



两种疟疾快速诊断试剂盒检测效果的比较

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Comparison of Two Rapid Diagnostic Tests in Detection of Malaria Parasites

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摘要

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摘要 【摘要】目的 比较两种疟疾快速诊断试剂盒(RDTs)检测疟疾患者血样的效果。方法 在云南采集流行区疟疾患者血样200份,上海地区采集健康者血样60份,以显微镜镜检为金标准,比较胶体金免疫层析法(GICA)和瑞士产OptiMAL试剂盒检测疟原虫的敏感性和特异性。并用这两种RDTs试剂盒分别检测10份原虫密度梯度样品,比较其疟原虫最低检出限并分析检测效果。结果 本次共检测血样260份,镜检确诊为恶性疟原虫阳性100份,间日疟原虫阳性100份,阴性60份。GICA检测疟疾患者血样的敏感性和特异性分别为87.5% (175/200)和93.3% (56/60),恶性疟和间日疟患者血样的敏感性和特异性分别为83.0% (83/100)、89.0% (89/100)和96.9% (155/160)、98.8% (158/160)。OptiMAL的敏感性和特异性分别为95.5% (191/200)和100.0% (60/60),恶性疟、间日疟的敏感性和特异性分别为90.0% (90/100)、96.0% (96/100)和99.4% (159/160)、97.5% (156/160)。两种试剂盒检出疟原虫的差异具有统计学意义($\chi^2=8.23$, $P<0.05$)。两种试剂盒检测恶性疟($\chi^2=2.10$)和间日疟($\chi^2=3.53$)的差异无统计学意义($P>0.05$)。GICA检测恶性疟原虫和间日疟原虫3个级别原虫密度血样的检出结果差异均无统计学意义($P>0.05$); OptiMAL检测间日疟原虫不同密度的差异无统计学意义($P>0.05$),检测恶性疟原虫不同密度的差异有统计学意义($P<0.05$),高密度原虫检出率较高。两种试剂盒检测疟原虫的最低检出限约为100~200个/ μ l血。结论 OptiMAL试剂盒检测疟原虫的敏感性、特异性和检出率均高于GICA试剂盒, GICA检测疟原虫的最低检测限较低,且重复性较好。

关键词: 快速诊断试验 恶性疟原虫 间日疟原虫 比较

Abstract: 【Abstract】 Objective To compare the performance of two rapid diagnostic tests (RDTs) for malaria parasite detection. Methods Blood samples of 200 malaria patients and 60 non-malaria persons were collected from Yunnan and Shanghai, respectively. The sera were detected by gold-colloidal immunochromatography(GICA)and OptiMAL, and microscopy was used as gold standard in species identification. The sensitivity, specificity, minimum detection limit of the two RDTs was compared. Results Of the 260 samples, malaria parasites were found in 200 by microscopy, of which 100 each were *Plasmodium falciparum* and *P. vivax*, respectively. Compared with microscopy, the sensitivity and specificity of GICA and OptiMAL for the samples were 87.5% (175/200) and 93.3% (56/60), 95.5% (191/200) and 100.0% (60/60), respectively. The sensitivity and specificity of GICA and OptiMAL for detection of *P. falciparum* were 83.0% (83/100) and 96.9% (155/160), 90.0% (90/100) and 99.4% (159/160), respectively; and for detection of *P. vivax*, they were 89.0% (89/100) and 98.8% (158/160), 96.0% (96/100) and 97.5% (156/160), respectively. There was a significant difference in malaria detection between GICA and OptiMAL ($\chi^2=8.23$, $P<0.05$). No statistical difference was found between the two RDTs in *P. falciparum* and *P. vivax* detection ($P>0.05$). OptiMAL showed better result in detection of *P. falciparum* when the parasite density was higher. The minimum detection limit of the two RDTs was about 100-200 parasites/ μ l blood. Conclusion Compared to GICA, OptiMAL has higher sensitivity and specificity. However, GICA shows lower minimum detection limit and better reproducibility in blood samples with different densities than that of OptiMAL.

Keywords: Rapid diagnostic test *Plasmodium falciparum* *Plasmodium vivax* Comparison

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