

ORIGINAL PAPER

China rubra for side-effects of quinine: a prospective, randomised study in pregnant women with malaria in Cotonou, Benin



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Background: In endemic areas, gestational malaria is responsible for low birth weight and maternal anaemia. Quinine is the reference treatment for acute malaria in pregnant women, irrespective of term. However, quinine administration is associated with various side-effects. We evaluated the impact of the homeopathic medicine *China rubra* 7CH on the side-effects of quinine used as treatment for acute malaria in pregnant women in Cotonou, Benin.

Methods: This prospective, comparative, randomised study was carried out between June and December 2007 in the Saint Jean-Baptiste Medical Centre, Cotonou. Women were included if they were >3 months pregnant and had a clinical diagnosis of malaria confirmed by a positive thick blood smear. The study population was divided into two groups: (i) patients who presented between the 1st and 15th of each month and who received *China rubra* 7CH plus quinine (China group); and (ii) patients who presented from the 16th to the end of each month and who received treatment with quinine only (Standard group). The aim was to compare the frequency of side-effects of quinine in the two groups until day 6 after the start of treatment. Neither the patients nor the care givers were blinded to study treatment. Statistical comparison of the two groups was carried out with an alpha risk fixed at 5%.

Results: 211 women were recruited: 105 received quinine plus *China rubra* 7CH (China group) and 106 received quinine only (Standard group). A decrease in proportion of patients presenting with side-effects was observed in the China group from day 0 to day 6 of follow-up (53.9%–23.3%) whereas the proportion of patients with side-effects in the Standard group did not change significantly (85.9% on day 0 vs. 82.5% on day 6). Ninety-six (72.4%) patients in the China group and 103 (97.2%) in the Standard group reported at least one side-effect during follow-up ($p < 0.0001$). The most frequently reported side-effects were tinnitus, dizziness and asthenia.

Conclusions: This preliminary study shows the interest of *China rubra* 7CH in limiting the side-effects of quinine used for the treatment of acute malaria in pregnant women.

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Keywords: Homeopathy; *China rubra*; Quinine; Side-effects; Malaria; Pregnancy

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Background

It has been estimated that 216 million malaria attacks occurred worldwide in 2010, of which 81% were in Africa. In the same study, the number of malaria-related deaths was estimated at 600,000, principally among infants, young children and pregnant women.¹

Over the past few years, malaria has become a priority for the international community in general and for Benin in particular. Ranked as the principal cause of disease in Benin, malaria is found in approximately 40% of patients presenting at medical centres. The incidence of uncomplicated malaria in Benin is estimated as 108‰, with much higher figures in children <5-years of age. In an attempt to reduce the impact of malaria in Benin, the National Malaria Control Programme (NMCP) adopted new policies whose main aim was to reduce the morbidity and mortality attributable to malaria in 2010 by at least 50% compared to 2001.^{1,2}

Malaria is particularly dangerous during pregnancy. It can lead to severe anaemia and is one of the main causes of maternal death in regions where the disease is endemic. Furthermore, pregnant mothers who have malaria and are seropositive have a greater risk of transmitting their seropositivity to their child.

The World Health Organisation (WHO) recommends three main actions against malaria in pregnant women in order to reduce these risks: (i) the use of mosquito nets impregnated with insecticides; (ii) intermittent preventative treatment (IPT); and (iii) good management of cases of malaria.³

IPT consists of administering a curative dose of an anti-malarial drug twice during pregnancy. Sulphadoxine–pyrimethamine (SP), sold under the name Fansidar[®], is the drug currently recommended for IPT.⁴

The NMCP in Benin has modified the WHO recommendations and advocates the use of quinine for malaria attacks in pregnant women^{5,6} and for the pre transfer of severe malaria. However, quinine treatment is associated with various biological and clinical side-effects, the latter of which could hinder good compliance by these patients. The side-effects of quinine include hypoglycaemia,⁷ signs of cinchonism (tinnitus, dizziness, headaches, visual problems, decrease in hearing acuity, nausea and diarrhoea), cardiotoxicity and allergic manifestations or anaemia.^{8–10} Many of these side-effects are dose-dependent and diminish as the dose is decreased or when treatment is stopped altogether.^{8,11–13} Commonly used antiparasitic medicines such as quinine are the commonest drug class associated with side-effects.¹⁰

As a result of observations made previously by a doctor during the use of the homeopathic medicine *China rubra* 7CH in a medical centre in Cotonou, we carried out a preliminary study to evaluate the interest of *China rubra* 7CH in limiting the side-effects of quinine in pregnant women with malaria.

Patients and methods

Study design

This prospective, open, comparative, randomised study was carried out in the Saint Jean-Baptiste Medical Centre in Cotonou, Benin, in 2007. The inclusion period was June 20th to December 28th 2007, a time of year when the incidence of malaria is highest in Benin. Ethical approval for the study was granted by the Benin Ethics Committee on 21st February 2007.

A midwife working in the centre was responsible for the recruitment of patients. The study was proposed to women presenting at the centre with an acute malarial attack. Women were included if they were >3 months pregnant and had a clinical diagnosis of malaria confirmed by a positive thick blood smear. All patients who participated in the study gave their written consent. For illiterate patients, the investigating midwife was assisted by other midwives who spoke French or one or more of the languages of Benin.

In practice, the diagnosis of malaria is usually based on simple clinical factors, which can sometimes result in unnecessary quinine treatment. In this study, it was important that the clinical diagnosis of malaria was confirmed biologically. Patients for whom the diagnosis of malaria was not confirmed by a positive thick blood smear were not included. These patients were considered to have another disease for which quinine would be ineffective. Similarly, diabetic patients were also excluded from the study since the potential development of hypoglycaemia during treatment could be caused by their underlying disease and not by quinine.

All patients received quinine treatment for 7 days during their malaria attack, administered by the health workers. Prior to the study, a random decision was made to treat patients who presented in the first half of each month (1st to 15th) with quinine in association with *China rubra* 7CH (Boiron Laboratories) (China group) and those who presented in the second half of each month (from 16th to the end of the month) with quinine only (Standard group). This method of randomisation simplified the allocation of the different treatments and the constitution of two treatment groups.

The patients attended the medical centre for the inclusion consultation on day 0. Follow-up consultations then took place on days 1, 2, 3, 4, 5 and 6, either as outpatients to the medical centre or in the hospital, depending on the clinical condition of the patient.

The women participating in the study each received free care, financial cover for their transport and a mosquito net. The medical team in the centre (doctors and midwives) did not receive any remuneration for the study.

Estimation of population size

The incidence of malaria increases during the rainy season (between June and October, with a peak in August). A study of the statistics of the activity of the Saint Jean-

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