51° CONGRESSO NAZIONALE AMCLI

P328

Clinical validation of a *point-of-care* test for the screening of schistosomiasis in the migrant population

Margherita Ortalli1,2, Bianca Granozzi3, Michele Bacchiega3, Concettina Di Lillo2, Greta Roncarati2, Bianca Nuti3, Elisa Vanino4, Silvia S. Longoni5, Zeno Bisoffi5-Stefania Varani1

1 Department of Medical and Surgical Sciences, Alma Mater Studiorum University of Bologna, Bologna 2 Microbiology Unit, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna 3 Infectious Diseases Unit, Department for Integrated Infectious Risk Management, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna 4 Infectious Diseases Unit, Ospedale "Santa Maria delle Croci", AUSL Romagna, Ravenna 5 IRCCS Sacro Cuore Don Calabria Hospital, Negrar di Valpolicella, Verona

BACKGROUND AND AIM. Schistosomiasis is a parasitic disease caused by trematodes of the genus *Schistosoma*, and it is globally the second most important neglected tropical disease. Its clinical presentation is often silent for long time, but the infection can progress to severe urogenital or hepato-intestinal forms. For this reason, migrant health guidelines recommend screening tests for individuals coming from endemic areas. The aim of this study is the evaluation of the diagnostic accuracy of a new immunochromatographic test (ICT black) on capillary blood for the detection of *Schistosoma* antibodies, to be introduced as a *point-of-care* test for screening individuals from endemic regions

METHODS. This is a prospective study that involved 198 individuals from endemic countries (Table 1), who underwent the ICT Black test at the Infectious Diseases Unit of the IRCCS AOU in Bologna. The results of this test were compared with parasitological tests for the detection of eggs in stool and/or urine, as well as serological tests for *Schistosoma* antibodies: ELISA, Western Blot (WB), and ICT on serum. In the absence of a diagnostic *gold standard*, two different reference standards were used: the *Primary Reference Standard* (PRS), which considers the detection of *Schistosoma* eggs by microscopy as the criterion for positivity, and a *Composite Reference Standard* (CRS), which defines a patient as infected if he has positive microscopy or at least two positive results among ELISA, WB, and ICT on serum.

RESULTS. From September 2021 to May 2023, 215 individuals from schistosomiasis-endemic areas were enrolled, of whom 198 were included in the study. The analyses indicated a prevalence of schistosomiasis in the studied population of 32% using the Composite Reference Standard (CRS), while the prevalence was 6% using the Primary Reference Standard (PRS) (Figure 1). Considering the CRS, the parasitological examination showed low sensitivity (16%), followed by Western Blot (WB) at 75% and ELISA at 78%; however, the ICT on serum demonstrated the highest sensitivity (97%) (Table 3). In evaluating the diagnostic accuracy of ICT Black according to CRS, it was noted that this test exhibited good sensitivity (86%) and specificity (88%). Furthermore, the concordance study showed substantial agreement between ICT Black and ICT on serum (k = 0.68) and between ICT Black and the ELISA test (k = 0.73), making them the optimal screening tests for schistosomiasis to date (Table 4).

Age (years, median and IQR)	29 [22-36]
Sex	M 147 (74.2%) F 51 (25.8%)
Born in Sub-Saharan Africa	166 (83.8%)
High eosinophil count	46 (23.2%)
Clinical symptoms	14 (7.1%)

Tab. 1. Characteristics of the study population

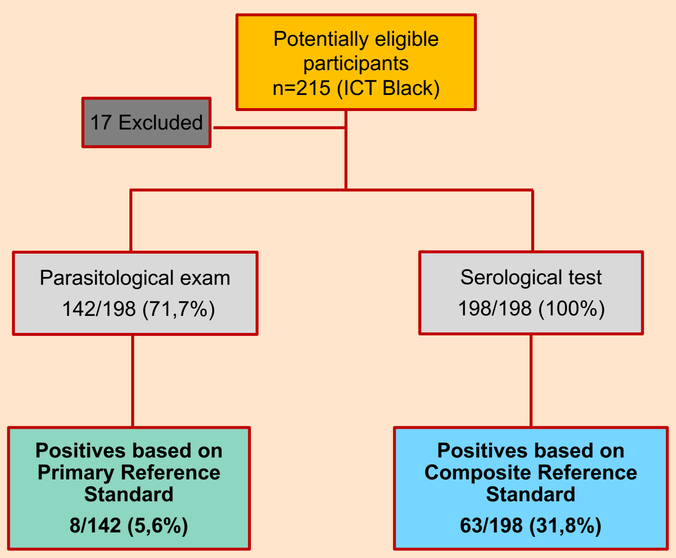

Fig. 1. Flow chart of the study

	ELISA	Serum ICT	capillary blood ICT	Western Blot
Sensitivity	100% (IC 100-100)	100% (I.C 100-100)	100% (IC 100-100)	86% (I.C 83-92)
Specificity	73% (IC 67-79)	59% (I.C 52.66)	63% (IC 56-70)	75% (IC 69-81)
PPV	18% (IC 12-23)	13% (I.C 8-17)	12% (IC 8-17)	17% (IC 12-22)
PNV	100% (I.C 100-100)	100% (I.C 100-100)	100% (IC 100-100)	99% (IC 98-100)

Tab. 2. Diagnostic accuracy of the tests according to the Primary Reference Standard

	ELISA	Serum ICT	Capillary blood ICT	Western Blot	Parasitological exam
Sensitivity	**78%** (IC 72-83)	**97%** (I.C 94-99)	**86%** (I.C 81-91)	**75%** (I.C 69-81)	**16%** (I.C 11-21)
Specificity	**96%** (IC 93-98)	**88%** (I.C 84-93)	**88%** (I.C 83-92)	**90%** (I.C 85-94)	**100%**
PPV	**89%** (I.C 85-93)	**79%** (I.C 74-85)	**77%** (I.C 71-83)	**77%** (I.C 71-83)	**100%**
PNV	**90%** (I.C 86-94)	**98%** (I.C 97-100)	**93%** (I.C 89-96)	**88%** (I.C 84-93)	**69%** (I.C 62-75)

Tab. 3. Diagnostic accuracy of the tests according to the Composite Reference Standard

	Cohen's Kappa	Agreement
ELISA	**0,73**	**Substantial**
Serum ICT	**0,68**	**Substantial**
Western Blot	**0,65**	**Substantial**

Tab. 4. Agreement between the ICT test on capillary blood (ICT Black) and other serological methods

CONCLUSIONS. Based on the results obtained, ICT Black could be an excellent resource as a future screening test for schistosomiasis in the migrant population. The introduction of a *point-of-care* test using capillary blood could assist in infection screening and, for positive patients, enable treatment to be administered during the first outpatient visit. This test could therefore also be performed in first reception centers for migrants.