevented by your pain.

1. **Family/Home responsibilities.** This category refers to activities related to the home or family. It includes chores and duties performed around the house (eg. yard work) and errands or favours for other family members (eg. driving the children to school).

0 1 2 3 4 5
none severe

2. **Recreation.** This category includes hobbies, sports, and other similar leisure time activities.

0 1 2 3 4 5
none severe

13. **Social Activity.** This category refers to activities which involve participation with friends and acquaintances other than family members. It includes parties, theatre, concerts, dining out, and other social functions.

0 1 2 3 4 5
none severe

4. **Occupation.** This category refers to activities that are a part of or directly related to one's job. This includes nonpaying jobs as well, such as that of a housewife or volunteer worker.

0 1 2 3 4 5
none severe

5. **Self care.** This category includes activities which involve personal maintenance and independent daily living (eg. taking a shower, driving, getting dressed, etc).

0 1 2 3 4 5
none severe

6. **Life-Support activity.** This category refers to basic life-supporting behaviours such as eating, sleeping, and breathing.

0 1 2 3 4 5
none severe

APPENDIX C

RESULTS

TABLE 1. FREQUENCY OF MIGRAINE HEADACHES

A: Treatment group

	<1/month	1/month	2-3/month	1/week	>1/week
consult 1	0	0	6	3	6
consult 2	0	3	11	1	0
consult 3	1	5	9	0	0
consult 4	5	4	6	0	0

B: Placebo group

	<1/month	1/month	2-3/month	1/week	>1/week
consult 1	0	0	11	1	3
consult 2	0	2	7	2	4
consult 3	0	0	12	0	3
consult 4	0	0	10	2	3

TABLE 2. SEVERITY OF MIGRAINE HEADACHES:

A: Treatment group

	none	mild	mild-mod	mod	<severe	severe
consult 1	0	0	0	1	3	11
consult 2	0	0	0	5	3	7
consult 3	1	0	1	8	3	2
consult 4	5	2	2	2	3	1

B: Placebo group

	none	mild	mild-mod	mod	<severe	severe
consult 1	0	0	0	2	6	7
consult 2	0	0	0	3	3	9
consult 3	0	0	1	2	5	7
consult 4	0	0	1	2	4	8

TABLE 3. DURATION OF MIGRAINE HEADACHES

A: Treatment group

	<4 hours	4-12 hours	12-24 hours	24-72 hours
consult 1	2	5	5	3
consult 2	4	5	5	1
consult 3	5	7	2	1
consult 4	9	3	2	1

B: Placebo group

	<4 hours	4-12 hours	12-24 hours	24-72 hours
consult 1	1	4	8	2
consult 2	1	6	6	2
consult 3	2	5	6	2
consult 4	1	6	6	2

TABLE 4. SEVERITY OF NAUSEA

A: Treatment group

	none	mild	moderate	<severe	severe
consult 1	0	0	0	3	12
consult 2	3	0	1	5	6
consult 3	7	1	1	5	1
consult 4	8	2	2	2	1

B: Placebo group

	none	mild	moderate	<severe	severe
consult 1	0	0	0	10	5
consult 2	0	0	3	10	2
consult 3	1	0	2	9	3
consult 4	0	0	2	10	3

TABLE 5. SEVERITY OF VOMITING

A: Treatment group

	none	mild	moderate	<severe	severe
consult 1	4	0	2	6	3
consult 2	11	0	1	2	1
consult 3	11	0	1	3	0
consult 4	14	0	0	1	0

B: Placebo group

	none	mild	moderate	<severe	severe
consult 1	12	0	1	2	0
consult 2	12	0	1	2	0
consult 3	12	0	1	2	0
consult 4	12	0	1	2	0

TABLE 6. SEVERITY OF PHOTOPHOBIA

A: Treatment group

	none	mild	moderate	<severe	severe
consult 1	0	0	0	2	13
consult 2	2	0	1	6	6
consult 3	4	0	4	6	1
consult 4	8	2	2	3	0

B: Placebo group

	none	mild	moderate	<severe	severe
consult 1	0	0	0	7	8
consult 2	0	0	0	7	8
consult 3	0	0	1	6	8
consult 4	0	0	1	6	8

TABLE 7. SEVERITY OF PHONOPHOBIA

A: Treatment group

	none	mild	moderate	<severe	severe
consult 1	0	0	0	3	12
consult 2	3	0	0	7	5
consult 3	3	1	4	7	0
consult 4	9	1	1	4	0

B: Placebo group

	none	mild	moderate	<severe	severe
consult 1	0	0	2	8	5
consult 2	0	0	1	8	6
consult 3	0	0	3	7	5
consult 4	0	0	3	7	5

TABLE 8. AGGRAVATION BY MOTION

A: Treatment group

	none	mild	moderate	<severe	severe
consult 1	0	0	0	2	13
consult 2	0	0	1	9	5
consult 3	2	1	4	8	0
consult 4	6	2	3	4	0

B: Placebo group

	none	mild	moderate	<severe	severe
consult 1	0	0	0	5	10
consult 2	0	0	0	3	12
consult 3	0	0	1	4	10
consult 4	0	0	1	4	10