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Adverse Drug Reactions and Changes in Haematological and Clinical Chemistry to Two ACTs among Nigerian Children with Acute Uncomplicated Malaria

Réactions Indésirables Aux Médicaments, Modifications Hématologiques Et De La Chimie Clinique À Deux ACT: L'artémisinine-Pipéraquline (AP) Et L'artéméther-Luméfántrine (AL) Chez Les Enfants Nigériens Atteints De Paludisme Aigu Non Compliqué

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ABSTRACT

BACKGROUND: Adverse drug reaction (ADR) is a global and frequently occurring medical emergency with increased cases of mortality annually. ADRs can occur with the use of all drugs including artemisinin-based combination therapy (ACTs) which are currently the treatment of choice for acute uncomplicated malaria globally. Numerous doses of ACTs are administered daily in malaria endemic areas.

AIMS: This study determined the incidence, pattern of presentation and factors associated with ADRs to two ACTs- artemisinin-piperaquine (AP) and artemether-lumefantrine (AL) among children with confirmed acute uncomplicated malaria in Ibadan, Nigeria.

METHODS: Children aged 2-10 years enrolled into a larger study evaluating the safety and efficacy of artemisinin /piperaquine (AP) and artemether /lumefantrine (AL) using the WHO 28-day protocol were studied. Monitoring for ADR was based on history from the parent and /or child (for occurrences of treatment emergent signs and symptoms), physical examinations and abnormalities in laboratory investigations- full blood count, blood chemistry and liver function tests. Causality assessment for the ADR was by the Naranjo algorithm scale.

RESULT: 108 of 114 (94.7%) children completed the study. Over half [61(56.5%)] were males. The mean age of enrollees was 65.1±30.0 months. Day 28 adequate clinical and parasitological response (ACPR) for AP was 96.1% and 90.4% for AL. Observed ADRs were cough, diarrhea, loss of appetite, abdominal pain, rash, irritability, insomnia and headache. The prevalence was similar in the two treatment groups (AL=14%, AP= 11%; $p=1.000$). The incidence of ADR to both ACTs was 12/1000 patients per day. All ADRs were mild and resolved spontaneously. No notable associated factor to ADR was detected in this study.

CONCLUSION: Artemether-lumefantrine and Artemisinin-piperaquine were found to be safe in the study population.

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KEYWORDS: Adverse drug reactions, Artemisinin based combination therapy, Malaria, Nigeria.

RÉSUMÉ

CONTEXTE: La réaction indésirable aux médicaments (ADR) est une urgence médicale mondiale fréquente avec une augmentation des cas de mortalité chaque année. Les ADR peuvent survenir avec l'utilisation de tous les médicaments, y compris les thérapies à base d'artémisinine (ACT), qui sont actuellement le traitement de choix pour le paludisme aigu non compliqué dans le monde entier. De nombreuses doses d'ACT sont administrées quotidiennement dans les zones d'endémie palustre.

OBJECTIFS: Cette étude a déterminé l'incidence, le modèle de présentation et les facteurs associés aux ADR à deux ACT - l'artémisinine-pipéraquline (AP) et l'artéméther-luméfántrine (AL) chez les enfants atteints de paludisme aigu non compliqué confirmé à Ibadan, au Nigeria.

MÉTHODES: Des enfants âgés de 2 à 10 ans, inscrits dans une étude plus vaste évaluant l'innocuité et l'efficacité de l'artémisinine/pipéraquline (AP) ou de l'artéméther/luméfántrine (AL) selon le protocole de l'OMS sur 28 jours, ont été étudiés. La surveillance des ADR était basée sur l'anamnèse des parents et/ou de l'enfant (pour les signes et symptômes émergents liés au traitement), les examens physiques et les anomalies des investigations de laboratoire - numération globulaire complète, chimie sanguine et tests de la fonction hépatique. L'évaluation de la causalité pour l'ADR a été effectuée selon l'échelle algorithmique de Naranjo.

RÉSULTATS: 108 enfants sur 114 (94,7%) ont terminé l'étude. Plus de la moitié [61 (56,5%)] étaient des garçons. L'âge moyen des participants était de 65,1±30,0 mois. Le taux de RCAP jour 28 pour AP était de 96,1% et de 90,4% pour AL. Les ADR observées étaient la toux, la diarrhée, la perte d'appétit, les douleurs abdominales, l'éruption cutanée, l'irritabilité, l'insomnie et les maux de tête. La prévalence était similaire dans les deux groupes de traitement (AL=14%, AP=11% ; $p=1,000$). L'incidence des ADR aux deux ACT était de 12/1000 patients par jour. Tous les ADR étaient légers et se sont résolus spontanément. Aucun facteur associé notable aux ADR n'a été détecté dans cette étude.

CONCLUSION : AL et AP se sont révélés sûrs dans la population étudiée. WAJM 2023; 40 (12): 1332- 1340

MOTS-CLÉS: Réactions indésirables aux médicaments, ACT, Paludisme, Nigeria

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