Original Article

An observational study to ascertain the role of a group of predefined homoeopathic medicines in the management of Malaria

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ABSTRACT

Background: Malaria is one of the foremost public health problems in India. **Objective**: The objective of the study was to ascertain the role of a group of predefined homeopathic medicines in the management of malaria. **Methods**: A total of 31 patients were enrolled, out of 173 screened cases. Patients presenting with classical clinical manifestations of malaria and showing a positive blood test for Malaria parasite were included in the study. Out of 15 predefined trial medicines, according to the principles of the need of the Case. The cases were monitored by assessing the improvement status Homoeopathy the similimum was prescribed in 30/200 potency and repeated as per the need. The result was analyzed using SPSS version 20.0. **Results**: The total mean Malaria symptom scores (MSS) evaluated at baseline and end were 13.2± 1.9 and 5.9±4.4, respectively. The difference in the mean scores was found to be statistically significant (P=0.001, <0.05; CI: 5.7-8.9). Most frequently prescribed medicines as per indications were *Arsenicum album* (n=12, 38.7%), *Natrum muriaticum* (n=8, 25.8%), *China Officinalis* (n=4, 12.9%), *Rhus Toxicodendron* (n=3, 9.7%), Ipecac (n= 2, 6.5%), Gelsemium (n=1, 3.2%), Nyctanthus (n=1, 3.2%). **Conclusion**: It was observed that the Arsenicum album was the most useful and frequently indicated medicine in the treatment of malaria. The outcome of the study shows that homeopathic medicines are useful in managing malaria. This study infers that homeopathy has a positive role in the treatment of malaria but needs further study with larger samples.

Keywords: *malaria, homeopathy, ars. alb., nat. mur., china, nyctanthus arbt., rhus tox*

Malaria is commonly associated with poverty but is also a cause of poverty and a major hindrance to economic development. Malaria is one of the foremost public health problems in India. Malaria is commonly associated with poverty but is also a cause of poverty and a major hindrance to economic development [1-3]. It is the fifth leading cause of death worldwide and almost half the world's population (3.3 billion) [4] is at risk. Children and women are among the most vulnerable. Along the same lines, it can be expected that patients with a depressed immune system – like HIV positive patients - have a higher risk of contracting malaria and are prone to a more severe course of the disease.

It is described in the literature that malaria cases can be more severe in HIV positive patients; however, there is no conclusive evidence to prove it [5]. The biggest burden of malaria in India is borne by the most backward, poor and remote parts of the country, with >90-95% cases reported from rural areas and <5-10% from urban areas; however, the low malaria incidence in urban areas may be due to almost non-existing surveillance. The state of Orissa, with a population of 36.7 million (3.5%), contributes about 25% of the total annual malaria cases, more than 40% of P. falciparum malaria cases and nearly 20–30% of deaths caused by malaria in India, followed by Meghalaya, Mizoram, Maharashtra, Rajasthan, Gujarat, Karnataka,

Goa, southern Madhya Pradesh, Chhattisgarh, and Jharkhand that also report the significant number of malaria cases and deaths [1-6].

The proportion of *P. vivax* and *P. falciparum* varies in different parts of India; *P. falciparum* accounts for 30–90% of the infections in the forest areas inhabited by ethnic tribes and <10% of malaria cases in mostly Indo-Gangetic plains and northern hilly states, northwestern India, and southern Tamil Nadu [10]. Malaria is caused by protozoan parasites of the genus Plasmodium (phylum *Apicomplexa*). In humans, malaria is caused by *P. falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*. *P. falciparum* is the most common cause of infection and is responsible for about 80% of all malaria cases, and is also responsible for about 90% of the deaths from malaria [6-8].

Symptoms of malaria include fever, shivering, arthralgia (joint pain), vomiting, anemia (caused by hemolysis), hemoglobinuria, retinal damage, and convulsions [9,10]. The main symptom of malaria is a periodic occurrence of sudden chill followed by rigor and then fever and sweating lasting four to six hours. If not treated, malaria can quickly become life-threatening by disrupting the blood supply to vital organs. In many parts of the world, the parasites have developed resistance to several malaria medicines [11].

Malaria is one of the most important infectious diseases in the world12. A major contributor to malarial morbidity and mortality is certainly the increasing resistance of malaria parasites to available drugs [12]. Resistance is primarily seen in *P. falciparum*, the most virulent malaria parasite. Considering increasing resistance to available agents, there is a broad consensus that there is a need to evaluate the role of homeopathy in the management of malaria. The advent of homeopathy relates to the use of Cinchona in Malaria and ever since there have been innumerable cases of successful treatment of malaria/intermittent fevers reported by various homeopathic physicians. However, most of this evidence has remained anecdotal rather than experimental. In recent years many studies have tried evaluating alternative prevention and treatments of malaria [13].

The Central Council of research in homeopathy, therefore, undertook clinical studies for eliciting the usefulness of homeopathic treatment in Malaria at Port Blair, and Jaipur during the years 1980-89. Another study was conducted at Regional Research Institute at Jaipur (1979 – 2003), Clinical Research Units (Tribal) at Diphu (1987-2003) and Aizawl (1992-2003). These studies although confirmed the usefulness of homeopathic treatment in malaria, yet there remained a lack of scientific validity of these findings due to the absence of appropriate protocols.

The Council designed a protocol and an observational study was undertaken at its Regional Research Institute, Guwahati (May 2007-Oct 2007). The results of this study pave the way for an elaborate multicentric study on scientific lines and the success of homeopathic intervention in treating malaria. The objective of the study was to ascertain the role of a group of predefined homeopathic medicines in the management of malaria.

MATERIAL AND METHODS

This is an observational study conducted at Regional Research Institute (Homoeopathy), Guwahati, Assam during the period May, 2007- October 2007. The study protocol was following the Declaration of Helsinki. Necessary ethical clearance was obtained from the Council's Ethical Committee. To begin with, a survey was conducted with the help of local health authorities to locate the places where the prevalence of malaria was high. Finally, a center was set up in the PHC Sonapur, Distt. Kamrup, Assam. The screening and referral of malaria cases were augmented by the regular house to house visits by a team of doctors and Lab technician in the adjacent localities.

Total 173 patients of all the age groups, both sexes, were screened, out of which a total 31 cases showing a positive blood test for Malaria parasite were enrolled. Informed consent was obtained from all the patients and in the minors; the same was obtained from parents/ guardians. Each patient was followed up to 7th day of the illness. Laboratory confirmation was done pre and post-treatment. Patients with classical clinical manifestations of Malaria were included in the study and treated as outdoor patients.

Classical manifestations considered for enrolment of a patient in the study are well-defined stages of fever i.e. chill, heat, and sweat in that order. It is also accompanied by symptoms like headache, nausea and vomiting, body

and muscle ache, fatigue, and abdominal discomfort. Major signs observed were elevated temperature, perspiration, and enlarged spleen. Patients presenting with all the above mentioned primary symptoms were enrolled in the study and subjected to laboratory investigation for confirmation of diagnosis. Patients with *P. falciparum* infection and presenting with the symptoms such as severe anemia, jaundice, fluid in the lungs (pulmonary edema), kidney failure, convulsions, paralysis, coma, marked prostration, and marked delirium were excluded from the study.

Laboratory investigations of blood and urine were performed. A thick blood film observation every 10 – 12 hours for 3 days was performed for the demonstration of the parasite along with Hb (at entry and after the fever subsides or after 7 days, whichever is earlier), TLC, DLC, and ESR. Routine and microscopic urine examinations were performed to rule out the cases with albumin, sugar, bile salts, and bile pigments.

The selection of trial medicines was done from standard homeopathic literature, [15,16] based on common symptoms of Malaria. The trial medicines were *Natrum muriaticum*, *Nyctanthus arbortristis*, *Arsenicum album*, *Cinchona officianalis*, *Pulsatilla*, *Rhus toxicodendron*, *Eupatorium perfoliatum*, *Ipecacuanha*, *Chininum sulphuricum*, *Chininum arsenicum*, *Natrum sulphuricum*, *Gelsemium*, *Azadirachta indica*, *Caesalpinia bonducella*, and *Alstonia constricta*.

These trial medicines were procured from a licensed homoeopathic company [Sharda Boiron Laboratories (SBL), Pvt. Ltd. Sahibabad, Uttar Pradesh, India]. The prescription was based on the totality of symptoms of the patient. The full scope was given for individualization of the patient and the final selection of medicine was done in consultation with the Materia Medica. However, if the choice of medicine was outside the trial medicines, then that patient was not enrolled, but treated in theGeneral Out-Patient Department.

The detailed case recording was done in each case and the medicine (simillimum) was prescribed according to the principles of Homoeopathy. All medicines were prescribed in 30/200 potencies. Potency was raised as per need of the case and medicine was repeated every few minutes to hours depending on the frequency, duration and intensity (FDI) of the symptoms, till perceptible change appeared (improvement of signs and symptoms, the appearance of new symptoms, worsening of signs and symptoms). All follow up actions were taken as per homeopathic principles. All patients were called for follow-up daily or on an alternate day till the seventh day of enrolment or till the fever disappeared, whichever was earlier.

A Malaria symptom scale (MSS) was designed by the council as an indicator of the severity of illness. The MSS was measured by considering 08 signs & symptoms (Table 1) viz. temperature, stages of fever, spleen enlargement, headache, nausea, vomiting, body pain, fatigue, and perspiration. The total MSS score was considered as S1. Another scale (S2) from 1-7 was designed whereby a patient reporting for the treatment on the first day of infection was assigned the highest value of 7 and one reporting on the seventh day, the value, 1. The maximum attainable score was 32. As per the baseline symptom score, patients were categorized into three intensity groups mild (1-11), moderate (12-22), and severe (23-32) as shown in table 1.

Table 1: Malaria symptom score MSS (devised by the Council) assessment on every visit

Symptoms	Score	0	1	2	3	4	**Concomitants**
Temperature		100	101	102	103	104	
Stages of fever			Only chill	Only heat	Chill followed by heat	All stages prominent	
Spleen enlargement		0 - Not palpable		2 - palpable			
		0	1	2			3
Headache		absent	mild	moderate			Severe
Nausea &vomiting		absent	mild	moderate			Severe
Body & muscle ache		absent	mild	moderate			Severe
Fatigue		absent	mild	moderate			Severe
Perspiration		absent	mild	moderate			Severe

Table 2: Demographical data

Variables	Number (%)	Mean±SD
Sex		
Male	10(32.3)	
Female	21(67.7)	
Age group		
0-10	10(32.3)	22.5±15.2
11-20	5(16.1)	
21-30	5(16.1)	
31-40	7(22.6)	
41-50	3(9.7)	
51 and above	1(3.2)	
Duration of disease		
One day	2(6.5)	4.5±1.52
Two days	6(19.4)	
Three days	8(25.8)	
Four days	8(25.8)	
Five days	8(25.8)	
Six days	1(3.2)	
Seven days	6(19.4)	

The improvement of the cases was assessed based on this MSS devised by the Council and the blood test for Malaria parasite. The primary outcome measure was a negative blood test for Malaria parasite and the secondary outcome measure was the reduction in MSS scale. Statistical analysis was carried out using IBM SPSS 20.0. Lost to follow up cases were also included for the analysis by using the last observation carry forward method (LOCF). The data were examined for normality. The qualitative data were expressed in terms of Median/IQR and the quantitative data in the form of mean ± SD. Accordingly, the statistical methods used in the study are Friedman's test, paired t-test, Repeated measure ANOVA, odds value, and confidence interval also.

RESULTS

Over the study period of six months, 173 patients were screened out of which 31 patients (10 males; 21 females) were diagnosed as malaria positive and followed up to seven days. During the follow-up period of seven days only 10 patients completed the follow up and the remaining cases are dropped out. By using the last observation carry forward method (LOCF), 31 cases were analyzed.

The demographical details of the cases are mentioned in Table 2. Baseline data is given in Table 3. MSS was used to assess each patient's condition from baseline to seven days of regular follow up. The mean MSS evaluated at baseline and end were 13.2± 1.9 and 5.9±4.4, respectively. The difference in the mean scores was found to be statistically significant (P=0.001, <0.05; CI: 5.7-8.9) (Table 4).

Table 3: Status of Baseline data

Symptoms	Number (%)
Temperature	
Up to 100^{o} F	0(0)
101^{o} F	8(25.8)
102^{o} F	13(41.9)
103^{o} F	10(32.3)
104^{o} F	0(0)
Stages of fever	
Only chill	0(0)
Only heat	9(29.0)
Chill followed by heat	19(61.3)
All the stage present	3(9.7)
Spleen enlargement	
Not palpable	25(80.6)
Palpable	6(19.4)
Headache	
Absent	1(3.2)
Mild	8(25.8)
Moderate	21(67.7)
Severe	1(3.2)
Nausea & vomiting	
Absent	5(16.1)
Mild	6(19.4)
Moderate	20(64.5)
Severe	0(0)
Body & muscle ache	
Absent	2(6.5)
Mild	6(19.4)
Moderate	20(64.5)
Severe	0(0)
Fatigue	
Absent	2(6.5)
Mild	18(58.0)
Moderate	11(35.5)
Severe	0(0)
Perspiration	
Absent	0(0)
Mild	10(32.3)
Moderate	20(64.5)
Severe	1(3.2)

Table 4 shows the symptom status at the entry and the end of the treatment. In this study temperature, fever, headache, nausea, and vomiting, bodyache, fatigue, and perspiration showed statistically significant results ($p<0.05$) apart from the spleen enlargement. Malaria is the problem that recurs periodically.

The temperature of 31 patients noted at the beginning of the study was 101.9 ± 0.9 and it was reduced 100.6±0.9 during the seven days of follow up. 14 patients did not report any fever at the end of the treatment and showed a statistically significant result. The mean MSS score at the starting was 13.2±1.9 and the end of the treatment it became 5.9±4.4 ($p <0.05$). ESR and lymphocyte value also reduced and it showed statistically significant results (Table 5).

In this study, 31 cases were found positive for malaria parasites and were treated. During the treatment period 5 cases were dropped out on the 3rd day of follow up, 7 cases on the 4th day, 5 cases on the 5th day of follow up, two cases on the sixth day, and 2 cases on the last day of follow up. So the blood smear report of 10 patients is available and these cases showed the parasite negative at the end of the treatment. The proportion rate of the study was 0.6, the odds value was 2.1, 95 % CI of the odds was 1.0 – 4.3 and the result showed there was no statistical significance for the final status ($p=0.7$) (Table 5).

Total 7 trial medicines were used for treating the malaria cases. Out of 31 cases, 38.7% of cases were prescribed the Arsenicum album (n=12) and 5 cases got cured (Table 6). An analysis of trial medicines showed that enrolled patients required only seven trial medicines as per the individualization of patients. The prescribing indications of the required trial medicines are presented in table 7. It was observed that Arsenicum album was the most frequently indicated and useful medicine in the treatment of malaria.

Table 4: Symptoms assessment at the entry and end of treatment

Symptoms	Number of Patients (Entry/End)	Median/ IQR		Chi Square Value	Friedman's P Value
		At entry	At end		
Temperature	31/17	2/(2-3)	0/(0-1)	98.81	0.0001*
Stage of fever	31/17	3/(2-3)	1/(0-1)	120.29	0.0001*
Spleen enlargement	7/6	0/(0-0)	0/(0-0)	6.00	0.423
Headache	30/15	2/(1-2)	0/(0-1)	86.78	0.0001*
Nausea & vomiting	26/10	2/(1-2)	0/(0-1)	92.98	0.0001*
Body & muscle ache	29/21	1/(1-2)	1/(0-1)	23.26	0.002*
Fatigue	30/28	2/(2-2)	1/(1-2)	26.17	0.0001*
Perspiration	21/21	2/(1-2)	1/(1-1)	91.60	0.0001*

Friedman's test is significant at $p<0.05$*

Table 5: Malaria symptom score and laboratory findings at entry

Investigations	Mean±SD (At entry)	Mean±SD (At End)	95% CI	P Value
MSS score	13.2±1.9	5.9±4.4	5.7 - 8.9	0.001*
Hb	10.9±2.2	10.9±2.2	-0.2 - 0.2	0.951
ESR	20.7±12.1	18.7±11.3	0.04- 3.9	0.046*
WBC	7641.9±1755.3	7416.1±1473.7	-59.4 - 511.0	0.116
polymorph	63.3±4.2	64.0±4.8	-1.5 - 0.2	0.167
Lymphocyte	29.9±4.0	29.0±3.8	0.1 - 1.7	0.028*
Monocyte	1.0±0.3	0.9±0.4	-0.0 - 0.1	0.572
Eosinophil	6.1±2.2	6.1±2.1	-0.4 - 0.4	1.000

The paired t-test is significant at $p<0.05$*

Table 6: Medicine used and the Improvement status of Malaria

Medicine used	No. Of cases (%)	Improvement status	
		Cured	Not cured
Ars. Alb.	12(38.7)	5	7
China	4(12.9)	1	3
Gels.	1(3.2)	0	1
Ipecac	2(6.5)	0	2
Nat.mur.	8(25.8)	2	6
Nyctanthus arb.	1(3.2)	1	0
Rhus tox.	3(9.7)	1	2

Table 7: Characteristic indications of medicines found useful.

Name of medicine	Characteristic indications	Number	
		Treated	Improved
Nat.mur.	Continuous chill with headache and perspiration, Debility with shortness of breath, Blister on lips, Cracked tongue, History of recurrent malaria, Patient feels better in open air	08	02
Ars. alb.	Chill state predominant, Prostration and weakness, Periodical nocturnal pyrexia, Restlessness with nausea and abdominal pain, Thirst (frequent but for small quantity of water).	12	05
Rhus tox.	Pyrexia with weakness of whole body, Bruised and sore sensation in extremities, less during rest, Prostration and trembling during fever, Rashes and vesicular eruption with itching, Clean and dry tongue with red tip.	03	01
China	History of malaria, Intermittent fever with chill especially at night and in forenoon, Marked debility, Thirst during heat stage, Excessive flatulence, belching and water-brash, Sweat profuse during sleep.	04	01
Nyctanthusarb.	Bilious and bitter vomiting, Constipation with remittent pyrexia, Scanty sweat, Cramps in both extremities.	01	01

DISCUSSION

This pilot study aimed to evaluate the efficacy of homeopathic therapy with predefined medicines in the treatment of malaria with positive results confirms that homeopathic medicines prescribed based on the totality of symptoms are useful in treating patients of malaria. It was found that the medicines found useful in our study namely *Natrum muriaticum, Arsenicum album, China officinalis, and Rhus toxicodendron* are also mentioned in Therapeutics of Intermittent fever by H.C Allen [14]. In Boericke Materia Medica, *Nat. mur. Ars.alb*., Gels., *Ipecac*., and *China* are mentioned as 1st-grade medicines and Rhus toxicodendron has been mentioned as 2nd-grade medicine for malarial fever [15]. *Natrum muriaticum, Arsenicum album, China officinalis,* and *Ipecac* are also mentioned in Synthesis Repertorium Homoeopathicum under the rubric "malaria" in chapter "Generalities" [16].

In Kent's Repertory, *Arsenicum album,*and *Natrum Muriaticum* are mentioned in 1st grade under the rubric "intermittent fever" in chapter "Fever" [17] in Homoeopathic Medical Repertory *Arsenicum album, Natrum Muriaticum, Ipecac,*and *China* are mentioned as 1st-grade medicines and Rhus toxicodendron, Gelsemium as 2nd-grade medicines under the rubric "intermittent fever" in chapter "fever" [18]. Nowadays Anti-malarial conventional medication remains fruitless as the parasite got resistant to these drugs [19]. Chloroquine resistance has been associated with a dramatic increase in malaria mortality. After the emergence of chloroquine resistance, the risk of malaria death among children in the age group of 0–9 years has multiplied by 2.1, 2.5, and 5.5 times, respectively [20]. In a clinic in Tamale (Ghana, Northern Region) patients with malaria were treated with

homeopathic drugs in an open study (n=75), of whom 90.7% (n=68) showed clinical improvement [21].

Subsequently in a randomized, double-blind, clinical trial, one group (n=30) received homeopathic drugs, of which 83.3% improved clinically, whereas the other group (n=25) received chloroquine with improvement in 72%of patients. This difference is not statistically significant due to the limited samples. The results do, however, suggest further research with larger groups [21]. Considering the increasing resistance to available agents and limited scientific proof on the effectiveness of homeopathic remedies, there is an immediate need to evaluate the role of homeopathy in the management of malaria. In addition, Homeopathic therapy can be a better choice due to its cost-effectiveness, in developing countries like India.

CONCLUSION

From this study, we conclude that homeopathic medicine is effective and can be safely used for the management of malaria. It further confirms the general rule that homeopathy is a system of individualizing the treatment. Controlled studies should be undertaken to further validate the efficacy of homeopathic medicines in malaria.

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