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EFFECTS OF MALARIA RAPID DIAGNOSTIC TEST ON THE OUTCOME OF HOME-BASED CARE OF FEVER IN THE UNDER FIVES IN MBONGE HEALTH DISTRICT, CAMEROON: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: The World Health Organisation has recommended the use of malaria rapid detection and testing in communities without access to laboratory facilities. This study was carried out to assess the effects of malaria rapid diagnostic testing on the outcome of home-based managed fever in children less than five years in Mbonge Health District, in Cameroon.
Materials and Methods: The design was a parallel randomized controlled trial in which 124 febrile children were recruited and randomized either to be submitted to malaria rapid diagnostic tests (intervention) or to be managed presumptively (control).
Results: Sixty-two febrile children were assessed per group and mean time to fever clearance was 0.54 days (95% CI: -0.88, -0.20) lower in the intervention group compared to the control group (p=0.007). The risk of referral to a health facility was reduced by 88% (RR=0.12: 95%CI: 0.03, 0.59; p=0.007). No effect was observed on the proportion of children being admitted (RR=0.14, 95% CI: 0.12, 1.09; P=0.05), mean time of admission duration (MD= -1.13, 95%CI:-4.90, 0.70; P=0.118) and the outcomes of admission observed.
Conclusion: Implementing Rapid Diagnostic Tests in home-based-care in the under fives produced desirable fever outcomes as compared to presumptive home-based managed fever. Hence this study provides evidence that the use of malaria rapid diagnostic tests will give better outcomes for home-based care of fever compared to presumptive treatment in children less than five years in an endemic area.

KEYWORDS: malaria, rapid diagnostic tests, effects, under fives, home-based care.

INTRODUCTION

In 2005, the World Health Organisation (WHO) recommended that mRDTs should be used in areas where laboratory facilities could not be easily used [1]. As of 2006, this recommendation was not adopted in areas without access to microscopy [2]. Due to the change of first line treatment of malaria from the less expensive monotherapies to the more expensive combined therapies, WHO changed its treatment guidelines in 2006 [2]. The major change was that presumptive treatment should be carried out only in the under fives and where laboratory facilities were not readily available but D'Acremont *et al*., [3,4] reported over-diagnosis with presumptive treatment and argued that parasitological diagnosis should be carried out even in the under fives. Ukwaja *et al*., [5] in their study in Nigeria reported that mixed malaria and pneumonia infections accounts for 40% of under five mortality in African children. The overlap of Malaria symptoms with other infections necessitates the improvement in the management of fevers all settings include home-based care. Fever being the most apparent clinical manifestation that parents/guardians recognises as the presence of malaria by Dunyo *et al*., [6]; if it persists following management can mare home management of malaria (HMM) like the case of Uganda which had a 25% reduction in utilization of CHWs with HOMOPAK due to parents believing that the drug was ineffective by Nsabagasani *et al*., [7]. A negative view of HMM will result to delay in access to prompt treatment as most fevers are managed at home [8].

The extension of treatment following parasitological diagnosis to the under fives faced a lot of debates but studies showed it to be safe and a means of improving the management of fevers in children less than five years [9]. Finally, the WHO has recommended that diagnosis should be part of fever case management in all age groups and settings [10]. However, implementing this policy in home-based care of fevers in Cameroon is still being assessed.

In 2010, WHO recommended that Home-based Management of Malaria (HMM) should be modified by including mRDTs to the treatment package [10]. The implementation of mRDTs in HMM is still under pilot studies in some regions of the Cameroon and these studies are carried out to assess the community relay agents' ability to perform these tests before large scale deployment of mRDTs in the country (11).

There are arguments that large scale implementation of *m*RDTs should be assessed carefully in different settings to ensure that their use will actually reduce over-diagnosis, drug wastage and prevent patient suffering [12]. In order to evaluate the effect of mRDTs on fever case management and prevention of patient suffering in children less than five years at the level of the home, a randomized controlled trial was carried out in a malaria endemic district in the South West Region of Cameroon (Mbonge Health District). The main objective was to assess the effect of mRDTs on the outcomes of fever and specifically assess the effect of *m*RDTs implementation on the time to fever clearance, the rate of home referral to health facility, the admission rate, the average duration of admission and the outcomes of the admission given that the child had been managed at home.

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MATERIALS AND METHODS

Research Procedures

The study was a parallel-group controlled trial with balance randomization of 1:1 carried out in September 2011. This was carried out in Mbonge Health District in the South West Region of Cameroon having five Health Areas namely: Boa Balondo, Bokosso, Kombone, Kotto Barombi and Mbonge (District EPI Micro Plan, 2011). It has a population of 70,619 inhabitants distributed according to health area as follows: Boa Balondo = 5,069, Bokosso = 4,864, Kombone = 27,571, Kotto Barombi = 13, 752 and Mbonge = 19,363.

Eligible participants were children between the ages of 2-59 months whose parents/guardians consented, had fever or a history of fever within the past 48 hours and had not been on any antimalarial drug within the past 14 days in four sampled Health Areas of the Mbonge Health District.

Multi-stage random sampling was carried out by balloting. Firstly, health areas were sampled and secondly a working community sampled from it and two from Kombone Town because of its large population. Concealment allocation was achieved by blind sequential numbering of the child upon arrival and those with odd numbers were assigned to the intervention arm while those with odd numbers were in the control arm. The intervention arm was submitted to rapid diagnostic testing and positive cases together with those in the control arm were treated with Artesunate-Amodiaquine combination and Paracetamol and followed-up on day seven by phone call for time to fever clearance, referral to a health facility, number admitted, admission duration and admission outcomes; each community was visited only once. A single visit was to further avoid bias since we allocated participants into the control or intervention group based on the numbers they were given upon arrival. We believed repeating exercise in the same village will make the use of numbers known to participants. Most participants owned cell phones and only a few were without phones. Those without phones agreed and were followed up through the community relay workers who were very close to them as all had phones. It was easy as these communities are very closely knit together and we used the vaccination outreach approach were the community relay workers did the mobilization and communicated with us at the district level.

Ethical and administrative clearance reference no. R11/MPH/SWR/RDPH/FP-R/4087/56 was obtained from the South West Regional Delegation of Public Health. Informed consent was obtained from parents/guardians and confidentiality was ensured by using sequential numbers on their questionnaires. Parents/guardians filled the questionnaires with assistance from the community relay workers and heads of health centers when need arouse. The intervention group was subjected to a malaria rapid test (Ag p.f/PAN). This rapid diagnostic test was manufactured by Standard Diagnostic Bioline (SD Bioline) a combination of the Histidine-Rich Protein (HRP2) for detecting *P. falciparium* and the parasite Lactate Dehydrogenase (LDH) for detecting the other three species- *P. ovale, malariae* and *vivax* (PAN). This was carried out by the researcher and the results recorded in the questionnaire and explained to the parent/guardian. The procedure was according to the manufacturer and as recommended by WHO [13] in the guide for training CHWs on how to use RDTs. The expiry date on the package was verified, a pair of gloves worn before beginning the procedure and a new pair of gloves was used for each patient. The package was opened and the content removed.

The patients' daily number was then written on the test kit using a bold marker. The third or fourth finger was disinfected using the alcohol swap provided by the manufacturer and allowed to air dry. The swap was placed in its package for later use in stopping the bleeding. The finger was then pricked using the provided sterile lancet and the used lancet dropped in a safety box. The patients' arm was turned so their palm faced downward and the pricked finger squeezed and a drop of blood allowed to well up below the finger tip. The drop was collected using the plastic loop provided and the parent/guardian given the swap to stop the bleeding. The drop was placed in the well labeled A and four drops of buffer placed in the well labeled B. The test cassette was placed on a flap surface and the results read after 15 minutes and maximum of 20 minutes. The used materials were discarded and the procedure repeated for each child to be tested.

The positive cases together with their negative pairs were treated and followed up by phone call on day seven.

Data Analysis

Data was analyzed using STATA Version 10.0. The analysis of the data was descriptive using whole numbers and percentages, measures of central tendency and measures of dispersion like the Interquartile. Range (IQR) and Standard Deviation (SD). Student t-test, Wilcoxon Rank Sum test and the Chi-square test (X^2) were used to measure the association between variables and multivariate analyses were used to control for the effects of the independent variables and to calculate the strength of the relation between treatment outcomes and the use of mRDTs. Statistical significance was assumed when $P < 0.05$.

RESULTS

A total of 124 febrile children were randomized in the intervention arm (62) and control arm (62). Participants showed no statistical significant differences in demographic and clinical variables as shown on table 1. The number who recovered at home and after hospitalization are shown on figure 1.0 and 2.0.

Mean time to fever clearance was 2 days (I QR 2-3 days) in the intervention group and 3 days (IQR 2- 4 days) in the control group (Z- test P=0.0247) and was significantly lowered by 0.54 days (95% CI: -0.88, -0.20) in the intervention arm compared to the controls (P=0.002).

Referral to a health facility stood at 3.33 % (2) in the intervention group as opposed to 24.19% (15) in the control group (X^2 p=0.001), risk ratio (RR) of 0.12 (95% CI: 0.03, 0.47) (P=0.002). Hence children in the intervention arm were 0.12 times less likely to be taken to a health facility.

Admission rate was 1.67 % (1) in the intervention group as opposed to 12.90 % (8) in the control group (Exact p=1.000) with a risk ratio of 1.15 (95% CI: 0.33, 6.73)

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(p=0.593).Therefore Children in the intervention arm were as equally likely to be admitted compared to the control arm. Children in the control group had mean admission duration of 2 days with (IQR 2-3 days), as opposed to 1 day (IQR 1-1) in the intervention (Z p=0.112) and a mean difference of -1.13 days (95% CI:-4.94, 0.70). Hence at the time of intervention, there was no difference in admission duration comparing the intervention to the control arm (P=0.118).
During the study all who were taken to a health facility recovered. No referral to the district hospital and no death occurred among the study participants giving a 100% recovery.

DISCUSSION

Malaria ranks second among the top ten causes of death in Africa [14]. The three-prong approach recommended for fighting the disease, namely rapid detection followed by combination therapy, the use of mosquito bed nets and targeted mosquito destruction [15, 16], are being implemented in Cameroon, though at varying degrees. Malaria is the most important public health problem in Cameroon and accounts for 40.1% morbidity and 2.2% mortality in the general population, and 4.2% mortality in children less than 5 years [17, 18].

An intervention of this sort also illustrates the feasibility and acceptability of home management of malaria, targeting a highly vulnerable population, in a semi-rural setting. The intervention indicated a significant reduction in time to fever clearance by 0.58 days. Hence reducing the time to fever clearance would increase the credibility of home management of malaria (HMM) and enable the attainment of its goal which depends on prompt access to correct antimalarial drugs, according to WHO. This finding agrees with Kidane & Morrow [19] and Sirima *et al*., [20] that improving HMM reduces progression of malaria to severe disease by more than 50% and under-five overall mortality by 40%.

The study also showed 88% reduction in consultation rate at a health facility amongst the intervention group. This also implies a reduction of the burden on the health facilities and reduction in time and expenditure by affected families. Other authors, Lemma *et al*., [21] in Ethiopia reported similar results; using Artesunate–Lumefantrine combination at the level of the community and justified significant reduction of malaria burden at the level of health facilities.

However, this study has been unable to show the differential diagnosis and manifestations during admission, admission duration, and the complications that occurred during admission. All those who were admitted for further management at the level of the health facility recovered, and might have returned home with unidentified complications that necessitated follow-up.

This study has added more value on the use of mRDTs through the significant achievement on home-based care of febrile children in a rural community in Cameroon. The intervention reduced time to fever clearance and the rate of seeking care form the health facility. Home-based management of malaria using malaria rapid diagnostic tests will improve fever management in children less than five years. The high economic loss inflicted on countries, communities and families by malaria alone, is enough reason for the propagation of rapid testing and management techniques in local communities, involving all age groups. If individuals can be trained to control diabetes through the use of rapid tests, then selected family members and not just community relay agents can be trained to diagnose and treat malaria at home, and only complicated cases will visit the health facility. Being the most important public health problem in Cameroon, accounting for 40.1% of morbidities, the creation of malaria rapid screening and treatment centers in highly endemic communities can be a major initiative to control and subsequently eradicate the disease.

COMPETING INTEREST

The authors declare that they have no competing interests.

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Table 1: Demographical and clinical distribution of participants.

		GROUP		
VARIABLE Age (mean, SD) in months		INTERVENTION 28.29±17.55	CONTROL 31.27±16.78	P-VALUES P= 0.334
Sex (N, %)	Females	35 (56.45%)	30 (48.39%)	X^2 P=0.369
	Males	27 (43.55%)	32 (51.61%)	
Fever at the start (N, %)	Present	47 (75.81%)	43 (69.35%)	X^2 P=0.422
	History	53 (85.48%)	51 (82.26%)	X^2 P=0.625
Fever duration (median, IQR) in days		3 (2-4)	2 (2-3)	Z-test p=0.446
Temperature (mean, SD) in ˚C		37.86±0.89	37.61±0.87	Z-test p=0.116
Compliance to treatment (N, %)		60 (96.77%)	62(100%)	t-test p=0.154