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Research Article

Evaluation of Factors contributing to Artemether-Lumefantrine Treatment Failure in Pediatric Falciparum Malaria: Study at Wad-Medani Pediatric Teaching Hospital, Sudan

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Abstract:

Artemether-lumefantrine (AL) remains the frontline therapy for uncomplicated *Plasmodium falciparum* malaria in Sudanese children. However, rising treatment failure rates have prompted concern. This prospective, single-arm interventional study, conducted from November 2022 to May 2023 at Wad-Medani Pediatric Teaching Hospital, investigated factors contributing to AL treatment failure. Data included clinical assessments, parasite quantification, and adherence evaluations using the Morisky Medication Adherence Scale. Key findings revealed poor adherence as a major determinant: 21% of caregivers discontinued treatment early, and 5% missed doses. High initial parasite densities were linked to delayed clearance in 10% of failures. Only 35% of patients consumed AL with fatty food, reducing drug absorption, while 6% who vomited post-dose did not receive replacements. Notably, 25% of physicians were unaware of national guidelines, and 80% lacked access to them. The study highlights the need for improved patient education and physician training to enhance treatment outcomes and curb AL failure in pediatric malaria management.

Keywords: Artemether-lumefantrine, Plasmodium falciparum, malaria treatment failure, pediatric malaria, adherence, Sudan.

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1. Introduction

Artemether-lumefantrine (AL), a fixed-dose oral combination therapy, is currently the first-line treatment for uncomplicated *Plasmodium falciparum* malaria in Sudanese children. This recommendation, endorsed by the Malaria Technical Advisory Committee and the Federal Ministry of Health, is outlined in the Sudan Malaria Treatment Protocol (2017) (1). AL has demonstrated high efficacy, with cure rates exceeding World Health Organization (WHO) standards (>95%), along with rapid parasite and gametocyte clearance (2). Despite its proven clinical and parasitological efficacy, emerging reports of treatment failure are raising concerns. Several contributing factors have been proposed, including parasite resistance, pharmacokinetic variability, poor patient adherence, and elevated initial parasite burden (3). Artemisinin-based combination therapy (ACT) resistance, while more prevalent in Southeast Asia, poses an emerging threat to sub-Saharan Africa, necessitating proactive surveillance and management (3,4).

Pharmacokinetic factors—particularly those affecting lumefantrine—significantly influence treatment success in pediatric populations. Lumefantrine is highly lipophilic, exhibits variable oral bioavailability, and requires co-administration with fatty food for optimal absorption (5,6,7). It is primarily metabolized in the liver by cytochrome P450 3A4 enzymes and is highly protein-bound, particularly to high-density lipoproteins (6). These properties, coupled with age-related metabolic differences in children, can result in sub-therapeutic plasma concentrations, particularly in those with low body weight, compromising efficacy (8,9).

Adherence to the AL regimen is another key determinant of treatment success. Suboptimal adherence—due to missed doses or premature discontinuation—can result in inadequate drug exposure and facilitate resistance development (5, 10). Pediatric adherence depends heavily on caregivers' understanding and compliance. In a Sudanese study, Musa et al. (2019) found a significant association between poor adherence and increased treatment failure rates, underscoring the importance of caregiver education (11).

Additionally, healthcare system challenges, including limited physician awareness and access to national malaria protocols, further compromise treatment quality. Interventions led by clinical pharmacists, including structured counseling and protocol training, could mitigate modifiable risks and enhance outcomes.

Initial parasite density also plays a pivotal role in predicting therapeutic response. Patients with higher baseline parasitemia may demonstrate delayed parasite clearance, increasing the risk of persistent infection and treatment failure (3,10).

Although AL remains effective, increasing reports of failure—such as the 15.7% treatment failure rate observed at Wad-Medani Pediatric Teaching Hospital between 2018 and 2019—underscore the need for re-evaluation of treatment practices (11). This study aims to identify and analyze the factors associated with AL treatment failure among pediatric patients in Wad-Medani, focusing on patient adherence, pharmacologic factors, and healthcare delivery, with the goal of informing targeted interventions to optimize malaria management in Sudan.

2. Materials and Methods

2.1 Study Design

This study employed a prospective, single-arm interventional design conducted between November 2022 and May 2023. The study monitored patients receiving partially supervised artemether-lumefantrine (AL) treatment over a 28-day follow-up period to evaluate therapeutic efficacy and identify factors influencing treatment outcomes.

2.2 Study Area

The study was conducted at Wad-Medani Pediatric Teaching Hospital, a referral center for children in Gezira State, Sudan. The hospital provides outpatient and inpatient services and includes 204 beds for patients aged from one day to 16 years. The region has a high prevalence of *Plasmodium falciparum* malaria, with climatic conditions conducive to malaria transmission.

2.3 Study Population

Children aged 6 months to 16 years who visited the outpatient clinic or were admitted to Wad-Medani Pediatric Teaching Hospital and who were prescribed AL or admitted due to AL treatment failure were included. Additionally, all available medical doctors (consultants, registrars, medical officers, and house officers) at the hospital were included.

2.4 Inclusion Criteria

Children who met WHO criteria for uncomplicated malaria: febrile (axillary temperature >37.5°C) or had a history of fever within the previous 24 hours, body weight >5 kg, and microscopically confirmed *P. falciparum* malaria. Additional criteria included residing in Wad-Medani and being prescribed AL or having taken AL within the previous two weeks.

2.5 Exclusion Criteria

Children were excluded if there was refusal of consent; mixed or mono-infection with *Plasmodium* species other than *P. falciparum*; features of severe malaria; hemoglobin <5.0 g/dL; known hypersensitivity to AL; presence of chronic or severe illnesses; or fever due to non-malarial causes.

2.6 Sample Size and Sampling Techniques

All eligible children presenting during the six-month study period were included. For physicians, systematic random sampling was used, with a sample size of 50 calculated from a population of 57 doctors using the formula: n = N / (1 + N * e^2) at a 95% confidence level and 5% margin of error. Due to the minimal difference, total coverage of the population was considered.

2.7 Data Collection Method

Stage I: Baseline Screening

Socio-demographic and clinical data were recorded. Axillary temperature and body weight were measured. Finger-prick blood samples were used for thick and thin smears, stained with 10% Giemsa, and examined by expert microscopists to identify and quantify parasitemia and gametocytes.

Clinical evaluation assessed the AL dosage regimen, and physical examination excluded signs of severe malaria or other illnesses. The hospital dispensed AL (20 mg + 120 mg) free of charge and dosed it per WHO weight-based guidelines. Morning doses were directly supervised; evening doses were administered at home with caregiver instructions and follow-up phone calls.

Adherence was evaluated using the Morisky Medication Adherence Scale (MMAS). Medical doctors completed a questionnaire assessing their awareness of national malaria treatment protocols.

Stage II: Clinical Pharmacist Intervention

A clinical pharmacist conducted educational sessions with physicians, reviewed the Sudan Malaria Treatment Protocol, provided counseling to caregivers, and assessed drug therapy and potential interactions affecting AL pharmacokinetics/dynamics.

Stage III: Post-Intervention Monitoring

Adherence to the regimen and any adverse drug reactions were recorded. Scheduled follow-ups occurred on Days 3, 7, 14, 21, and 28.

2.8 Data Analysis

Data were entered and analyzed using SPSS version 20. Descriptive analyses were performed, and associations were evaluated with a 95% confidence interval. A p-value < 0.05 was considered statistically significant.

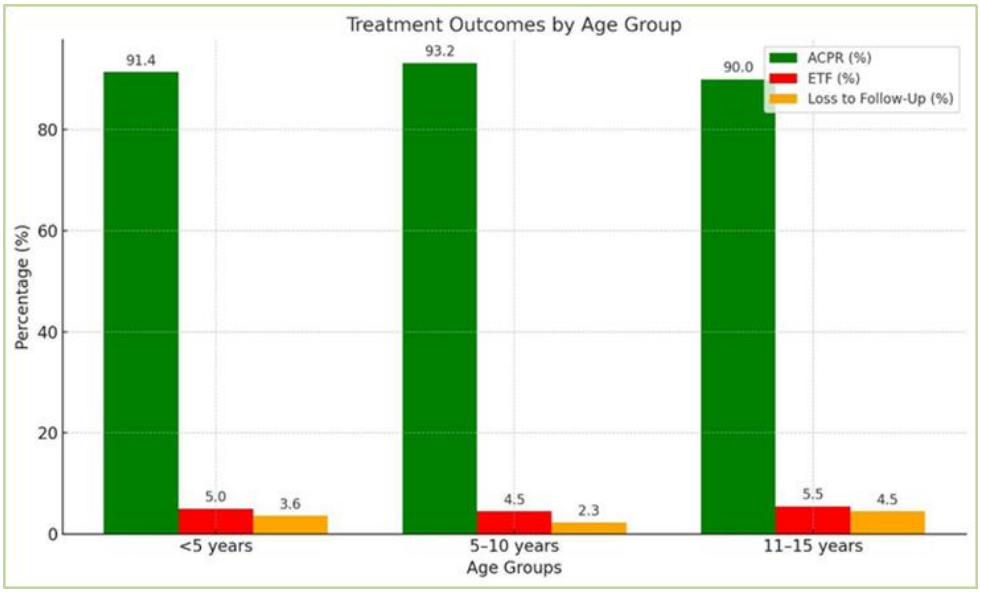
2.9 Ethical Approval

Ethical clearance was obtained from the University of Gezira's ethical committee and the Gezira State Ministry of Health. Written informed consent was obtained from all participants' parents or guardians.

3. Results

A total of 2950 screened patients ; 1520 confirmed malaria cases; 178 consented to study;80 enrolled in study, 70 participants (40 males and 30 females) completed the 28-day follow-up.

Early Treatment Failure (ETF) rates were slightly higher in the 11–15 years age group (5.5%) compared to the other groups. The ETF rates were lowest in the 5–10 years group (4.5%) as shown in Figure(3. 1).



Figure(3.1): Treatment outcomes by age group

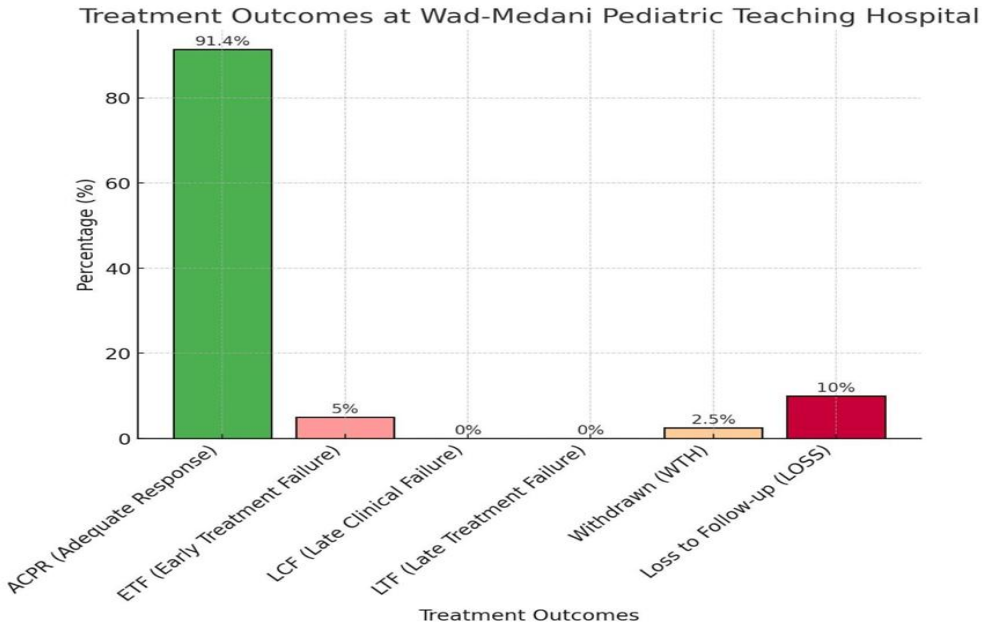


Figure (3.2): Treatment outcomes at Wad-Medani Pediatric Teaching Hospital

No cases of late clinical failure (LCF) or late treatment failure (LTF) as showed by Figure 2.

Table (3.1): Factor effect on Adherence of patient/ parent to the treatment of AL (n=100)

Forgetting to give medications to child	5(5%)
People sometimes miss taking their medications for reasons other than forgetting.	7(7%)
Stop or cut medications without telling the doctor, because felt worse when you took it	21(21%)
Higher primary parasite density	10 (10%)

Table(3. 2): Assessment of factor effect on pf. treatment failure

Variable	n=50	Yes	No
Patient adherence with the regimen		48(96%)	4(8%)
Patient adherence with regimen and ingested with fatty food		35(7%)	15(3%)
Vomiting with 30 min. and did not repeated the dose		3(6%)	5(1%)
A concomitant disease that would interfere with treatment outcome		1(2%)	13(26%)
A patient-related factor that enhances treatment failure		6(12%)	10(2%)
A healthcare-related factor that enhances the treatment failure		3(6%)	5(5%)

Fifty medical doctors responded by (50%) to the self-administered questionnaire used to assess their awareness and the factors that affect adherence of medical doctors to national protocol for treatment of malaria.

Six (12%) consultants, 12 (24%) registrars, 12 (24%) medical officers and 20 (40%) house officers, the majority were females 40 (80%).

Regarding age of physicians that included in this study, majority 38 (76%) were in the age group (25-30 years) and mean of experiences two years. see Table-3.3

Table-(3.3): Demographic Characteristics of medical doctors:

Characteristic	Frequencies n(50)	Percentage 100%
Gender		
Male	10	20
Female	40	80
Job specialties		
Consultants	6	12
Registrars	12	24
Medical officers	12	24
House officers	20	40
Age/Years		
>25	1	2
25-30	38	76
30-35	7	14
<35	4	8
Years of Experience		
1	31	62
1-5	13	26
6-10	5	10
>10	1	2

Most medical doctors 40 (80 %) followed the national protocol in the treatment of malaria. 100% consultants and registrars were aware about the national protocol while, 25% of medical officers and 50% of house officers weren't aware about the national protocol; most of house officer didn't have this protocol.

15(30%) of physicians had national protocol in soft format, followed by 8 (16%) who had in hard format, while 24(46%) didn't have the protocol as illustrated in Table-3.4.

Table-(3.4): Association between Job Specialties and Adherence to Protocols:

Characteristic	Job Specialties				P -value
	Consultant	Registrars	Medical officer	House officer	
1.Adherence to guidelines					
National	**5** (83.3%)	**9** (75%)	**9** (75%)	**17**(85%)	**0.866**
International	**1**(16.7%)	**3** (25%)	**3** (25%)	**3** (15%)	
2. Awareness about Sudan malaria treatment protocol					
Yes	**6** (100%)	**12** (100%)	**9** (75%)	**10** (50)	**0.006**
No	**0** (0%)	**0** (0%)	**3** (25%)	**10** (50%)	
3. Had the protocol					
Yes	**6** (100%)	**11** (91.6%)	**5** (41.7%)	**4** (20%)	**0.001**
No	**0** (0.0%)	**1** (8.3%)	**7** (58.3%)	**16** (80%)	
4. Type of the protocol					
Soft	**2** (33.3%)	**10** (83.3%)	**2** (16.7%)	**1**(5%)	**0.070**
Hard	**3** (50%)	**1** (8.3%)	**1** (8.3%)	**3** (15%)	

p-value less than 0.05 significant.

4. Discussion

This study evaluated of Factors contributing to Artemether-Lumefnatrine Treatment Failure in Pediatric Falciparum Malaria. The prospective observational study spanned from November 2022 to May 2023 and included 80 enrolled patients, with 70 completing the 28-day follow-up. Our findings demonstrate an Adequate Clinical and Parasitological Response (ACPR) rate of 91.4%, an Early Treatment Failure (ETF) rate of 5%, and no reported cases of Late Clinical or Parasitological Failure (LCF/LPF). These findings align closely with a prior study conducted in Kassala, eastern Sudan, where the efficacy of AL reached 98.7% over 28 days of follow-up, confirming AL's continued reliability in Sudanese contexts under supervised conditions (12). However, a slightly lower ACPR in the present study (91.4%) may indicate the influence of factors such as adherence, pharmacokinetics in children, or emerging resistance.

Similarly, in Ethiopia, a systematic review and meta-analysis reported AL's PCR-corrected treatment success rate as 98.7%. The lower efficacy observed in the present study may be attributable to variability in treatment adherence, absorption rates in children, or the level of supervision, which were more rigorously controlled in the Ethiopian trials (13). Conversely, our results are more consistent with data from Western Kenya, where the PCR-corrected ACPR was 88.5% in children aged 6–59 months (14). These findings support the hypothesis that AL efficacy may be declining in certain regions, emphasizing the need for localized surveillance and updated treatment strategies. Adherence emerged as a significant determinant of therapeutic success. Our chi-square analysis ($p = 0.000096$) confirmed a strong association between adherence to the treatment protocol and achieving ACPR. Among the 50 caregivers assessed, 21% admitted to stopping medication when symptoms improved, and 5% forgot to administer doses, illustrating behavioral barriers to adherence.

This is consistent with findings from (15), who reported a 100% cure rate in Nigerian patients adhering to AL and an ACPR of 95% in children under five. Likewise,(16) identified cultural and behavioral factors, such as sharing medications or saving them for future use, that compromised treatment success in Uganda. Similarly, (17) in Ethiopia found poor adherence linked to caregiver illiteracy, the use of concomitant medications, and early symptom relief.

These findings reinforce the role of patient and caregiver education in malaria treatment programs. The inclusion of the Morisky Medication Adherence Scale (MMAS) in our study offered a practical tool for identifying at-risk patients and tailoring educational interventions accordingly.

Pharmacokinetic variability may partially explain differences in treatment outcomes. Lumefantrine, the longer-acting component of AL, is known for its variable bioavailability, particularly in children. A study by (18) in Uganda revealed significantly lower lumefantrine exposure in children compared to adults, potentially contributing to sub therapeutic drug levels and increased risk of treatment failure.

Moreover, lumefantrine's absorption is heavily dependent on co-administration with fatty foods. (19) highlighted the importance of this factor, which was also addressed in our study. We found that only 70% of caregivers ensured co-administration with fatty meals, possibly influencing plasma concentrations and efficacy. Inadequate absorption due to vomiting, another key determinant, was also recorded. Three patients experienced vomiting within 30 minutes of drug intake without dose repetition, contributing to their subsequent treatment failure.

The awareness and adherence of healthcare providers to national protocols also played a pivotal role. Our survey of 50 medical doctors revealed that 80% claimed adherence to the national malaria treatment protocol, but discrepancies existed across professional ranks. While all consultants and registrars were aware of the protocol, 50% of house officers were not, and 80% lacked access to a copy. This indicates a gap in protocol dissemination and continuing medical education.

This is supported by (20), who found low adherence to ACT guidelines in Ghana, particularly among less experienced healthcare providers. Similarly, (21) in Mozambique and (22) in Kenya highlighted systemic issues such as reliance on empirical diagnoses, inadequate training, and limited access to diagnostics.

These findings suggest that improving physician education, providing universal access to treatment guidelines, and reinforcing diagnostic support systems are crucial to maintaining AL's efficacy.

This study uniquely assessed the impact of clinical pharmacist-led interventions, including patient education, regimen review, and follow-up support. These interventions likely contributed to the relatively high ACPR observed, echoing findings from (22) who demonstrated improved outcomes with supervised AL administration. Pharmacist-led interventions have been underutilized in malaria case management but can play a transformative role in enhancing adherence, monitoring, and rational drug(23).

5. Conclusion

The findings highlight the need for enhanced caregiver education, improved physician adherence to treatment protocols, and routine pharmacokinetic assessments to optimize AL therapy. Strengthening malaria management strategies through these interventions can significantly reduce treatment failure and improve clinical outcomes in pediatric malaria.

6. Patents

Author contribution: Conceptualization , investigation, methodology : prof: Imd-Eldeen Mohamed Taj Eldeen, Huda M. Harron, Bakri Y.M. Nour and Ibrahim O.M. Omer. Data curation ,software, formal analysis, writing original draft and visualization Dr. Nehal

Ahmed Mohamed Musa. Resources (patients) prof: Huda M. Harron and Dr. Nehal Ahmed Mohamed Musa. Malaria test confirmation by Bakri Y.M. Nour. Role of clinical pharmacist by Ibrahim O.M. Omer and Nehal Ahmed Mohamed Musa. Validation prof: Imd-Eldeen Mohamed Taj Eldeen, Huda M. Harron, Bakri Y.M. Nour and writing editing by Dr. Nehal Ahmed Mohamed Musa.

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Intuitional Review Board Statement: This study conducted after it had been approved by Ministry of Health Gezria State and Ethical Committee of University of Gezria before Patients had been approached, recruited, and enrolled in the in the study. This article was a part of author study carried out by same authors. So, ethical approvial was taken for the whole study and it possessed the number 6-22 date 23/2/2022 ; however, this article involved no experimental test on humans or animals.

Informed Consent Statement : Informed consent was obtained from all subject involved in the study.

Conflicts of Interest: The author declare no conflict of interest.

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