Herbal Medicine or Artemisinin Combination Therapy for the Home-based Management of Malaria: A Randomised Controlled trial

Merlin L Willcox\textsuperscript{a,b}, Bertrand Graz\textsuperscript{a,b}, Chiaka Diakite\textsuperscript{b,d}, Jacques Falquet\textsuperscript{a,b}, Mathieu Forster\textsuperscript{f}, Florent Dackuo\textsuperscript{c}, Oumar Sidibe\textsuperscript{b,d}, Sergio Giani\textsuperscript{e}, Drissa Diallo\textsuperscript{d}

\textsuperscript{a} Antenna Technologies, Geneva, Switzerland
\textsuperscript{b} Research Initiative for Traditional Antimalarial Methods
\textsuperscript{c} Faculte de Medecine, Pharmacie et Odonto-Stomatologie, Universite de Bamako
\textsuperscript{d} Departement de Medecine Traditionnelle, Bamako, Mali
\textsuperscript{e} Aidemet, Bamako, Mali
\textsuperscript{f} Universite Laval, Canada

WHO recommends home management of malaria with Artemisinin Combination Therapies (ACTs). Since the target of reaching 60% of the patients has proved difficult to achieve, we explored a complementary strategy for remote areas. This involved using a widely available validated herbal medicine as first line, with an ACT as a second-line backup, in order to reduce logistical problems in the supply of ACTs.

In an attempt to reflect the real situation in a remote village, 301 patients presumed by the local health worker to have uncomplicated malaria were randomised to receive a herbal preparation (\textit{Argemone mexicana} decoction, AM Group) or artesunate-amodiaquine (ACT Group) as a first-line home treatment. The median age of patients was 5 years in each group, and 87% were thick film positive for \textit{Plasmodium falciparum}.

From a health policy perspective, a complementary strategy was deemed worthwhile if incidence of severe malaria was lower than in other comparable settings. In children aged <=5 years, confirmed severe malaria occurred in 1.0% (95% CI 0.02 – 5.3) of the AM Group and 1.9% (0.05 – 10.3) of the ACT group. None had coma or convulsions. There were no cases of severe malaria in patients aged >5 years. 89% of patients in the AM group did not require treatment with an ACT up to day 28, as compared to 95% in the ACT group who did not require a second-line ACT (p=0.1). The incidence of adverse events was similar in both groups (14% and 19%); no serious adverse events were observed.

The incidence of severe malaria was kept to a lower level than reported in other studies of home-based management of malaria. It seems that \textit{Argemone mexicana} decoction could be tested as a useful complement to standard modern drugs in the home-based management of presumptive uncomplicated malaria in high transmission areas. In view of the good protection afforded against severe malaria, and the good safety profile, \textit{Argemone mexicana} decoction could be used as a treatment for semi-immune patients and in case of interruption in the supply of standard antimalarials or as first aid in the case of delay in starting treatment.