MALARIA AND HOMEOPATHIC REMEDIES IN GHANA

An Open Study and a Double-Blind Randomized Clinical Trial

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1. Introduction

Malaria is a disease caused by four parasites: *Plasmodium falciparum*, *P vivax*, *P. ovale* and *P. malariae*. Each of them has its own morphological signs, period of incubation, clinical picture and sensitivity to medical drugs. (Meuleman, 1989). All the parasites are transmitted by different species of the female *Anopheles* mosquito (Zahar, 1984).

General symptoms are intermittent fever, headache, general malaise, bone- and waist pain. The diagnosis is confirmed by clinical presentation and a thick blood smear. Malaria tropica, caused by *P. falciparum* has as possible complications cerebral malaria and renal insufficiency (Peters, 1985), due to parasite infestation of the capillaries in the brain and the kidneys; these complications can be fatal. In many countries malaria is endemic; people are not clinically ill from malaria, but many of them have chronic complaints like weakness and loss of concentration. They have usually a positive thick blood smear; this was the case in the area where this study was done.

Standard treatment in Ghana according to WHO-protocols is chloroquine, 25mg/kg bodyweight, in resistant cases quinine in combination with antibiotics like tetracycline (Afro technical papers, 1992). Other drugs exist for chloroquine resistant malaria, like halofantrine (Peters, 1987)

Malaria is a major health problem in most developing countries (World Health statistics, 1992). Resistence against chloroquine, a rather cheap and easy available treatment, has been assessed at several places (Notten, 1992). Also resistence against other drugs is reported. These circumstances make malaria a difficult disease to cure. Trials to develop a vaccine have not yet been successful on a large scale (Valero *et al.*, 1993).

The clinic where the study was done, is in a rural area, where the large majority of the population has endemic malaria. In this clinic a teaching programme of "Homeopaths without Borders" is given at regular intervals since 1993, to train the staff in treating common diseases as diarrhea, feverish conditions, trauma and skin suppurations.

The study was performed to see whether a substantial number of patients would react on homeopathic treatment. Until now there was only casuistice evidence of malaria patients being treated, described in the homeopathic literature. This is the first controlled study of the efficacy of homeopathy on malaria.

As every patient can have different accompanying signs to his classical symptoms of malaria, the treatment is individualized according to the inter-individual differences. The homeopathic diagnosis consists actually of determining the susceptibility of a given person for a homeopathic remedy, at the basis of a similar set of symptoms of that person to cases being cured in the past. Although a standard treatment might not be possible on theoretical grounds, an "epidemic approach" is however useful (Hahnemann, 1986). This means that in epidemics as diarrhea and endemic diseases as malaria, a limited number of remedies might be indicated for 70 to 80% of all cases. In diarrhea this limitation is already shown by studies in Nicaragua (Jacobs *et al.*,1994). This might be also important for the future transfer of knowledge to e.g. health assitants in clinics in developing countries about the homeopathic treatment of malaria. The cases are described in the literature, of which is given now a brief account.

In the *"Materia Medica Pura"*, Hahnemann's documentation (1988) of the symptoms arising from provings, drug pictures are described which resemble malaria. In the clinical literature descriptions are found of treatment of malaria with homeopathic remedies. Already in the beginning of this century, in Allen's *"Therapeutics of fever"* (1983) and Farrington's *"Comparative Materia Medica"* (1989) (both reprinted) clinical cases are described with the main remedies used. Other casuistic evidence for individual prescribing of homeopathic remedies in malaria was shown afterwards. (Puhlmann, 1920; Fenner, 1925). However until now no controlled group study was done, comparing standard malaria treatment (chloroquine) with homeopathy.

Research comparing chloroquine with homeopathic treatment seems to be relevant because it could offer an additional perspective in treating malaria.

2. Material and Methods

The main research-questions were: "Would homeopathic treatment work better than chloroquine?" and: "Which homeopathic remedies can be mainly used, when prescribed individually?"

The research took place from october until december 1993 at the Shekhinah clinic in Tamale, in the Northern

Region of Ghana. The open study was done during the wet season, the double blind at the end of it. The patient selection was done by the nurse in charge.

2.1. Inclusion And Exclusion Parameters

Patients were included in the research if the patient had some of the following clinical parameters:

- fever (T > 37.5 ^{o}C rectal) eventually remittent fever
- chills
- general headache
- headache above the eyes
- waist-pain (paravertebral pain, lumbar region)
- bone-pain
- anemia: Hb women < 7,4 mmol/l; men < 8,0 mmol/l
- eventually splenomegaly
- other complaints: abdominal pains; dizziness, palpitations
- parasitology: a positive thick blood smear

The usual parasitological parameter: a positive thick blood smear (Meuleman, 1989), was problematic as a valuable parameter for evaluation, as in a prestudy screening, almost all subjects had a positive smear, if they had clinical signs of malaria or not. This is often the case in endemic malaria (WHO, 1992). For the evaluation of the efficacy of the therapy therefore, this is not used. The central outcome measurement thus is defined in terms of the clinical symptoms, listed above.

Exclusion criteria were: children younger than ten years and pregnant women. Patients treated by the research protocol with no signs of improvement, were counted as negative results and got chloroquine or quinine. (WHO, 1991).

2.2. Objectives Of The Treatment

The malaria-treatment can have different objectives: i) to finish an attack; ii) to achieve complete cure; iii) to improve a patient's resistence against a next attack, during a certain period

2.1.1.To Finish an Attack

- an improvement in at least **three** of the six clinical symptoms: chills, headache above the eyes, general headache, bone-pain, waist-pain.
- a decrease in temperature with 0.5° C rectal

2.1.2. A Cure is Defined as

- being free of fever episodes during five days after treatment
- a rise in Hb of 0.3 mmol/l
- a negative thick blood smear

2.1.3. Improvement Evaluation

The improvement of patient's resistance against a next attack can be measured if the frequency of malaria-attacks in one year has been reduced.

The duration of the research period was not sufficient for evaluating the follow-up after six or twelve months; moreover, a positive thick blood does not seem to be related to the presence of clinical symptoms, pathognomonic for an attack of malaria. Therefore this study was meant only for evaluating the possible difference in effect on an attack of malaria by chloroquine and homeopathic treatment, based on an assessment of clinical symptoms.

2.3. Choice Of The Treatment

The homeopathic remedy was given after repertorization with Kent (1974), using the following rubrics

-time of onset of chills

-part of the body where the chills begin and extend from

-periodicity of chills and/or fever

-succession of stages of chill, heat and perspiration

-thirst/thirstlessness/quantity of thirst/time of maximal aggravation

-location of headache

-kind of headache

-nausea/vomiting

-stool/diarrea

It is emphasized that these symptoms were used for the diagnosis of the remedy-picture, and that the evaluation of the treatment was done with the clinical symptoms mentioned in the definition of finishing an attack.

Some examples of remedies are given (Allen, 1983; Farrington, 1989; Gaucher *et al.*, 1993):

*** Arsenicum Album**

Often used in quotidian, tertian and other types of malarial intermittent fever with marked periodicity.

Symptoms

- irregular chills preceded by yawning and stretching
- hot stage is intense, longlasting and dry burning
- stages not clearly defined

Characteristic signs

- drinks frequently but little at a time
- drinking causes nausea and vomiting
- heat is as if hot water is running through blood vessels

*** Natrium Muriaticum**

Every type of fever with a characteristic paroxysm of fever in the morning.

Symptoms

- chills beginning in the fingers and toes
- long severe heat with excessive weakness
- stupifaction and unconsciousness

Characteristic signs

- drinks often and much at a time
- bursting headache
- water tastes putrid

*** Pulsatilla**

Intermittents of irregular type with irregular stages which are apt to overlap each other; Accompanied by digestive irregularities and stomach disorders.

Symptoms

- chills begins in the hands and feet
- general heat sometimes with coldness of single parts

Characteristic signs

- no thirst

2.4. Clinical Trials

In order to assess the feasibility of the clinical trial to be undertaken, the research was started with an open study. This had a duration of four weeks. All patients received homeopathic treatment. Depending on the frequency of attacks previously of the treatment the patient returned for check-up in one or three weeks. The division for follow-up was as such that if the patient had an attack daily he returned after one week, while if the patient had weekly relapses he returned after three weeks.

After the positive results of the open study, it seemed relevant to try to confirm these preliminary results in a double blind study, using the double-dummy method.

Every patient was assigned at random to one of two groups. One group received placebo-homeopathic treatment and verum-chloroquine tablets. The other group received verum-homeopathic treatment and placebo-chloroquine tablets. The number of tablets were five for chloroquine (verum or placebo) and one homeopathic grain of C200-potency (verum or placebo). So every patient got the same number of drugs, and with the same visual aspect and

taste. For chloroquine the standard dosis was used: 25mg/kg bodyweight. None of the patients was treated by both chloroquine and homeopathic remedie nor only by placebos. All patients entered the study after informed consent.

3. Results

In the open study 92 patients were treated: 17 patients did not return for the follow up. Moreover, 68 out of the 75 (90,7%) remaining patients had at their follow-up check improvement of complaints.

TABLE 1. Frequency of utilized homeopathic remedies in > 5% of cases

	open/double blind study
Arsenicum	10.9 / 9.5
China	7.6 / 5.4
Eupatorium Perfolatum	5.4 /
Natrum Mur	10.9 / 6.8
Nux Vomica	5.4 / 14.9
Pulsatilla	10.9 / 17.6
Rhus tox	5.4 /
Sulphur	8.7 / 17.6
TOTAL %	**61.4 / 71.8**

The following homeopathic remedies have been mainly used: Arsenicum album, China, Eupatoriatum perfoliatum, Natrum muriaticum, Nux vomica, Pulsatilla, Rhus toxicodendron and Sulphur.

In the double blind study 74 patients were treated: 41 in group I (= homeopathy verum and chloroquine placebo) and 33 in group II (= homeopathy placebo and chloroquine verum). 11 patients of group I and 8 patients of group II didn't return on their follow-up visit. Twenty five out of 30 (83.3%) patients in group I showed improvement of at least three symptoms of the listed symptoms. The 95% reliability-interval is 65.3-94.4%. In group II were 18 patients out of 25 (72%), who showed an improvement. The 95% reliability-interval is 50.6%-87.9%. The difference between the homeopathic treatment and the chloroquine treatment is 11% in favor of the homeopathic-treatment. The X^2-test is 1.03 with a p-value of 0.31.(non-significant)

In case of all the dropped out would have had no improvement the percentages would be 61.0% (25/41) and 54.6% (18/33) instead of 83.3% and 72%. The X^2-test is 0.31 with a p-value of 0.57. In case all the dropped out would have had improvement the percentages would be 87.8% (36/41) and 78.8% (26/33). The X^2-test is 1.09 with a p-value of 0.29. In both cases there would have been no statistically significant difference between group I and II.

TABLE 2. Results of the Double-Blind Study

	group I (%)	group II (%)	total (%)42 (56.8)
average age*	36.0	37.1	36.6
dropouts	11 (26.8)	8 (24.2)	19 (25.7)
improvement	25	18	43
improvement in % (95% CI)	83.3%	72%	78.2%
	(65.3-4.4%)	(50.6-87.9%)	
no improvement	5	7	12
no improvement in % (95% CI)**	16.7%	28%	21.8%

* the age is an estimate made by the nurse, because the exact age is not known in general

** X2-test is 1.03 and p = 0.31

4. Discussion

Kent (1974), Fenner (1925) and Farrington (1989) listed 45 homeopathic remedies; most frequently were used: *Arsenicum album*, *Bryonia*, *Ipecacuanha*, *Eucalyptus globulus*, *Natrum muriaticum* and *Veratrum album*. In Puhlmanns Handbuch (1920) the following remedies were added: *Nux vomica*, *Pulsatilla*, *Carbo vegetabilis*,

Ignatia, *Digitalis* and *Rhus toxicodendron*. Recent databases as Reference Works (Macintosh) list 113 remedies; most of these are rarely indicated, at least they are not of much use in a situation where many patients are to be treated daily, like in the rainy season.

In this research the following remedies have been used: *Arsenicum album*, *China, Eupatoriatum perfoliatum*, *Natrum muriaticum*, *Pulsatilla*, *Rhus toxicodendron*, *Nux vomica* and *Sulphur* (each of them has been used in > 5% of the cases - see table 1).

The difference with the literature can be possibly explained by historical differences. Considering the experience that in two studies, which have been undertaken in the same area and by the same person, it would be more likely that this is an indication of what is a main feature of homeopathy: the adaptation of the therapy to different individuals as well to groups of patients. Moreover, the rainy season can account for the differences between the open and the double blind study. Two remedies used only in the open study during the wet season, *Eupatorium perfoliatum* and *Rhus toxicodendron*, are known for acting especially in humid climate circumstances.

The percentage of 90.7% in the open study and 83.3% in the double blind study can be attributed to the homeopathic treatment, but it is also possible considering the remittent character of the disease that these results are not caused by the treatment, but are partly coinciding with the natural course of the disease; however, an attack usually lasts for several days, while most of the patients recovered within the usual period. This would need to be assessed with a daily report scale; the compliance of the patients needed for that, would require more staff than was available given the small budget. To draw definite conclusions about the efficacy of the treatment, a study with a longer follow-up period would be necessary to assess the number of disease-episodes comparing the chloroquine group with the homeopathic group.

The criterion of at least three symptoms for a clinical improvement can be used in an area where a positive blood smear has no correlation with the clinical picture, and if only the treatment of the acute attack is the object of the study.

5. Conclusion

The question: "Would homeopathic treatment work better than chloroquine?" cannot be answered from this research. The only conclusion that can be drawn is that homeopathy has an effect, comparable with and slightly (non-significantly) better than chloroquine. The effect of chloroquine might be difficult to calibrate as the level of resistance against chloroquine is not known in the population studied.

The second question "Which homeopathic remedies can be mainly used?" can be answered as follows: *Arsenicum album*, *China, Natrum muriaticum*, *Nux vomica*, *Pulsatilla* and *Sulphur*. Interesting is the difference with the remedies used in the literature. This confirms the general rule that homeopathy is a matter of individualizing the treatment.

Given these results, and the potential interest for health care, it would be advisable to repeat this research with larger samples, combined with making thick blood smears before and after treatment, and thus be able to evaluate also the second and third objective of malaria-treatment, i.e to achieve a complete cure, and to improve the resistance against next attacks, respectively.

The following parameters can be taken: clinical symptoms, Hb, temperature, parasitology and a follow up after six months, assessing disease episodes and use of medication in these episodes.

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