Evaluation of a real-time recombinase polymerase amplification assay for rapid detection of Schistosoma haematobium infection in a resource-limited setting

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Accurate diagnosis of urogenital schistosomiasis is vital for surveillance and control programs as well as achieving the WHO 2012–2020 road map for the total eradication of schistosomiasis. Recombinase polymerase amplification (RPA) has emerged as a rapid and simple molecular tool adaptable for fewer resources with diagnostic accuracy similar to a polymerase chain reaction (PCR). This rapid molecular assay employs the use of enzymes for the amplification of nucleic acid targets at a constant temperature. The aim of this study was to validate a real-time RPA assay targeting the Dra 1 repetitive sequence of Schistosoma (S.) haematobium and evaluate its use in urogenital schistosomiasis diagnosis. S. haematobium Dra 1 molecular DNA standard was applied to determine the assay’s analytical sensitivity. DNA extracts of S. haematobium, other Schistosoma species, protozoa and bacteria species were used to determine the specificity of the RPA assay. The clinical performance of the assay was validated with a panel of 135 urine samples from volunteers of schistosomiasis endemic communities. The developed assay was evaluated with DNA from urine samples extracted by just boiling and with a SpeedXtract® DNA extraction kit. A specific fragment of S. haematobium Dra 1 repetitive sequence was amplified within 15 minutes at a constant 42°C temperature using the developed S. haematobium RPA assay. The detection limit was 15 copies of Dra1 molecular DNA standard per reaction. There was no cross-reaction with other protozoan and bacterial species except Schistosoma species- S. mansoni and S. japonicum. Using 135 urine samples, the Schistosoma RPA assay had a clinical sensitivity and specificity of 98.4% (95% CI, 91.6-100) and 100% (95% CI, 94.9-99) respectively when compared to S. haematobium Dra 1 qPCR assay. The diagnostic performance of S. haematobium real-time RPA assay was not affected by the use of crude DNA extracted from samples. The S. haematobium RPA assay can serve as an alternative to PCR, especially in low-resource settings.