



ISSN: 0975-766X
Research Article

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**TEN-YEAR PHARMACOTHERAPEUTIC STUDY OF ANTIMALARIAL DRUGS IN THE
TREATMENT OF HOSPITALISED CHILDREN UNDER FIVE YEARS AT THE TERTIARY
HOSPITAL IN SOUTH WEST NIGERIA.**

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Received on 03-02-2011

Accepted on 18-02-2011

ABSTRACT

Evidence has linked the development of drug resistance to irrational use of antimalarials at various levels. The use of antimalarial drugs in hospitalized children at the University College Hospital, U.C.H, Ibadan from 1999 to 2008 was studied, retrospectively. The primary objective was to assess the pharmacotherapy of the prescribed antimalarial drugs and their conformity with the National treatment guidelines and World Health Organization (WHO) recommendations. A total of 301 case files were selected from the central medical record. Thirty (30) case files were excluded due to incomplete data and patients having primary treatment other than malaria. Forty eight (48) case files were missing. Therefore 223 case files were used for the study. Results showed that more males 121 (54.3%) were affected than females 102 (45.7%). Fever with convulsion 97 (43.5%) was the most common presenting complaint. Majority of the patients (180) (80.7%) presented with severe malaria. Quinine 180 (80.7%) was the most prescribed antimalarial drug followed by Artemether-lumefantrine 58 (21.4%). Antibiotics, particularly Cephalosporins 257 (33.3%) were found to be the most prescribed drugs concurrently with the antimalarials. Paracetamol 112 (90.3%) was the highest prescribed antipyretics. Antimalarial prescriptions 196 (68.1%) were mostly in generic forms. Monotherapy was found to be high. Use of antimalarial drugs at UCH was found to conform to National treatment guidelines and WHO recommendations, however, measures should be taken

to detect and document adverse drug reactions. Training and retaining of prescribers, including private practitioners, on rational use of antimalarial drugs should be encouraged at all levels.

INTRODUCTION

Malaria is a mosquito-borne protozoal infection caused in humans by plasmodium parasite¹. It is the most prevalent parasitic disease with more than half of the World's population (3.3 billion) at risk². It has remained a major public health problem in Nigeria³ and indeed the world over with staggering statistics. Malaria is the fifth cause of death from infectious diseases worldwide following respiratory infections, HIV/AIDS, Diarrhoeal, and Tuberculosis respectively. It is second cause of death in Africa, following HIV/AIDS⁴. According to World Health Organization (WHO), approximately 300 to 500 million clinical cases causing more than a million death occur each year, especially among children and pregnant women in sub-Saharan Africa^{6,7}.

Nigeria accounts for a quarter of all malaria cases in the WHO African region⁴ with more than 100 million people at risk and about 50% of children having up to 3-4 episodes of malaria every year⁸. The spread and strength of antimalarial drug resistance is one of the greatest challenges facing effective malaria control in the World today³. Several control efforts are frustrated due to emergence of multidrug resistance^{9,10}, particularly with the rapidly growing resistance of *Plasmodium falciparum* to conventional monotherapies such as Chloroquine and Amodiaquine¹¹. Multidrug resistant *falciparum* is widely prevalent in South – East Asia, South America and Africa, the later being the continent with the highest burden of Malaria¹¹. *Plasmodium falciparum* causes the most severe and fatal form of malaria infection. It is responsible for nearly 90% of malaria deaths in sub-Saharan Africa¹².

Evidence has linked the development of drug resistance to inadequate and inappropriate use of antimalarials at various levels, leading to exposure by the parasite to less than the therapeutic drug levels³. Consequently, the efficacy of the most affordable antimalarial drugs, such as Chloroquine, has declined remarkably in the last 15 – 20 years³.

Nigeria loses over N132 billion, every year, from cost of treatment and absenteeism from work, schools and farms on malaria¹³. This figure is likely to increase in the future if resistance is not adequately controlled. Development

of resistance should, therefore, be taken seriously into consideration when utilizing antimalarials. A vital means of preventing or minimizing the development and/or spread of resistance is close monitoring and careful assessment of how antimalarials are used in the treatment of malaria, especially in children under five years. Since children less than five years are more affected by the disease with resultant high morbidity and mortality, use of antimalarial drugs is also more common in this age group than in any other. Special attention should be given to assessing rational use of antimalarial drugs in this age group. In addition, young children including neonates and infants are of particular risk of adverse drug reactions, as a consequence of immaturity of their organ systems¹⁴. This research work studied the use of antimalarial drugs in children under five year, with the main objective to assess the pharmacotherapeutic use of prescribed antimalarial drugs and their conformity with the National treatment guidelines and WHO recommendations with a view of providing and promoting pharmaceutical care.

PATIENTS AND METHODS

This was a retrospective study involving data obtained from case notes of children under five years that were diagnosed, admitted and treated for malaria at the paediatric unit of UCH between January 1999 and December 2008. The study was carried out between March 2nd and May 20th 2009, following the ethical approval by the hospital ethical committee. A total of 301 case files were selected from the central medical record, 30 case notes had to be removed from the study due to incomplete data (13 cases) and patients having primary treatment other than malaria (17 cases) and 48 case notes were missing. A total of 223 case notes of children under five years diagnosed, admitted and treated for malaria infection between January 1999 to December 2008 were therefore used for the study. Information extracted from the case files are demographic data (age, sex, weight), body temperature and packed cell volume (PCV) at the time of admission, type of malaria, presenting complaint, past medication history, referrals, educational status of the mothers, breastfeeding details, antimalarials prescribed including dosage regimen, drugs other than antimalarials prescribed and adverse drug reactions if any. Analysis was made using SPSS version 11 and EPI. Frequency tables and bar charts were also used in data presentation.

RESULTS

Table 1 show that there were more males 121 (54%) than females 102 (46%). Age bracket 1 year to less than 2 years 66 (29.6%) was the highest population followed closely by the age bracket 2 years to 3 years 64 (28.7%), the least population being the age bracket 0-1 year 25 s(11.2%). Referral from the private hospitals 66 (29.6%) was the highest followed by referral from secondary hospital 39 (17.5%). Fever 220 (35.3%) was the most frequent sign and symptom followed by convulsion 97 (15.5%). The least population 5 (0.8%) had cough and difficulty in breathing each (Table-2). Those with severe malaria 180 (80.7%) were more than those with uncomplicated malaria 43 (19.3%) (Table-3). School certificate education and above 150 (67.3%) accounted for the highest education population while those who had below school certificate 16 (7.2%) accounted for the lowest population.

Table-1: Sex, Age, Weight distribution of the patients.

Sex	Number (Frequency)	Percentage (%)
Male	121	54
Female	102	45.7
Total	223	100
Age		
0 - <1 year	25	11.2
1 year - < 2 years	66	29.6
2 years - < 3 years	64	28.7
3 years - < 4 years	33	14.8
4 years - < 5 years	35	15.7
Total	223	100.00
Weight		
0 - < 5kg		6.3
5 - <10kg	14	30.9
10 - <15kg	69	50.2
>15kg	112	50.2
	28	12.6
Total	223	100.0

Table-2: Pattern of referral, signs and symptom presented by the patients and types of malaria.

Referred	Number (Frequency)	Percentage (%)
From PH	66	29.6
From GH	39	17.5
Verbal	5	2.2
Not Referred	37	16.6
Not Indicated	76	34.1
Total	223	100
Sign and Symptom	(Frequency)*	
Fever	220	35.3
Convulsion	97	15.5
Loss of consciousness	23	3.7
Jaundice	14	2.2
Coca-cola colored urine	39	6.3
Vomiting	51	8.2
Poor/loose of appetite	14	2.2
Rashes	5	0.8
Cough	5	7.2
Diarrhea	33	5.3
Difficulty in breathing	5	0.8
Pallor	18	2.9
Chills and Rigor	19	3.0
Others	41	6.6

Table-3: Temperature and PCV on admission, breast feeding and educational status of mothers.

Parameter	Number (Frequency)	Percentage (%)
Temperature on admission		
< 35.5 ⁰ C	33	14.8
> 35.5 ⁰ C	99	44.4
Not indicated	91	40.8
Packed cell volume (PCV)		
< 15%	59	26.5
> 15%	136	60.9
Not indicated	28	12.6
Breast Feeding		
EBF	55	24.7
MF	52	23.3
Not indicated	116	52.0
Education of mothers		
Below school certificate	16	7.2
School certificate and above	150	67.3
Not indicated	57	25.6
Total	223	100

EBF= exclusive breast feeding; MF= mixed feeding; PCV= packed cell volume.

Quinine 108 (39.9%) was the most prescribed antimalarial drugs with Chloroquine 19 (7.0%) being the least prescribed antimalarial drug (Table 4). Paracetamol 112 (26.2%) was the drug mostly used at home before

presenting to hospitals (Table 5). Antibiotics 257 (33.3%) was the mostly prescribed drugs with antimalarials (Table 6). There was a high incidence of quinine usage as the first line 100 (64.0%) and second line (47.1%) monotherapy while the use of artemeter-lumefantrine was the highest first line 49 (62.0%) and second line 9 (47.4%) combination therapy (Table 7). Antipyretics (28%) were the most common drugs used by the patients before presenting to hospital (Fig 1) while antibiotics (33.3%) were the most common drugs prescribed along with antimalarials in the hospital (Fig 2).

Table-4: Number and pattern of antimalarial drugs prescribed.

Description	Number *(Frequency)	Percentage (%)
Quinine	108	39.9
Artemether – lumefantrine	58	21.4
Amodiaquine	30	11.2
Chloroquine	19	7.0
Artemether	15	5.5
Amodiaquine + SP	13	4.8
Amodiaquine + DHA	9	3.3
Amodiaquine + Artemether	7	2.6
Amodiaquine + Artesunate	2	0.7
Quinine + SP	3	1.1
Pyrimethamine – Sulphadoxine	2	0.7
DHA + SP	2	0.7
Chloroquine + SP	2	0.7
Camoquine	1	0.4
Total	271	100.0

*
Multiple response

Table-5: Pattern of drugs used before presenting to Hospital (n = 428).

Drug	Number *(Frequency)	Percentage (%)
Antipyretics		
Paracetamol	112	26.2
Analgin ^R	12	2.8
Antibiotics		
Cotrimoxazole	22	5.1
Amoxicillin	13	3.0
Metronidazole	9	2.1
Ampiclox	5	1.2
Erythromycin	4	0.9
Others	20	4.7
Known antimalarials		
Chloroquine	62	14.5
Quinine	7	1.6
Other	4	0.9
Unknown antimalarials		
	13	3.0
Haematinics		
	59	13.8
Anticonvulsants		
	15	3.5
Unknown drugs;		
Injections	36	8.4
Oral	35	8.2
Total	428	100

Analgin^R = Dipyron; Ampidox = ampicillin + cloxacillin

* Multiple response

Table-6: 1st and 2nd line Monotherapy and 1st and 2nd line Combination therapy.

Description	1 st line (n = 156)	2 nd line (n = 17)
	No (%)	No (%)
Quinine	100 (64.0)	8 (47.1)
Amodiaquine	26 (16.7)	4 (23.5)
Chloroquine	19 (12.2)	-
Artemether	11 (7.1)	4 (23.5)
Camoquine	-	1 (5.9)
Artemether – lumefantrine	49 (62.0)	9 (47.4)
Sulphadoxine – pyrimethamine	1 (1.3)	1 (5.3)
Amodiaquine + SP	10 (12.7)	3 (15.8)
Amodiaquine + Artemether	5 (6.3)	2 (10.5)
Amodiaquine + DHA	7 (8.7)	2 (10.5)
Amodiaquine + Artesunate	2 (2.5)	-
Chloroquine + SP	2 (2.5)	-
Quinine + SP	3 (3.8)	-
DHA + SP	-	2 (10.5)

SP = Sulphadoxine – pryimethamine; DHA = Dihydroartemisinin

Table-7: Pattern of drugs and antibiotics prescribed with antimalarials (n = 257).

Description	Number *(Frequency)	Percentage (%)
Antibiotics	257	33.3
Analgesics/Antipyretics	178	23.0
Haematinics	164	21.0
Intravenous fluids	103	13.0
Anticonvulsants	57	7.4
Mannitol	14	1.8
Total	773	100.0
Class of Antibiotics		
Cephalosporins		
Cefuroxime	36	14.0
Ceftriaxone	33	12.8
Cephalexine	4	1.7
Others	4	1.7
Penicillins		
Crystalline penicillin	49	19.1
Others	25	9.7
Aminoglycosides		
Gentamicin	44	17.1
Amikalin	16	6.2
Chloramphenicol	46	17.9
Total	257	100

* Multiple response

DISCUSSION

Males 121 (54.3%) were more affected than females (45.7%) (Table 1). Although no correlation between gender and malaria exist, several studies have reported similar findings of higher incidence in males^{15,16,17,18}.

Patients with ages between 1 to less than 2 years 66 (29.6%) constituted the highest percentage in this study while those with ages between 0 to less than 1 year 25 (11.2%) constituted the least (Table 1). The low incidence in the latter age group supported the finding that children born to immune mothers are protected from malarial infections due to passive immunities from their mothers^{19,20}. This immunity wanes after 3 to 6 months²¹ which probably explained the higher incidence in the former age group 1 to less than 2 years. Interestingly, 4 patients had ages below 3 months. This could be due to transmission via the perinatal route, which has been shown to be rare. The fewer number of these patients further suggests the rare nature of such transmission.

Most of the patients were referred either from private hospitals 66 (29.6%) or government hospitals 39 (17.5%) or verbal referral 5 (2.2%) (Table-2). This is expected as UCH is a tertiary hospital that receives referrals from other healthcare centers. Referrals from private hospitals/clinics 66 (29.6%) were the highest. This indicates a high patronage of private hospitals, which could be due to proximity, lesser congestion and, probably, other reasons. Unfortunately, a study conducted recently has shown significant insufficiency of these private practitioners¹⁹. One hundred and eighty (180) (80.7%) of total study population had severe malaria (Table 2). This could, likely, be due to Nigeria being an endemic region, where children and pregnant women are more at risk of severe malaria and death^{22,23}. Percentages of patients were dehydrated due diarrhea, 33 (5.3%), vomiting 51 (8.2%) and loss of appetite 14 (2.2%) (Table-2).

Although the current guideline recommends combination of antimalarials to avoid development of resistance, the reason for monotherapy being highest in this study is due to high incidence of quinine usage. In terms of combination therapy, Artemether – lumefantrine combination 58(21.4%) predominates followed by Amodiaquine + SP 13 (4.59%) (Table-4). Both combinations are recommended by WHO guidelines with strong emphasis on the

Artemether–lumefantrine combination^{3,13,23}. In addition to artemether – lumefantrine being effective, its use in such a high percentage is also associated with the National free coartem^R programme. Proprietary prescribing was relatively high (31.9%) (Table-4). This could be due to the national free coartem^R programmes that may have made physicians to prescribe coartem^R as such. Generic prescribing was, however, found to be used more frequently (68.1%) (Table-4). The antimalarial drugs used were from the Essential drug list. There was no case of adverse drug reaction documented in the cases studied. This could mean that the reactions did not occur, were ignored or were not detected at all. Quinine 108 (39.9%) was the most frequently prescribed antimalarial drug (Table5). Use of quinine in severe malaria is, in conformity with current WHO guidelines on treatment of severe malaria²³. In this study, most patients 108 (80.7%) had severe malaria and, therefore, required quinine or artemisinin derivatives in parenteral forms as recommended by National antimalarial treatment guideline³ and WHO recommendations²³. Chloroquine 62 (14.5%) (Table 5) was the most commonly used antimalarial drug at home. This coincides with results of other studies^{17,18,24,25}. The reason may not be farfetched from availability and affordability of the drug. However, use of chloroquine is no longer recommended due to high incidence of resistance^{3,13}. Parents/guardians are also more likely to use it irrationally¹⁸, thus facilitating development of further resistance. Antibiotics (Table 5) (Fig1) usage at home was also found to be high. Their usage at home without prescription and proper counseling especially by a pharmacist is likely to result in therapeutic failure and, in turn, promote resistance or toxicity due to under dosage or over dosage, respectively, which can further complicate the malaria. Superimposition of doses was observed in 8 (3.6%) cases. This is improper as doses may be read incorrectly. As children, particularly neonates and infants, are more at risk of drug toxicity as a consequence of immaturity of their organ system¹⁴, care must be taken in writing their doses. All prescriptions should be written legibly so as to avoid any doubt or incorrect interpretations. Quinine must never be given by IV injections, as lethal hypotension may result. Quinine dihydrochloride should be given by rate – controlled infusion in saline or dextrose solution at a rate not exceeding 5mg salt/kg body weight per hour²³. This is WHO recommendation and may explain why intravenous fluids were used in high percentage.

Oral route 35 (8.2%) (Table 5) was used more frequently in administering the antimalarials probably because certain antimalarials exist only in oral dosage forms such as Coartem^R, amodiaquine, and cotecxin^R. WHO recommends that, in severe malaria, the parenteral route should be used for faster onset of action but the patient should be switched to oral forms once they can take it^{3,23}. This has been the observed trend at UCH, especially with quinine prescribed from parenteral to oral. Achievement of therapeutic concentrations of antimalarials is a key and essential component in the treatment of severe malaria. Death from this infection often occurs within hours of admission to hospital. Parenteral routes 36 (8.4%) (Table 5) are therefore very vital in the treatment of severe malaria as observed in this study. The most common drugs used for the children by their parents/guardians at home before coming to the hospital were found to be analgesics, antibiotics and antimalarials (Table 5) (Fig 2). This finding agrees with other similar studies conducted elsewhere¹⁷. Use of paracetamol, which constituted the highest frequency, could be due to its availability and affordability. Its use by parents/guardians at home is rational as this may reduce the chances of febrile convulsions.

Antibiotics 257 (33.3%) were the most prescribed drugs with antimalarials followed by analgesis/antipyretics 178 (23.0%) (Table 6) (Fig 2). Severe malaria has symptoms that are similar to those of other clinical conditions such as septicemia and pneumonia. These conditions may coexist with malaria resulting in more complications and difficulty in differential diagnosis^{23,26}. In this study, bacteria were detected in 7-14% patients admitted with severe malaria²⁷. Broad – spectrum antibiotic treatment should therefore, be started immediately until the diagnosis can be confirmed^{23,24}. This explains the high use of antibiotics in this study. Use of antipyretic – paracetamol was found to be very high (90.3%). This is because most of the patients were presented with high temperature (>37.5⁰C) on admission. Use of paracetamol conforms with treatment guidelines^{3,23}. Use of intravenous fluids (IVF) was also found to be common. Chloroquine was only prescribed in 19 (7.0%) of cases (Table 7) and was highest in 1999 before the National and WHO guidelines were implemented. Drug efficacy studies, conducted by Federal Ministry of Health in 2002 and 2004, in six geopolitical zones of Nigeria, indicated that chloroquine and sulphadoxine – pyrimethamine are no longer effective for national first line use¹³.

Fig-1: Drugs used before presenting to the hospital.

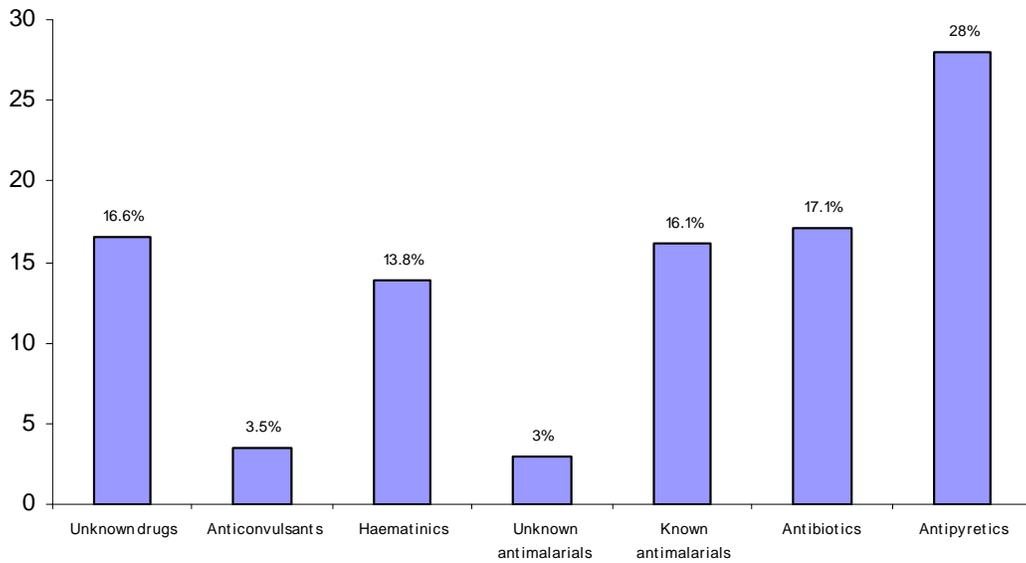
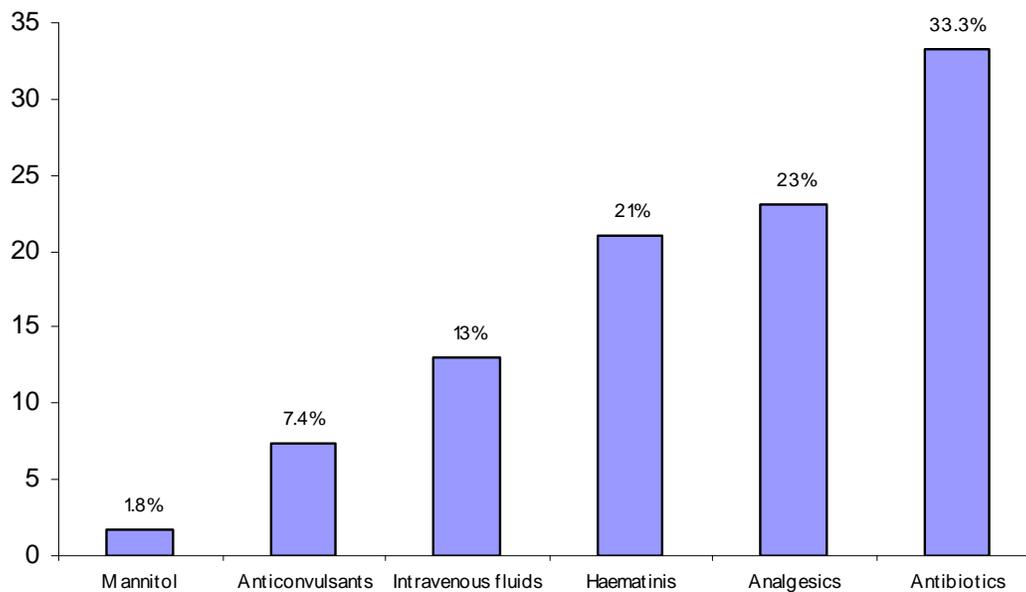


Fig-2: Drugs prescribed with antimalarials.



CONCLUSION

Use of antimalarial drugs at UCH was found to generally conform with National treatment guidelines and WHO recommendations. However, measures should be taken to detect and document adverse drug reactions, including active participation of clinical pharmacists in ward rounds and medication history taking. Training and retraining of prescribers, including private practitioners, on rational use of antimalarial drugs should be encouraged at all levels.

ACKNOWLEDGEMENTS

We hereby acknowledge the technical support of the staff in the medical out-patient department of the University College Hospital, Ibadan, and the cooperation of the management of the hospital.

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