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Applicability of malaria rapid diagnostic tests in diagnosing non-falciparum malaria infections in Sri Lankaunder zero indigenous malaria setting

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With the renewed global interest in the elimination of malaria, and the World Health Organization recommendation of malaria case management based on parasite diagnosis in all cases, the number of rapid diagnostic tests (RDT) available and the scale of their use have increased rapidly. As Sri Lanka is trying to maintain its "malaria-free" status since certified by the WHO in 2016, it is mandatory that the diagnostic strategy should be able to detect all imported malaria cases and species. The operational characteristic of RDTs varies under different disease endemic conditions. The WHO's results of the RDT product testing, shows that the detection rate is higher for *P. falciparum*, compared to *P. vivax*, while other parasite species were not evaluated. Hence, the efficacy of the RDT used in Sri Lanka under zero indigenous malaria setting in detecting non-falciparum malaria infections was evaluated. From 245 suspected malaria patients referred to the Anti Malaria Campaign Headquarters, Carestart™ malaria histidine-rich protein 2/ *Plasmodium* lactate dehydrogenase (HRP2/pLDH;Pf/PAN) Combo Test, (index test) and microscopy and nPCR (reference tests) were performed in a blind manner, using capillary whole blood. Sensitivity, specificity and predictive values of RDTs were compared with reference tests. Malaria negative patients were considered as negative controls. The age range of the study participants was 1- 73 years. The majority were males (78%), while 96% had a recent visit to a malaria endemic country. Sensitivity and specificity of RDT in detecting *P. vivax* infections was 98.04%(95%CI 89.55, 99.95) and 99.48%(95%CI 97.16, 99.99) respectively. Positive and negative predictive values were 98.04%(95%CI 87.62, 99.72) and 99.48%(95%CI 96.52, 99.93) respectively. Positive and negative likelihood ratios were 190.2(26.92-1343.97) and 0.02(0.00-0.14) respectively. Sensitivity of RDT in detecting other non-falciparum malaria species was 54.55%(95%CI 23.38, 83.25) while specificity was 100% (CI=98.44-100). Positive and negative predictive values were 100% and 97.91%(95%CI 96.08,98.89) respectively. Negative likelihood ratio was 0.45(CI=0.24,0.87). The unacceptable low sensitivity of RDT for *P.ovale* and *P.malariae* should be considered when using this RDT as a point of care test whenever microscopy facilities are not available. It is recommended that RDTs are used in conjunction with microscopy and not as a substitute.

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