EVALUATION OF A MICROCURRENT DEVICE IN THE TREATMENT OF MALARIA

INTRODUCTION

Malaria is one of the most widespread diseases, having a global incidence of over 270 million cases/year. In Nigeria alone over 2 million deaths (500,000 being children below 5 years of age) per year.

Symptoms of malaria include headache, fever, muscular pain, shivering, chills or rigors. Severe cases may experience additional symptoms of marked abdominal pain, diarrhea and variable levels of consciousness. Laboratory manifestations of the disease are complex—ranging from anemia, hepatic dysfunction, kidney dysfunction and even hypoglycemia.

The occurrence of hypoglycemia in malaria cases has been linked to hepatic dysfunction and hyperinsulaemia, as reported on studies of adults in Thailand and children in the Gambia.

Of the four plasmodium species known to affect man, p. Falciparum infection is responsible for most of the acute cases of clinical malaria diagnosed in the West African region. Nigeria lies within this malaria endemic zone with a mortality rate estimated at 150/1000 live births for infants, 360/1000 deaths for under five years old.

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The rationale behind this work was to study primarily the effects of microcurrents of electricity on the malaria parasites and secondarily to determine the safety of the microcurrent units.

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PATIENTS AND METHODS

Samples of blood were collected from eligible adults aged above 18 years over a period of five months. In all cases venous blood was examined by laboratory analysis for the presence of malaria parasites and for females an additional blood test for pregnancy was done. Laboratory evaluation of subjects who showed the presence of p. Falciparum on the stained blood samples included a full blood count (total and diff), packed cell volume, mean corpuscular hemoglobin concentration, and for female subjects a pregnancy test. (FBC, HB, PCV,).

Thirty-seven subjects were eventually enrolled (17 asymptomatic subjects, 20 symptomatic subjects), blood samples collected and p. Falciparum was identified by a microscopic examination of a giemsa stained thick blood smear. Blood testing was done on days 0, 3, 7, 14 and day 28.

EXERCISE PROTOCOL

TIME AND EVENTS SCHEDULE

PROCEDURES	DAY 0 *	DAY 1	DAY 2	DAY 3	DAY 7	DAY 14	DAY 28
Consent form signed	X						
Medical History	X						
Physical Exam	X						
Hematology	X			X	X	X	X
Serum Chemistry	X			X	X	X	X
Malaria Test (Giemsa Stain)	X			X	X	X	X
Adverse Event Reporting	X			X	X	X	X
Study Treatment Applied**	X	X	X	X	X	X	X
Length of Treatment in Minutes	120	120	120	120	120	120	

* Enrolment Day

** Study treatment was applied every day until a zero parasite load was indicated through to the next testing day.

Male and female subjects were at least 18 years of age with uncomplicated clinical or no clinical symptoms of malaria and a malaria parasite load of Scanty, + or ++. Key exclusion criteria: pregnant or nursing mothers, and people with pacemaker or other active implanted device, etc.

Eligible patients were grouped into either asymptomatic or symptomatic malaria groups. They each received 120 minutes of microcurrent treatment every day until their malarial parasite load was zero. They continued receiving the treatment until the next test day confirmed a zero load. Subjects were treated as outpatients. Malaria loads and changes were recorded on days 0, 3, 7, 14 and 28 for those who completed the testing.

Clinical response was based on a change in the malaria parasite load.

Safety evaluations were assessed by the physical exams performed and post-therapy reporting of any adverse events.

Sixty participants were to be recruited for the study. Sample size was calculated based on the following assumptions:

- Minimum value of the difference to be detected between the groups
- Ratio of the number of participants = 1
- Level of significance = 5%
- Power of test = 90%

METHODS

Venous blood samples were collected for the following analysis:

- Haemoglobin
- PCV – Packed Cell Volume
- WBC including differential
- Hematocrit
- RBC
- Platelet count
- Malaria Load
- Pregnancy test – for female subjects

A complete blood count was taken, but only the above parameters were measured for the purposes of this study.

The malaria parasite load was determined using the following procedure:

> Giemsa stain of a thick blood smear using a light microscope to identify the parasites; at times (x) 100 magnification or less.

KEY TO MALARIAL PARASITE LOAD WITH HIGH POWER FIELD MICROSCOPE VIEW	
Scanty	Less than 3 trophozoites of P. falciparum per hpf
+	Three to four trophozoites of P. falciparum per hpf
++	Five to ten trophozoites of P. falciparum per hpf
+++	Eleven to twenty trophozoites of P. falciparum per hpf

Weight in kilograms and height in meters was measured using a standiometer balance. Other variables like blood pressure, pulse, respiratory rate and temperature were measured.

ANALYSIS/ RESULTS

Thirty seven subjects were enrolled in the study; twenty showed clinical symptoms of malaria, while seventeen subjects had no symptoms. Enrolment was based on the presence or absence of malaria parasites in the venous blood samples; as well as other enrolment criteria.

The results obtained in this study are displayed in the following tables:

TABLE 1 - GENERAL				
	ASYMPTOMATIC	SYMPTOMATIC	RESISTANT	TOTAL
NO OF SUBJECTS	17	20	0	37
TOTAL BLOOD SAMPLES	59	75	0	134

TABLE 2 – ASYMPTOMATIC

SUBJECT ID	DATE OF ENROLMENT	TEST DAYS	TEST DONE EACH TESTING DAY	HEMOGLOBIN	MPL	TIME PULSING
002	17/12/2002	1 3 7	PCV, HB, MPL, FBC/WBC	14.0gm	+ Scanty Neg	2hrs daily
003	18/12/2002	1 3 7 14 28		13.2	+ Neg Neg Neg Neg	
004	24/12/2002	1 3 7 14 28		15gm	+ Scanty Neg Neg Neg	
006	18/12/2002	1 3 7 14 28		14.2 14.2 14.1 14.2 14.5	+ Neg Neg Neg Neg	
009	23/12/2002	1 3 7 14		11.8 11.8 12.0 12.0	+ + + Neg	
010	28/12/2002	1 3 7 14 28		13.0 13.0 13.0 13.1 13.0	+ Neg Neg Neg Neg	

TABLE 2 – ASYMPTOMATIC CONTINUED

SUBJECT ID	DATE OF ENROLMENT	TEST DAYS	TEST DONE EACH TESTING DAY	HEMOGLOBIN	MPL	TIME PULSING
011	29/01/2003	1 3 7	PCV, HB, MPL, FBC/WBC	13.6 13.6 13.6	+ Scanty Neg	2hrs daily
016	06/03/2003	1 3 7 14		12.6 13.0 13.0 13.0	+ ?* ?* Neg	
018	06/03/2003	1 3 7 14		14.3 14.3 14.3 14.5	+ + Scanty Scanty	
021	07/03/2003	1 3 7		13.3 13.3 13.3	+ Scanty Neg	
024	07/03/2003	1 3 7		13.0 13.0 13.0	+ Scanty Neg	
026	07/03/2003	1 3 7		13.0 13.0 13.3	Scanty Neg Neg	

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TABLE 2 – ASYMPTOMATIC CONTINUED

SUBJECT ID	DATE OF ENROLMENT	TEST DAYS	TEST DONE EACH TESTING DAY	HEMOGLOBIN	MPL	TIME PULSING
027	07/03/2003	1 3 7	PCV, HB, MPL, FBC/WBC	13.0 13.0 13.3	+ + Neg	2hrs daily
028	07/03/2003	1 3 7		12.0 12.0 12.0	Scanty Scanty Neg	
029	07/03/2003	1 3 7		12.3 12.3 12.3	+ Scanty Scanty	
030	08/03/2003	1 3 7		14.3 14.3 14.3	Scanty ?* ?*	

TABLE 3 – SYMPTOMATIC

SUBJECT ID	DATE OF ENROLMENT	TEST DAYS	TEST DONE EACH TESTING DAY	HEMOGLOBIN	MPL	TIME PULSING
005	18/12/2002	1 3 7 14 28	PCV, HB, MPL, FBC/WBC	11.6 11.6 11.8 11.8 12.0	+ Scanty Scanty Neg Neg	2hrs daily
007	19/12/2002	1 3 7 14 28		15.3 15.3 15.3 15.2 15.3	+ + Neg Neg Neg	
008	20/12/2002	1 3 7 14 28		13.3 13.3 13.2 13.3 13.3	+ + Scanty Neg Neg	
012	28/02/2003	1 3 7 14		13.3 13.3 13.3 13.7	+ + Scanty Neg	
013	28/02/2003	1 3 7 14		10.6 10.6 11.0 11.0	++ + + Scanty	

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TABLE 3 – SYMPTOMATIC CONTINUED

SUBJECT ID	DATE OF ENROLMENT	TEST DAYS	TEST DONE EACH TESTING DAY	HEMOGLOBIN	MPL	TIME PULSING
014	28/02/2003	1 3 7 14	PCV, HB, MPL, FBC/WBC	14.6 14.6 15.0 15.0	+ + Scanty Neg	2hrs daily
015	28/02/2003	1 3 7 14		14.3 14.3 14.3 14.3	Scanty Neg Neg Neg	
017	06/03/2003	1 3 7		15.0 15.0 15.0	+ Scanty Scanty	
019	06/03/2003	1 3 7 14		12.3 12.3 13.0 13.0	+ Scanty ?* Neg	
020	07/03/2003	1 3 7		15.6 15.6 15.6	+ Scanty Scanty	
022	07/03/2003	1 3 7		15.3 15.3 15.3	++ + Scanty	
023	07/03/2003	1 3 7		14.6 14.6 14.6	+ Scanty Scanty	

TABLE 3 – SYMPTOMATIC CONTINUED

SUBJECT ID	DATE OF ENROLMENT	TEST DAYS	TEST DONE EACH TESTING DAY	HEMOGLOBIN	MPL	TIME PULSING
025	07/03/2003	1 3 7	PCV, HB, MPL, FBC/WBC	14.6 14.6 14.6	++ + +	2hrs daily
031	08/03/2003	1 3 7		13.0 13.0 13.0	+ Scanty Scanty	
032	08/03/2003	1 3 7		12.3 12.3 12.3	+ + +	
033	08/03/2003	1 3 7		14.0 14.0 14.0	+ Scanty Scanty	
034	11/03/2003	1 3 7		15.0 15.0 15.0	+ + ?*	
035	13/03/2003	1 3 7		15.3 15.3 15.3	+ Scanty Neg	
036	14/03/2003	1 3		15.6 15.6	+ ?*	
037	17/03/2003	1 3		13.0 13.0	+ Scanty	

* Indicates that no result showed posted on the lab work. The case report form shows negative.

SUMMARY/CONCLUSIONS

Our study shows some variations in hematological parameters during treatment using the microcurrent unit. Further research may be needed in this area in order to reach a solid conclusion.

Of the 37 people enrolled, 21 people reached a negative malaria load—most within 3-14 days. Twenty-nine people did not complete the protocol either because they tested negative and didn't return to continue the testing or because the study was stopped, but virtually all of them had significant reduction in their parasite load. One person was removed from the study immediately when she tested positive for typhoid which was outside the parameters of the study.

What was very significant is that virtually all of the subjects had a significant reduction or absence of the parasite on days 3, 7 and/or 14. They reported they felt better, symptoms were greatly reduced or absent on day 3.

A few of the enrolled subjects complained of mild itching/burning sensation on the wrist at the electrode points.

Apart from these minor complaints, there were no other serious adverse reactions reported by the participants. General physical examination, including blood pressure, pulse rate, respiratory rate and temperature did not show any significant changes before, during, or after the use of the microcurrent unit.

This study gives some insight into an alternative treatment of malaria. The study also shows that the microcurrent unit has very few adverse reactions and is thereby safe to use. The results obtained are very encouraging and may serve as baseline data for further research into the alternative management of malaria.

Notes: All subjects did not complete the testing schedule for two reasons:

1. Once symptoms disappeared or they tested clear, some did not return for further testing.
2. The study was stopped by the manufacturer of the microcurrent unit, who funded the research, on March 19, 2003 with only 37 of the projected 60 subjects enrolled. The study was concluded as the length of time for the study had been prolonged well beyond the original time frame.

The original plan was to include subjects with resistant malaria as well. When the study was concluded no resistant malaria subjects had been recruited.

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APPENDIX A

SUMMARY TABLE DAYS UNTIL SUBJECTS TESTED NEGATIVE

DAYS COMPLETED	DAY TESTED NEGATIVE	ASYMPTOMATIC	SYMPTOMATIC	TOTAL
28	3 7 14	3 1	1 2	3 2 2
14	3 14 Did not	2 1	1 3 1	1 5 2
7	3 7 Did not Unknown	1 6 1 1	1 8 1	1 7 9 2
3	Did not Unknown		1 1	1 1

APPENDIX B

SUMMARY TABLE OF ALL 36 SUBJECTS

COMPLETED TESTING TO	ASYMPTOMATIC	SYMPTOMATIC	TOTAL
28 days: Tested negative Reduced load	4	3	7
Only 14 days: Tested negative Reduced load	2 1	4 1	6 2
Only 7 days: Tested negative Reduced load Unknown	7 1 1	1 8 1	8 9 2
Only 3 days: Tested negative Unknown		1 1	1 1

APPENDIX C

BASED ON ALL 37 SUBJECTS

RESULTS	TOTAL
Total with blood showing clear of malaria	21
Total who had a reduced load	12
Total unknown	3
Removed	1