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EVALUATION OF NEAR POINT OF CONVERGENCE AND AMPLITUDE OF ACCOMMODATION AFTER TREATMENT OF MALARIA WITH *ARTEMETHER-LUMEFANTRINE*.

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Abstract

Background: Malaria induces a recession of the near point of convergence and a reduction of the amplitude of accommodation of the eye with symptoms such as blurred vision at near, difficulty reading, asthenopia, exophoria at near, and low accommodative convergence ratio occurring, all these symptoms lead to an interference in visual functioning and performance. *Artemether-Lumefantrine* anti-malaria drug is widely used and very effective as a first line treatment for uncomplicated plasmodium falciparum malaria infection. There is a need to determine if *artemether-lumefantrine* can reverse the effects of malaria on the amplitude of accommodation and near point of convergence.

Methods: This was a clinical study carried out using the convenient sampling method at the medical center and department of Optometry teaching clinic of the Federal University of Technology Owerri, Imo State, Nigeria to evaluate amplitude of accommodation and near point of convergence after treatment with *artemether-lumefantrine*. Informed consent was obtained from all subjects that participated in the study and ethical clearance from the Ethics Committee of the School of Health Technology, Federal University of Technology, Owerri. 143 subjects aged 18 to 30 years diagnosed with malaria were recruited for the study. The amplitude of accommodation was measured using the push-up to blur method with an accommodative target, and near point of convergence was determined using the push-up to break and recovery method with an accommodative target. Both measurements were taken after the diagnosis of malaria was made through laboratory analysis and before the administration of the drug. After drug administration, amplitude of accommodation and near point of convergence measurements were repeated 24-, 48-, 72-, and 336 hours. Effects of drug administration on parameters were analyzed using T-test and ANOVA.

Results: There was a significant increase in the amplitude of accommodation with time following administration of artemether-lumefantrine drug combination ($p<0.001$) while near point of convergence was not affected ($p>0.05$).

Conclusion: *Artemether-lumefantrine* used for the treatment of malaria countered the effect of malaria parasite on amplitude of accommodation by increasing it but had no significant effect on near point of convergence.

Keywords: Malaria, *Artemether-Lumefantrine*, Amplitude of Accommodation, Near Point of Convergence.

Introduction

Malaria is an acute febrile illness caused by a protozoan parasite of the genus *Plasmodium* and affects humans living in tropical regions. It is highly endemic in Sub-Saharan Africa of which Nigeria is part and is a major cause of ill health and death each year[1,2]. Approximately 229 million cases of malaria were reported in 2019 in 87 countries where malaria is endemic with Nigeria and the Democratic Republic of Congo accounting for 40% of estimated deaths due to malaria[1]. 65% of diseases reported in Nigeria have been attributed to malaria infection while the birth weight of infants born to 42% of pregnant women diagnosed with malaria was affected[2], the infants had reduced birth weights. Malaria affects all parts of the eye and its adnexa causing keratitis, uveitis, conjunctival pallor, retinitis, optic neuritis, lagophthalmos, retinopathy, ocular muscle paresis, subconjunctival and vitreous hemorrhage, papilledema, retinal edema, and hemorrhage[3] depending on severity. It has also been noted to cause a recession of the eyes near point of convergence (NPC) and reduction of the amplitude of accommodation (AA) with signs and symptoms such as blurred vision at near, asthenopia, exophoria at near and low accommodative convergence/accommodation ratio (AC/A ratio) which leads to an interference in visual functioning and performance[4].

For thousands of years, traditional herbal remedies were used to treat malaria, the first effective treatment came from the back of cinchona tree, which contains quinine[5]. It has been observed and documented that some of these drugs cause dose dependent, temporary to permanent adverse ocular reactions which include bull's-eye maculopathy, transient and reversible corneal changes, optic nerve pallor, cycloplegia and ptosis, lens opacity, and loss of accommodation[6]. These adverse effects of quinine and its derivatives led to the discovery of other more effective drugs like artemisinin with its derivatives - *artemether*, *artesunate* and *dihydroartemisinin*[5,7,8] and lumefantrine as first line therapy for uncomplicated *plasmodium falciparum* malaria[9]. Many of the cases of uncomplicated *plasmodium falciparum* malaria are treated with artemisinin combination therapies such as *artemether-lumefantrine*, *artesunate-amodiaquine*, *artesunate-pyronaridine*, *artesunate-sulfadoxine-pyrimethamine*, *artesunate-mefloquine* and *dihydroartemisinin-piperaquine*[8,9,10].

Artemisinin and its derivatives are used as first-line and second-line treatment for uncomplicated

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P. falciparum and *P. vivax* malaria resistant to chloroquine mostly as combination drugs[8,9,11] because artemisinin derivatives have short half-lives (2-6 hours), are rapidly eliminated from the system and repeated doses result in a reduction in plasma concentration with time[5,7]. The combination drugs have longer half-lives giving rise to different post-treatment duration of prophylaxis and preventing reinfection[9,10]. The half-life duration for lumefantrine is 1-10 days. *Artemisinin* provides rapid symptomatic relief by reducing the number of malaria parasites present while *lumefantrine* eliminates any residual parasites resulting in a cure[5,8,12]. *Artemether-Lumefantrine* contains 20mg *Artemether* and 120mg *lumefantrine* and is one of the most widely used artemisinin combination therapy followed by *artesunate-amodiaquine*[12].

AA measures the closest point at which a subject can maintain focus while NPC measures the amplitude of convergence which is the nearest point where fusion occurs, and objects are seen as one. Anomalies of accommodative and convergence systems result in symptoms such as double vision, blurred vision, and headaches after prolonged periods of near work. These anomalies are caused by many factors which include diseases like malaria and will affect students more because of the higher demand on reading at a near distance. NPC is used for the diagnosis of convergence insufficiency especially for people with demanding near tasks and is said to be low if greater than 10 centimeters (cm)[13] while insufficiency of accommodation occurs when the amplitude of accommodation is lower than expected for the subject's age.

Insufficient literature exists on the evaluation of NPA and AA after treatment with *artemether-lumefantrine* in Nigeria hence this study since malaria infection affects both parameters.

MATERIALS AND METHODS

The research was a clinical study involving 143 subjects of both sexes, within the age group 18 to 30 years who presented to the Federal University of Technology, Owerri Medical Center between September and November 2021 and were diagnosed with malaria. The convenient sampling method was used to obtain the subjects. Diagnosis for malaria was carried out at the Medical Center laboratory using the malaria blood smear test which is the gold standard for diagnosis[14], the Giemsa stain was used to quantify parasites and distinguish between species of falciparum and life cycle stages. Eye examinations were carried out at the Department of Optometry Teaching Clinic, Federal University of Technology, Owerri, Imo

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State, Nigeria. Informed consent was obtained from subjects who participated in the study. Ethical clearance was obtained from the Ethics Committee of the School of Health Technology, Federal University of Technology, Owerri, Nigeria with ethical approval number SOHT/ERC/2021/017. The study was conducted in accordance with the Helsinki Declaration. Case history, visual acuity, external examination, ophthalmoscopy, and retinoscopy were conducted on the subjects to establish their ocular, systemic, and drug history, rule out ocular pathologies, and determine the subjects' refractive states. The subjects' visual acuities were corrected to 6/6 or better in each eye, and subjects with allergies to *artemether-lumefantrine* and ocular pathologies, strabismus, and medications affecting the accommodative/convergence systems were ruled out. All subjects with ametropia wore their distance corrections for the procedures. Baseline AA and NPC were determined using push-up to blur and push-up to break and recovery respectively[15.16]. Measurements were taken from the spectacle plane using the Accommodation Convergence Rule (ACR).

Procedure for Measurement of AA

AA was measured under normal room illumination and the target (20/20 line on the near Snellen chart) was illuminated with a direct overhead lamp. The subject, while wearing his distance prescription was asked to fixate on the near target presented at 40 cm. The chart was slowly brought closer to the subject at about 1 to 2 cm/sec as the subject read the lines and was asked to report when the letters in the chart blurred and remained blurred (sustained blur). The distance from the test chart (blur point) to the spectacle plane was measured, recorded in cm, and converted to diopters by dividing 100 by the AA. The tests were performed twice on each subject and an average of the readings was obtained.

Procedure for Measurement of NPC

NPC was measured using the push-up to break and recovery method using an accommodative target[17]. The subject was asked to look at the 6/12 single target on the near Snellen chart fixed on a fixation stick as it was steadily brought closer and closer to the eyes from about 40cm away. The subject was asked to report when the target appeared double (break) as it was brought closer to the eyes and when it became one (recovery) as it was moved backward from the eyes, the deviation of the eyes at any point was also monitored. The break and recovery points were recorded in centimeters[17].

After obtaining the baseline AA and NPC readings, Artemether/Lumefantrine (Coartem, 20/120mg) was prescribed by the physician for each subject. The dosage was 4 tablets on the first day, another 4 tablets 8 hours later, and then 4 tablets every morning and night for the next two days[18]. Tablets were taken with food. Following drug administration, from the first day, the AA and NPC were measured at 24-, 48-, 72- and

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finally at 336 hours post-drug administration.

Statistical Methods and Analysis

Results obtained from the study were presented using tables and data uploaded into the Statistical Package for Social Sciences (SPSS) version 23 software. T-test and ANOVA were used to test hypotheses at 95% confidence interval and 0.05 significant level.

RESULTS

Demographic details such as age, gender distribution and mean baseline AA and NPC of 143 subjects of both sexes within ages 18 to 30 years that participated in the study are given in Table 1. The mean age of participants was 21.58 ± 2.77 years while the mean baseline values for AA and NPC were 13.17 ± 2.39 diopters and 6.77 ± 2.05 centimeters respectively.

Table 1: Descriptive Statistics of Subjects

	All participants with malaria (n=143) (Mean ± SD)	Male (n=73) (Mean ± SD)	Female (n=70) (Mean ± SD)	P value (T test) (Males vs Females)
Age (years)	21.58 ± 2.77	21.00 ± 2.74	22.20 ± 2.73	0.17
Mean Baseline AA (D)	13.17 ±2.39	13.06 ± 2.27	13.30 ± 2.48	0.37
Mean Baseline NPC (cm)	6.77 ± 2.05	6.98 ± 2.48	6.53 ± 1.52	0.24

D = Diopters; cm = centimeter; SD = Standard Deviation

There were no significant differences in age (p = 0.17), AA (p = 0.37) and NPC (p = 0.24) between male and female participants with malaria in this study.

Table 2: Effect of artemether-lumefantrine on AA and NPC at different time intervals

Time Interval (hours)	0 (Baseline)	24	48	72	336	P value (ANOVA)
Mean AA (D) ± SD	13.17 ± 2.39	10.87 ± 1.72	12.18 ± 1.89	13.58 ± 2.12	14.28 ± 2.58	0.00[a]
Mean NPC ± SD	6.77 ± 2.05	7.37 ± 1.88	6.88 ± 1.79	6.83 ± 1.79	6.34 ± 1.74	0.152

SD = standard deviation; D = diopters; cm = centimeters; a = Significant p-value

The effects of artemether-lumefantrine on AA and NPC from zero hours to 24-, 48-, 72- and 336-hour intervals after drug administration are shown in Table 2. ANOVA revealed a significant difference (p=0.00) in AA between the time intervals that measurements were taken till 336 hours (14 days) after administration of Artemether-Lumefantrine. There was an initial reduction in AA from 13.17 ± 2.39 to 10.87 ± 1.72 and

then a linear increase with about an 8.43% increase in AA (14.28 ± 2.58) at 336 hours after drug administration when compared with baseline values.

ANOVA showed no significant difference (p=0.152) in NPC values for all time intervals after drug administration. An initial 9% increase in NPC from 6.77 ± 2.05 to 7.37 ± 1.88 in 24 hours after initiation of treatment was observed after which the readings returned towards baseline values (6.34 ± 1.74 at 336 hours).

Table 3: Post hoc analysis comparing AA values at different time intervals

Time Interval (hours)	Mean AA ± SD (D) N = 143	Comparison time interval (hours)	Mean AA (D)	P value (T test)
0	13.17 ± 2.39	24	10.84 ± 1.72	0.00[a]
		48	12.18 ± 1.72	0.00[a]
		72	13.58 ± 2.12	0.00[a]
		336	14.28 ± 2.58	0.00[a]
24	10.84 ± 1.72	48	12.18 ± 1.72	0.00[a]
		72	13.58 ± 2.12	0.00[a]
		336	14.28 ± 2.58	0.00[a]
48	12.18 ± 1.72	72	13.58 ± 2.12	0.89
		336	14.28 ± 2.58	0.19
72	13.58 ± 2.12	336	14.28 ± 2.58	0.29

[a] = significant, SD = Standard deviation, D = diopters

Table 4: Post Hoc Analysis comparing NPC at different time intervals

Time Interval (hours)	Mean NPC± SD (cm)	Comparison time interval (hours)	Mean NPC± SD (cm)	P value (T test)
0	6.77 ± 2.05	24	7.37 ± 1.88	0.13
		48	6.88 ± 1.79	0.77
		72	6.83 ± 1.79	0.89
		336	6.34 ± 1.74	0.28
24	7.37 ± 1.88	48	6.88 ± 1.79	0.22
		72	6.83 ± 1.79	0.17
		336	6.34 ± 1.74	0.01
48	6.88 ± 1.79	72	6.83 ± 1.79	0.89
		336	6.34 ± 1.74	0.17
72	6.83 ± 1.79	336	6.34 ± 1.74	0.22

DISCUSSION

Mean baseline AA was slightly higher in females than males while mean baseline NPC was higher in males than females. The insignificant difference in gender of different ages with malaria may be because malaria is not gender blind since mosquitoes do not choose one sex over the other when they bite[19,20,21]. Some other studies[22,23] have reported a higher prevalence of malaria in men because of gender, economic, and cultural factors that expose men to certain work conditions making them vulnerable to mosquito bites while sociocultural and economic factors may hinder women from visiting clinics when they are sick thus causing an increase in the prevalence of malaria in females. A study[4] found a statistically significant recession of NPC which decreased with an increase in age in subjects with malaria while another study[24] reported that males had higher NPC than females which was not clinically significant though they did not conduct their study on subjects with malaria.

Post Hoc analysis (Table 3) using T-tests revealed that AA regressed during malaria episodes as there was a significant (p=0.00) and exponential increase in AA from 48 to 336 hours after treatment ended and malaria was cured when time interval values were compared with baseline. The result of this study agrees with the study[4] which reported a 20.54% reduction in AA during malaria infection with an increase in AA after recovery. The increase in AA in this study could be attributed to the mean parasite clearance time of 39 - 43 hours when artemisinin is used to treat uncomplicated *falciparum* malaria[7]. Artemisinin area under the plasma concentration-time curve and maximum plasma concentration values were about 6 times higher after the first dose on day 1 than on day 6 of multiple doses[24]. This decrease in artemisinin plasma concentration with time is suggestive of an increase in metabolic capacity due to pronounced autoinduction. This could lead to the possibility of a heightened systemic and ocular effect after the first 24 hours of therapy with artemisinin[24]. This might account for the initial reduction in AA values from 13.17 ± 2,39 to 10.84 ± 1.72 within 24 hours after drug administration. P-value between 72 hours into treatment and 336 hours was insignificant (p=0.24) and may be due to early response of subjects to therapy with *artemether-lumefantrine* with 96.5% fever clearance and 99.4% parasite clearance by 72 hours (3rd day) of therapy[25]. Parasite clearance is rapid with *artemether-lumefantrine* with approximately 90% clearance achieved in 40 hours[26].

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Despite the statistically significant increase in AA effect during treatment with *artemether-lumefantrine*, repeated measurements of AA require a change of at least 1.50D to be considered a significant variation. When changes in AA are smaller than 1.5D, they are accepted as expected variations[27]. The changes in AA in this study were below 1.5D when values obtained at other intervals were compared to baseline measurements and can be accepted as expected variations. Comparing values obtained at 48 hours to 72 and 336 hours post treatment using T test, the effect of *artemether-lumefantrine* on AA ceased to be significant ($p > 0.05$).

There was no significant difference in NPC ($p > 0.05$) between baseline values and end of test readings (336 hours) (Table 2). Post hoc analysis (Table 4) revealed a 9% increase in NPC which was observed 24 hours after treatment with *artemether-lumefantrine* was initiated from, after which it returned to normal. This initial increase in NPC indicates a recession which was not clinically significant before a return towards baseline values. NPC value greater than 10 cm was the criteria for diagnosis of convergence insufficiency[27], most of the values obtained were below 10 cm, indicating that despite the increase in NPC, convergence insufficiency was not diagnosed. We did not find any available information regarding the relationship between *artemether-lumefantrine* and NPC in Nigeria. Esenwah *et al*[28], found a recession of NPC during malaria attack which was higher in subjects with 2+ parasitemia of *plasmodium falciparum* (41.1%) than those with 1+ parasitemia (37.4%) after recovery from malaria attack. A study[29] on the effect of *Sulphadoxine* and *Pyrimethamine* on phoria and NPC found a 3% mean change (increase) in NPC after 45 minutes of drug intake which later returned to normal. The initial increase in NPC found in this study may be due to the mean parasite clearance time which ranges from 39 to 43 hours when artemisinin is used for treatment of uncomplicated falciparum malaria[7]. NPC is also influenced by four aspects of the total convergence which include fusional convergence, proximal convergence, accommodative convergence/accommodation, accommodative convergence and inter pupillary distance (IPD) and may be the reason for the insignificant effect obtained in this study. We could not find any established effects of *artemether-lumefantrine* drug on any of the parameters which influence NPC.

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CONCLUSION

The therapeutic use of *artemether-lumefantrine* for the treatment of malaria affects accommodation by an initial decrease in the AA of subjects after 24 hours which increased to near normal values after 72 hours. This has shown the drug use to be a good therapy against malaria parasite and its ocular side effects. These changes were also observed in the NPC when the mean values were compared, however the results were not up to the level of significance of our testing (0.05) hence *artemether-lumefantrine* has an insignificant effect on convergence.

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