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O0453 Molecular testing as routine approach for malaria diagnostics

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Background: Molecular approaches for the diagnosis of malaria have been developed but have largely remained restricted to few special indications. In recent years, signs of a paradigm shift have become obvious with European professional societies openly recommending the use of molecular tools for primary malaria testing. Here, we present experience with molecular assays for initial malaria screening and species differentiation in routine clinical samples.

Materials/methods: A total of 1,000 consecutive EDTA blood samples from patients with suspected or confirmed malaria were sent to the German National Reference Centre for Tropical Pathogens for malaria microscopy using thick and thin blood films. In addition, the samples were assessed by commercial loop-mediated isothermal amplification (LAMP) as well as commercial genus-specific real-time PCR for malaria. In addition, samples positive by microscopy and/or PCR were subjected to two different commercial multiplex real-time PCRs for the differentiation of *Plasmodium* spp. on species level.

Results: LAMP-based screening for malaria revealed sensitivity and positive predictive value of 98.7% each and specificity and negative predictive value of 99.6% each. Sensitivity of LAMP was higher than of microscopy (99.1% versus 92.5%), allowing earlier identification of malaria cases by molecular screening. Of note, specificity and positive predictive value of microscopy were 100%. The two assessed differentiation PCRs showed 98.9% concordance with microscopic species differentiation and were able to identify cases of mixed infections with *P. falciparum* and *P. vivax*, which would have gone undetected by microscopy. Including samples which were only positive by PCR, e.g. due to submicroscopic parasitemia or residual circulating parasite DNA after therapeutically cleared infections, PCR-based differentiation on species level was successful in 95.1% and 96.8% of cases, respectively.

Conclusions: The results confirm the usefulness of molecular approaches for initial malaria testing and species differentiation of *Plasmodium* spp. in human EDTA blood. Respective systems are particularly useful for laboratories in non-endemic settings with little experience in malaria microscopy. Increased availability of reliable molecular screening tools for malaria on commonly used point-of-care-testing (POCT) platforms is desirable for medical settings without 24/7 availability of experienced microscopists to adequately address the diagnostic emergency which is implied in cases of malaria suspicion.