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Article *in* Tropical Doctor · May 2008

DOI: 10.1258/td.2007.060184 · Source: PubMed

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The aim of our retrospectively designed study was to evaluate the influence of the permanence and qualifications of health-care professionals on blood disposal rates due to hepatitis seropositivity. A decrease in the rate of rejected blood units of 44.2% due to hepatitis B seropositivity was observed in the second period, where the self-exclusion forms and the blood donation candidates were evaluated by a family physician. However, a decrease due to hepatitis C seropositivity was not observed. In a similar study performed in Mexico by Lopez *et al.*[5] HCV seropositivity was investigated prospectively in blood donation candidates selected via self-exclusion forms and their results were similar to ours. A decrease of 44.2% in hepatitis B seropositivity was found in the second period of our study due, we suggest, to the change in the deferral criteria.

Deferral rate due to surgical interventions increased from 5.54 to 16% in the second period. This could be a major contribution to the reduction of hepatitis B seroprevalence. During the second period candidates underwent a more extensive questioning. Even candidates with a history of a minor surgical intervention less than 12 months prior to the study were excluded. The potential risk of inappropriate sterilization techniques led us to take this precaution which is normally applied to candidates who received a transfusion during their surgery.[6]

The greatest change was seen when candidates were deferred due to infections: the deferral rate of 5.77% in the first period increased to 29.33% in the second period. This was achieved by introducing longer interviews and a brief medical examination and, thus, increased the safety of transfusions. The highest ranking infections were upper respiratory tract and soft tissue infections. It should be borne in mind that several viral infections, including hepatitis, display an insidious disease pattern and present with signs in different organ systems.[7]

Behavioural risk factors and their recognition by health-care providers are of pivotal importance for transfusion safety. Lopez *et al.*[5] emphasized this in their recent study. An increase in deferrals due to behavioural risk factors was observed in our study: 2.77% in the first period and 6% in the second. This also could play a part in the reduction of candidates who have hepatitis B seropositivity. A physician who is permanently working in a blood banking facility can gain experience in the exclusion of candidates with these behavioural modalities.

Our study showed the importance of the need for qualified health-care professionals and emphasized that hepatitis B seroprevalence can be reduced and transfusion safety increased by the use of these precautions. This is especially important in countries where expensive high-technology laboratory tests are not available. A comprehensive evaluation of self-exclusion forms and a brief examination prior to donation will greatly increase transfusion safety.

Table 1 Serological results of donors

	First period	*Second period*	*P*
Total number of candidates	12466	14675	–
Accepted candidates	12033 (96.5%)	13269 (90.4%)	–
Deferred candidates	433 (3.5%)	1406 (9.6%)	$P < 0.0001$
HbsAg prevalence in disposed blood units	249 (2.06%)	152 (1.15%)	$P < 0.0001$
Anti-HCV prevalence in disposed blood units	28 (0.23%)	33 (0.25%)	$P = 0.66$

HCV, hepatitis C virus

Acknowledgments

The authors appreciate the help given by all the blood bank staff who participated in this study.

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Herba *Artemisiae annuae* tea preparation compared to sulfadoxine-pyrimethamine in the treatment of uncomplicated falciparum malaria in adults: a randomized double-blind clinical trial

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TROPICAL DOCTOR 2008; **38**: 113–116
DOI: 10.1258/td.2007.060184

SUMMARY Tea preparations from the herb *Artemisia annua* L. (Aa) which is used in traditional Chinese medicine might offer an inexpensive way of producing artemisinin drugs locally. We compared Aa with sulfadoxine-pyrimethamine (SP) in the treatment of uncomplicated falciparum malaria in semi-immune adults. After seven days, the cure rate was 7/10 for the Aa compared to 7/9 for SP; this dropped to 4/10 for Aa and 4/9 for SP at day 14 and to 1/9 for Aa and 3/8 for SP at day 28.

Introduction

Malaria, the most important parasitic infection causes more than a million deaths annually.[1] This disease hits households in poor communities the hardest, despite the existence of effective anti-malarial tools and interventions. Artemisinin-based anti-malarial therapy is effective,[2] but expensive. The herb *Artemisia annua* L. (Aa; annual wormwood) has been used in traditional Chinese medicine for the treatment of febrile diseases and malaria for many centuries. Its cultivation is relatively easy.[3] Tea preparations from Aa, prepared according to the current pharmacopoeia of the People's Republic of China, resulted in peak plasma levels of 240 ng/mL artemisinin in humans.[4] There have been several open-labelled clinical trials,[3,5] but we decided to conduct a randomized double-blind clinical trial evaluating the efficacy and safety of Aa tea preparations in the treatment of *Plasmodium falciparum* malaria.

Methods

The study was performed in a rural hospital in the Kigoma region of western Tanzania from September 2002 to March 2003. The protocol was approved by the ethical committee of the National Institute for Medical Research, Dar-es-Salaam, Tanzania. All patients gave written informed consent. Inclusion criteria were: *P. falciparum* malaria with parasitaemia between 2.000/μL and 40.000/μL; a minimum age of 18 years; residence in rural Kigoma or the Kasulu district for ≥5 years; and at least one of the following clinical symptoms – fever, chills, fatigue, vertigo, nausea, joint pain, vomiting, headache or abdominal pain. The exclusion criteria included: pregnancy or lactation; treatment for malaria within two weeks before recruitment; any clinical signs of complicated malaria; current medical treatment (modern or traditional) for other diseases; and known chronic, progressive or life-threatening diseases. Before randomization, and after seven days of medication, urine samples were examined by thin layer chromatography for medication with other anti-malarial drugs, and positive patients were excluded.

Patients were randomly assigned to one of the following treatment groups:

(1) A5 and A9 groups: Aa tea (5.0 g and 9.0 g herb/L, respectively); 1 L/day for seven days and placebo tablets day 1.
(2) Sulfadoxine-pyrimethamine (SP) group: sulfadoxine 25 mg/kg and pyrimethamine 1.25 mg/kg day 1 and placebo tea Radix Gentianae 3.5 g/L, 1 L/day for seven days.

The zero hypotheses were that at day 7 there would be no difference in the cure rate between the three groups. A difference would be defined as proportions showing a difference of 20% or more. The equivalence should be tested on a 5% significance level with 90% power. We presumed a cure rate at day 7 of CR_{SP} 90% in the SP group and a cure rate of CR_{HAa} 90% for the groups treated with the Aa-tea preparation. To meet the criteria, at least 48 patients per group who fitted the protocol would be needed; we planned to enrol 60 patients per group. Randomization was done by opening opaque envelopes prepared in blocks of 30 patients.

The Artemisia annua L. cv. Artemis (artemisinin content 1.4%) was supplied by Anamed, Waiblingen, Germany, and pre-packed in sealed plastic bags in doses of 5 and 9 g. The tea was prepared freshly in accordance with method C described by Rath *et al.*[4] Radix Gentianae was supplied by Caesar & Loretz, Hilden, Germany, and prepared in the same way. The tea preparations looked and tasted the same. SP was supplied by Pharmamed, La Valletta, Malta (Ch:16800071B).

Pulse, blood pressure and body temperature were recorded daily until day 7. On days 3, 7, 14 and 28 patients were interviewed using a standardized questionnaire for clinical symptoms and adverse events. Parasitaemia was determined from a finger prick using Field-stained thick blood smears. The number of trophozoites was counted in 100 high power fields.

The primary endpoint was the parasitological cure rate, i.e. the proportion of patients with negative blood smears on day 7. Secondary endpoints were cure rates on days 14 and 28, and a change of clinical symptoms. Criteria for treatment failure were: the development of severe malaria or danger signs; parasitaemia on day 3 equal or higher than the parasite count on day 0; parasitaemia on day 7 and any recurrence up to day 28. Treatment failures were appropriately treated.

Results

After randomization, we had to exclude four patients for the reasons shown in Figure 1. The baseline characteristics of the patients included in the analysis are shown in Table 1. The high rate of recrudescence in all patients randomized and treated according to protocol led to the decision to end patient recruitment in March 2003. Most of the reported malaria symptoms improved or resolved within three days after initiation of therapy – as quickly in the SP group as in the Aa groups (data not shown). We observed two adverse events not distinguishable from malaria-related symptoms. Due to excessive vomiting, one patient in the SP group had to be treated with quinine from day 2. One patient in the Aa 9 g/L group developed hyperparasitaemia and clinical signs of cerebral involvement at day 1 and was switched to quinine treatment. The Aa preparations were well tolerated.

Discussion

Despite the small number of patients recruited, our primary cure rates in the Aa groups at day 7 were similar to the 74% reported my Müller *et al.*[5] in their open pilot trial. Follow-up of patients was almost complete and showed high rates of recrudescence. Artemisinin-based combination therapy is being introduced in the treatment guidelines of several countries in sub-Saharan Africa. The expensive part is the artemisinin derivative. Local cultivation of Aa and the preparation of medicinal tea would reduce costs and might therefore be a consideration for financially restricted health systems. However, the artemisinin content of the traditional Aa preparations contained, at best, 94 mg artemisinin/L,[4] i.e. 19% of the usual clinical dose of pure artemisinin (500 mg/day). Insufficient doses and incomplete treatments without complete cure are major reasons for the

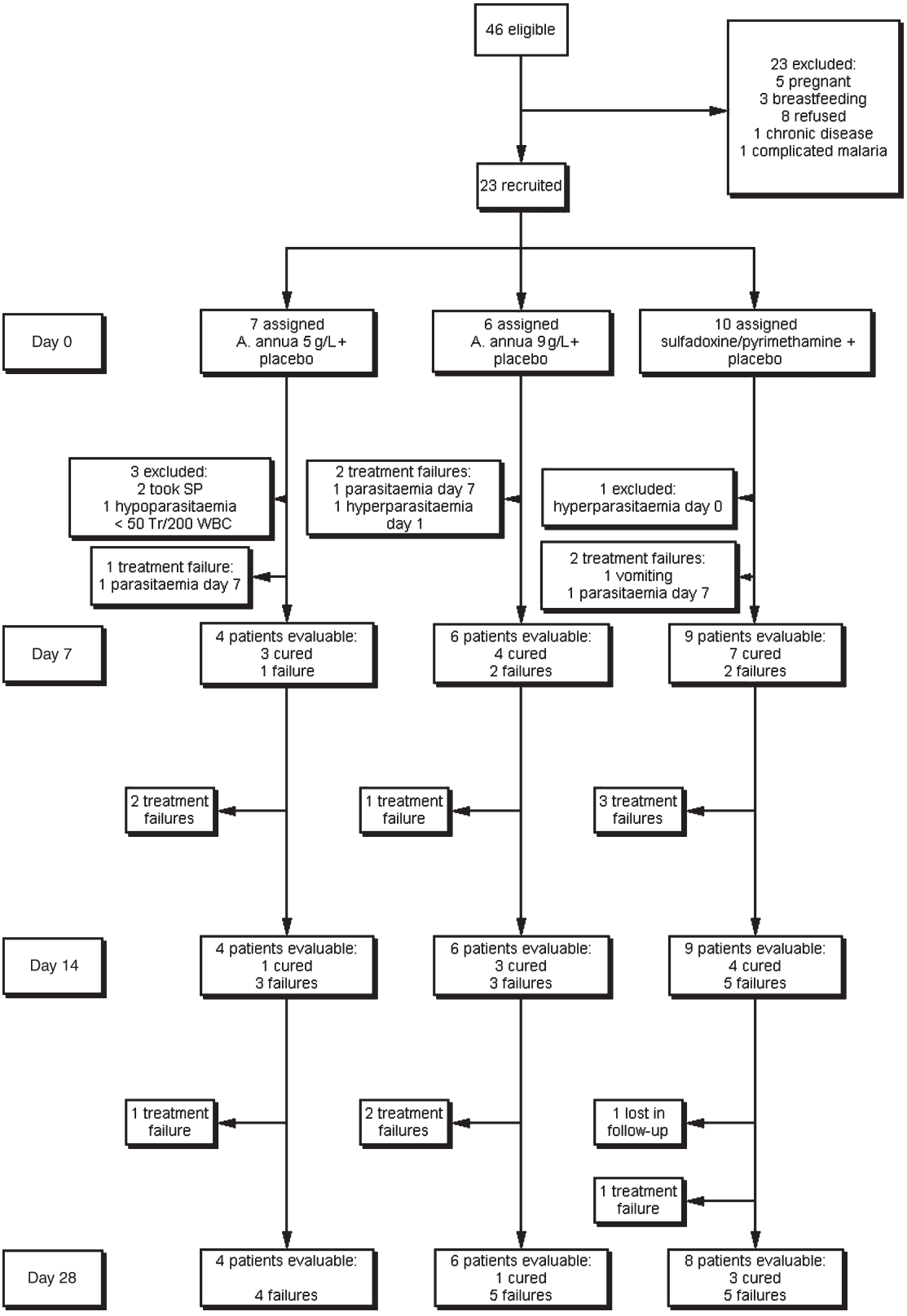

Figure 1 Trial profile

induction of resistance to many antimalarials. Inappropriate drug use in artemisinin-based combination therapies in French Guiana exerted selection pressures that favoured led to the emergence of parasites with an artemether-resistant *in-vitro* profile.[6] Therefore, it is important to introduce a risk assessment of the use of Aa tea preparations in treatment schedules in order to avoid under-dosing and to ensure patient compliance.

Table 1 Baseline characteristics of the patients

	Artemisia annua 5 g/L	*Artemisia annua 9 g/L*	*Sulfadoxine/pyrimethamine*
Age (years), median	23	22.5	20
Sex (male)	4 (100%)	3 (50%)	6 (67%)
Body weight (kg), median	63.5	60	53
Parasitaemia day 0 trophozoites/μL), median	10,220	4600	8000

We conclude that mono-therapy with a tea preparation of Aa cannot be recommended for the treatment of uncomplicated falciparum malaria in adults.

Acknowledgments

We are grateful to all study participants. We thank E J Kebelo for his help in the laboratory work, A Jäger MD in the clinical follow-up and H Bönning in the enrolment of patients, allocation to treatment groups and application of drugs. We also thank Mrs Gründler, Paul-Lechler Hospital Tübingen and DR J W Bailey, Liverpool School of Tropical Medicine and Hygiene for the quality control of thick films and M Tabende, Bukavu D R, Congo for training in thin film chromatography. We were sponsored by the German Institute for Medical Mission, Tübingen and Christliche Fachkräfte International, Stuttgart, Germany

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Of 'microbes' and 'millet': the practice of *tea tea* in northern Uganda

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TROPICAL DOCTOR 2008; **38**: 116–118
DOI: 10.1258/td.2007.060182

SUMMARY In northern Uganda, incisions called *tea tea* are commonly placed on the chests of children outside of the biomedical setting to relieve respiratory distress. To better characterize *tea tea*, we administered a questionnaire to 224 caretakers, whose children had evidence *tea tea* cuts. In 148 cases (66.4%), the grandparents made the decision to have the cuts performed, at times against the wishes of the caretakers. One seventy-six (80.0%) of the patients were seen by a medical professional just prior to receiving the cuts. Traditional healers and grandmothers, respectively, performed the cuts in 164 (73.5%) and 42 (18.8%) cases. Caretakers paid at least 500 USh (US$0.29) for *tea tea* in 129 cases (57.8%) and nothing in 71 cases (31.4%). This study shows that *tea tea* is a healing practice with associated costs that is regularly advocated for and performed by grandmothers and traditional healers.

Introduction

Health-care professionals in northern Uganda have long witnessed *tea tea*, a traditional practice in which incisions are made on the chests of children with respiratory distress (Figure 1). Traditional healers claim that *tea tea* removes 'millet grains' from the chest wall, which are believed to be the source of respiratory distress (Odong, personnal communication). Biomedical practitioners have identified these 'millet grains' as adipose tissue.[1]

In 2003, Accorsi *et al.*[1] found that 19.7% of the children attending an outpatient clinic in northern Uganda had *tea tea* cuts. In the majority of cases, razor blades were used to perform the incisions. Complications of *tea tea* and other traditional practices, such as septicaemia, were found to be the eighth leading cause of hospital admission.