Travel Medicine and Infectious Disease 64 (2025) 102807

Contents lists available at ScienceDirect

Travel Medicine and Infectious Disease

journal homepage: www.elsevier.com/locate/tmaid

Screening for schistosomiasis in a non-endemic setting: Accuracy of a rapid antibody test using finger prick blood

Margherita Ortalli [a,b,1], Bianca Granozzi [c,1], Michele Bacchiega [a], Concettina Di Lillo [b], Greta Roncarati [b], Silvia Stefania Longoni [d,*], Cristina Mazzi [d], Elisa Vanino [e], Zeno Bisoffi [d,2], Stefania Varani [a,2]

[a] Department of Medical and Surgical Sciences, Alma Mater Studiorum University of Bologna, Bologna, Italy
[b] Microbiology Unit, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy
[c] Infectious Diseases Unit, Department for Integrated Infectious Risk Management, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy
[d] IRCCS Sacro Cuore Don Calabria Hospital, Negrar di Valpolicella, Verona, Italy
[e] Infectious Diseases Unit, Ospedale "Santa Maria delle Croci", AUSL Romagna, Ravenna, Italy

ARTICLE INFO

Keywords:
Schistosomiasis
Immunochromatographic test
Finger-prick blood
Screening

ABSTRACT

Human schistosomiasis is a chronic neglected tropical disease caused by blood flukes of the genus *Schistosoma,* infecting 250 million people worldwide, mostly in sub-Saharan Africa. Recently, thousands of cases have been reported in immigrants to non-endemic countries, including Italy. Serological screening is recommended but so far, no accurate point-of-care (POC) and lab-free test is available.

We carried out a prospective evaluation of the accuracy of a new immunochromatographic test (Black- ICT, IgG-IgM) using finger prick blood for screening of schistosomiasis at the University Hospital of Bologna. Eligible immigrants were recruited regardless the presence of symptoms. The other tests used were microscopy on stools and urine, a serum-ICT (SCHISTOSOMA ICT IgG-IgM, LDBIO Diagnostics), an ELISA (NovaLisa Schistosoma mansoni IgG, Novatec) and a Western Blot (SCHISTO II Western Blot IgG, LDBIO Diagnostics). Statistical analysis was performed using a Bayesian latent class model.

We enrolled 198 subjects in the study. Black-ICT had a sensitivity of 86.6 % (95 % credible interval 76.9–94.7) and a specificity of 88.4 % (82.0–94.3). At the estimated prevalence level for the study sample, 32.6 % (25.5–40.0), the positive and negative predictive values were 78.2 % (66.4–89.4) and 93.2 % (87.7–97.6), respectively. Good agreement was found with the other antibody tests, with the highest sensitivity being observed for serum-ICT (91.0 %, 84.7–96.4) and the highest specificity for ELISA (92.6 %, 87.5–96.7).

The novel POC test for schistosomiasis showed satisfactory results and could improve the detection of this parasitic infection in non-endemic settings, as the lab-free approach could greatly expand the target group.

1. Introduction

Human schistosomiasis is a neglected tropical disease (NTD) caused by trematode blood flukes of the genus *Schistosoma* [1]. This parasitic infection largely contributes to the NTDs' epidemiological burden; according to the World Health Organization (WHO), *Schistosoma* spp. infects 250 million people worldwide, and 700–800 million individuals residing in Africa, Asia and Latin America are at risk of infection [2]. The highest prevalence of schistosomiasis is observed in sub-Saharan Africa, where more than 90 % of all infections occur, mostly caused by the species *S. mansoni* and *S. haematobium* [3].

Schistosomiasis is acquired by contact with freshwater contaminated with the larval forms penetrating the skin, subsequently adult worms place themselves in the blood vessels of the host where the females release eggs. Parasite eggs can be shed in stools or urine or remain trapped in body tissues, stimulating non-sterilizing immune reaction that can progressively cause damage [4].

If left untreated, chronic schistosomiasis may lead to severe

* Corresponding author.
E-mail address: silvia.longoni@sacrocuore.it (S.S. Longoni).
[1] These authors contributed equally to this work.
[2] These authors contributed equally to this work.

https://doi.org/10.1016/j.tmaid.2025.102807
Received 19 November 2024; Received in revised form 23 January 2025; Accepted 23 January 2025
Available online 24 January 2025

morbidity including anemia, nutritional deficiency, hepatic fibrosis, obstructive uropathies, and bladder cancer [5]. *S. haematobium* is also responsible for genital schistosomiasis that affects both females and males, contributing to infertility [1]. Despite the risk of severe and life-threatening sequelae, up to 50 % of patients remain asymptomatic for a long time after being infected [1].

The number of people in Europe at risk of having chronic schistosomiasis is potentially high, considering the unprecedented inflow of migrants and asylum seekers from schistosomiasis-endemic countries [6,7]. In a recent GeoSentinel paper on infections with long latency in international refugees and migrants worldwide, schistosomiasis ranked among the chronic infections with the highest prevalence (35 % by serology), with two European countries, Spain and Italy, accounting for over 50 % of the people tested [8]. Similarly, a systematic review and meta-analysis on the prevalence of strongyloidiasis and schistosomiasis among migrants in the USA, Canada, Australia, New Zealand, Israel, and 23 western European countries [7] found a 24 % seroprevalence of the latter among African migrants. In a recent prospective prevalence study on African refugees and asylum seekers in Rome and Lazio region, Italy, the estimated prevalence of schistosomiasis according to a composite reference standard (CRS) was 31 %, while in 11 % the direct faecal or urine examination was positive for eggs of *S. mansoni*, *S. haematobium*, or both [9].

These and other findings highlight the need of schistosomiasis screening programs, as indicated by the European Center for Disease Control guidelines [10]. Nevertheless, screening and diagnostic protocols for schistosomiasis are not standardized and their application among immigrants and travelers is limited.

According to Italian guidelines, schistosomiasis screening is recommended in all asymptomatic subjects who have lived or have spent at least 6 months in endemic countries and in all those who have spent even shorter period in endemic countries and may not exclude freshwater skin exposure. Furthermore, a diagnosis of chronic schistosomiasis must be taken into consideration in the presence of epidemiological criteria and concomitant gastro-intestinal symptoms (abdominal pain, hepatomegaly, splenomegaly, bowel movements), urogenital symptoms (haematuria, hemospermia, dysuria, suprapubic pain, low back pain) or eosinophilia [6].

To date, the diagnosis of schistosomiasis relies on direct parasitological examination and on indirect immunological tests. Microscopic detection of eggs in urine or stool specimens has been traditionally considered the reference standard while imperfect for diagnosis of schistosomiasis owing to its high analytical specificity (100 %), its low cost and simplicity in execution, despite its low sensitivity (<50 %) [11]. However, if microscopy may be an appropriate tool for control programs in endemic regions, allowing the identification of high transmission areas, the same is not true for screening in non-endemic regions. In the latter, considering that there is no risk of reinfection, the goal is the cure of all infected individuals regardless the parasitic load, and therefore more sensitive tools than microscopic examination of urine and stool are needed.

The Circulating Cathodic Antigen urine cassette assay (CCA), an antigen capture dipstick that detects schistosome circulating cathodic antigen in urine [12], was found to be an excellent test to detect *S. mansoni* infection in endemic regions, while for *S. haematobium* it was outperformed by proteinuria and haematuria [13]. However, when assessed in non-endemic regions the test performed poorly [14,15]. Interestingly, the ELISA-assessed circulating anodic antigen (CAA) levels in urine [16] or serum has long proved to be a highly sensitive and specific test for both species [17]. Moreover, the CAA test reacts to active infections and is an excellent tool for treatment monitoring [18,19]. Unfortunately, a commercially available version of this test has not been developed, and the test remains reserved to few, specialized laboratories.

Serological tests are currently the preferred tools for screening of schistosomiasis in non-endemic countries because of their high sensitivity [10], even if they cannot distinguish between active and past infections [18,20]. Further, these tests cannot discriminate between different *Schistosoma* species [21], which does not undermine the usefulness of serology in screening, as a chronic infection always needs to be treated, regardless of species [10]. A missed diagnosis may have serious consequences, while the treatment with praziquantel is relatively cheap and well tolerated, this being the main reason while, as far as screening is concerned, sensitivity is privileged over specificity.

The currently available commercial tests exhibit a wide range of performance [15,22,23]. In a study using Latent Class Analysis to obviate for the lack of a gold standard, an immunochromatographic test (ICT) licensed for use on serum (SCHISTOSOMA ICT IgG-IgM, LDBIO Diagnostics, Lyon, France) was the most sensitive serologic test, while an immunoenzymatic assay (Bordier ELISA, Bordier Affinity Products, Crissier, Switzerland) resulted to be the most specific test [15]. The excellent sensitivity of the ICT was recently confirmed by a large study in Spain [23].

An ideal screening test, besides being highly sensitive, would be a “point of care” (POC) test allowing to decentralize the screening at primary care sites with no lab facility. However, when tested for use on peripheral blood obtained by finger prick, the ICT IgG-IgM did not provide satisfactory results, exhibiting poor sensitivity and scarce concordance with the same test used on serum [24].

A POC test, based on a black-colored latex matrix (Black- ICT IgG-IgM), is in the validation phase and is a modified test of the commercially available SCHISTOSOMA ICT IgG-IgM test, which is patented for use on serum only. A preliminary study was performed testing the Black-ICT on serum samples; two technicians examined in blind the new POC and compared its performance with the patented serum ICT, showing a weak background signal in several samples, thus challenging the interpretation of the negative results [25].

The aim of the present study was to evaluate the accuracy of the Black-ICT to detect schistosome antibodies directly in finger prick blood from individuals at risk of infection in a non-endemic setting. As secondary aim, our study analyzed the diagnostic performance of three commercially available serological tests: serum ICT, Western Blot and ELISA.

2. Methods

2.1. Ethics statement

The study was approved by the Ethics Committee of the Area Vasta Emilia Centro (CE-AVEC), Protocol n. 4144/2020. All subjects signed an informed consent.

2.2. Study design and population

This single-center, prospective diagnostic study was conducted at the University Hospital of Bologna (Italy) from September 2021 to May 2023. Enrolment was carried out at the Infectious Disease Unit of the hospital among a population of migrants referred as part of a sanitary screening programme promoted by local authorities according to Italian recommendations, or sent by other physicians.

Subjects above 14 years of age that fulfilled the epidemiological criteria (origin or stay for at least 6 months in an endemic area for schistosomiasis) [26] were included in the study. We report no significant selection bias. Exclusion criteria were refusal to sign the informed consent and missing result for one of the serological tests. Subjects were recruited consecutively as part of the screening programme, regardless the presence of symptoms.

Detection of specific antibody was performed by ICT on blood drops obtained from finger prick (kit on validation, Black-ICT IgG-IgM, LDBIO Diagnostics) and on serum (SCHISTOSOMA ICT IgG-IgM, LDBIO Diagnostics), as well as by ELISA (NovaLisa Schistosoma mansoni IgG, Novatec Immunodiagnostica GmbH, Dietzenbach, Germany) and by

Western Blot (SCHISTO II Western Blot IgG, LDBIO Diagnostics). Coprouroparasitological tests were also carried out. Microscopy examination of urine and faeces as well as ELISA on serum were performed as part of the diagnostic routine for screening of patients at risk for schistosomiasis, while Western Blot and serum ICT were performed for the study purpose. Sera were kept frozen at −80 °C and the tests were carried out within 24 h from unfreezing.

The serological tests on serum samples as well as the parasitological examination of faeces and urine were carried out at the Microbiology Unit of the University Hospital of Bologna, while the ICT on finger prick blood (Black ICT) was performed during enrolment at the Infectious Disease Unit of the same hospital. Doctors who performed the Black ICT were unaware of the results of the tests for diagnosis of schistosomiasis on serum, faeces and urine. Conversely, index test results were available to laboratory staff performing microscopy examination of urine and stool for egg detection. For each subject included in the study, the following data were collected at baseline: demographics (age, sex, country of origin, stay in endemic area), date of enrolment/sampling, result of the routine serological test to diagnose schistosomiasis, result of parasitological tests on urine/faeces, laboratory tests (eosinophil count), comorbidities, HIV infection, clinical symptoms (abdominal pain, bowel habit alteration, itching, haematuria), results of the abdominal ultrasound.

2.3. Parasitological examination

Microscopic examination was performed on one to three faecal and urine samples collected on different days for each patient. The MINI-SYSTEM PARAGREEN kit (Biolife Italiana Srl Milan, Italy) was employed to concentrate stool samples, while urine samples were centrifuged at 720 g for 10 min; faecal concentrate or urine sediment were then placed on a labeled slide and diluted with weak Lugol's iodine solution. At least 4 slides for each sample were examined by optical microscopy (100x) for the detection of *Schistosoma* eggs.

2.4. Serological tests

2.4.1. Enzyme immunoassay (ELISA)

The NovaLisa Schistosoma mansoni IgG ELISA (Novatech Immundiagnostica GmbH) utilized a soluble worm antigen preparation (male and female; Puerto Rico strain) [22]. The test was carried out on 100 µl serum samples following the manufacturer's instructions. Antibody titers >11 U/ml were considered as positive according to manufacturers' instruction.

2.4.2. Western blot

The SCHISTO II Western Blot IgG (LDBIO Diagnostics) is a qualitative serological test to detect antibody against specific proteins of adult worms of *S. mansoni* and *S. haematobium* by employing 25 µl of serum. The test was performed following the manufacturer's instructions. A serum sample was considered as positive in case of appearance of one or more bands in the reading area between 8 and 34 kDa.

2.4.3. ICT on serum samples (Serum-ICT)

The SCHISTOSOMA ICT IgG-IgM assay (LDBIO Diagnostics) is a qualitative test that simultaneously detects anti-*Schistosoma* IgG and IgM in human serum. The device is based on a pink colored matrix coated with purified antigen from a crude lysate of *S. mansoni* adult worms. The test was performed according to the manufacturer's instruction. Briefly, 30 µl of serum were dispensed in the sample well followed by 3 drops of the respective eluent and the results were read after 20–30 min. The test was considered positive if both the control and test bands were positive. Inconclusive results (given by absent or uncompleted migration of blood along the strip) were registered as invalid test result.

2.4.4. ICT on finger prick blood (Black-ICT)

LDBIO Diagnostics developed a new ICT, modifying the patented SCHISTOSOMA ICT IgG-IgM assay (serum-ICT). This new ICT, not yet commercially available, is based on a black colored latex matrix (Black-ICT) instead of the pink colored latex matrix, in order to make the test more easily readable if performed on whole blood. The Black-ICT test was performed according to the manufacturer's instruction. Briefly, the blood obtained *via* finger prick was dropped on the device (30 µl), followed by 3 drops of the respective eluent and the results were read after a 20-min incubation period. The test was considered positive if both the control and test bands were positive, while inconclusive results (given by absent or uncompleted migration of blood along the strip) were registered as invalid; invalid tests were not repeated.

2.5. Statistical analysis

Convenience sampling was used to recruit participants attending the Infectious Diseases Unit at the Bologna University Hospital. Given the lack of a gold standard for the diagnosis of schistosomiasis, the accuracy of the Black-ICT was assessed using a primary reference standard (PRS) and a Bayesian latent class model (BLCM). The PRS was based on microscopic examination only: the patient was defined as infected if *Schistosoma* eggs were found in the faeces and/or urine. As for the BLCM, detailed model specifications are provided in the supplementary file. Briefly, in addition to accuracy measures, prevalence estimates, including the lowest, highest and mean values observed in different geographical regions (West Africa, East and Central Africa and other) were calculated and used to calculate PPVs and NPVs, with uncertainty quantified by 95 % Bayesian credible intervals (CI). Primary results were obtained using informative priors for the sensitivity and specificity of SCHISTO II Western Blot IgG, SCHISTOSOMA ICT IgG-IgM (serum-ICT) assay and microscopic examination, while minimally informative priors were used for all other tests. These priors for sensitivity and specificity were derived from previously published data for the same tests [15]. Sensitivity analyses were performed by considering different priors for the tests and by excluding one geographical area at a time from the model.

Concordance between the various diagnostic tests was evaluated using the Cohen's Kappa index. Cohen's Kappa measure (with its 95 % confidence interval) was used to assess agreement as follows: K = 0, no agreement; K = 0–0.20, poor agreement; K = 0.21–0.40, fair agreement; K = 0.41–0.60, moderate agreement; K = 0.61–0.80, substantial agreement; and K = 0.81–1.00, near perfect agreement [27].

All statistical analyses were performed using R software and the 'runjags' [28] and 'psych' package [29]. Bayesian latent class analysis (BLCA) models were run using Markov chain Monte Carlo methods implemented in JAGS software [30].

3. Results

From September 2021 to May 2023, 215 individuals at risk for schistosomiasis were enrolled at the Infectious Disease Unit of the University Hospital of Bologna, Italy. Of these 215 patients, 17 individuals were excluded (Fig. 1). Of the 198 individuals that were included in the study, 74.2 % (147/198) were males and 26 % (51/198) were females (Table 1). The study included a total of 441 samples, comprising 123 urine samples, 120 stool samples, and 198 serum samples. The recruited subjects were mostly from Sub-Saharan Africa (165/198, 83.3 %) or stayed there for more than 6 months (1/198, 0.5 %), while only two patients originated from North Africa (0.1 %); of the remaining enrolled patients, 13.1 % (26/198) were from Asia and 2.0 % (4/198) were from Latin America (Table 1). See Table S1 for details of the sub-populations by geographical region. The median age was 29 years (range 15–85 years).

The Black-ICT identified 69 out of 198 (34.8 %) individuals as positive for the presence of antibodies against *Schistosoma* (Fig. 1), while 5

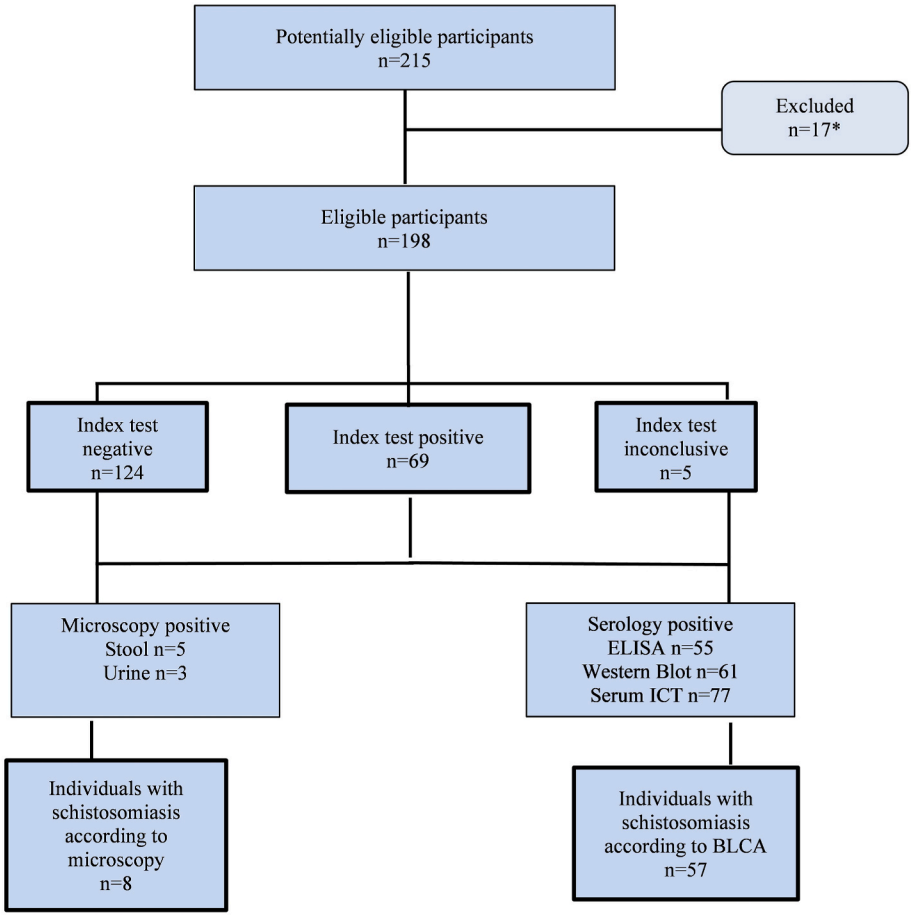

Fig. 1. Study flow chart. *Reasons for exclusion: missing result for one of the serological tests (n = 17). ICT; immunochromatographic test, BLCA; Bayesian latent class analysis.

Table 1
Demographic and clinical characteristics of the study population (N = 198).

Age (years, median and IQR)	29 [22–36]
Sex	M 147 (74.2 %)
	F 51 (25.8 %)
Born or lived in endemic area	186 (93.9 %)
Born in Sub-Saharan Africa	166 (83.8 %)
West Africa	108 (54.5 %)
East and Central Africa	58 (29.3 %)
Other	32 (16.2 %)
High eosinophil count	46 (23.2 %)
Absolute value (cells/μL; median and IQR)	150 [60–288]
Percentage	3 [1–6]
Clinical symptoms	14 (7.1 %)
Abdominal pain	5
Changes in bowel habits	1
Itching	5
Haematuria	3
US performed	57 (28.8 %)
US abnormalities	9 (15.8 %)
Bladder wall thickening	4
Bladder polyps	1
Hepatic fibrosis	4
Abdominal lymphadenopathies	3

IQR; interquartile range, US; ultrasound.

out of 198 (2.5 %) subjects had an invalid test result; NovaLisa Schistosoma mansoni IgG ELISA identified 55 out of 198 (27.8 %) individuals as positive; concerning the serum-ICT a positivity rate of 38.9 % (77/198) was observed, while this test had no invalid results. In addition, 61 out of 198 individuals (30.8 %) showed a positive result when tested by Western Blot. Finally, parasitological investigation detected *Schistosoma* eggs in 3 out of 123 (1.5 %) and in 5 out of 120 (2.5 %) individuals when testing urine and faecal samples, respectively. Cross tabulation of the tests' results is reported in Table S2.

According to microscopy, the sensitivity of the Black-ICT on finger prick blood was 7/7 (100.0 %, CI 59.0%–100.0 %) and so was, consequently, the negative predictive value (NPV), while the specificity was 84/134 (62.7 %, CI 53.9%–70.9 %) and the positive predictive value (PPV) was extremely low (7/57 or 12.3 %, CI 5.1%–23.7 %). Of the 5 invalid test results of the index test, one concerned a microscopy-positive sample.

The test sensitivity and specificity estimates of Black-ICT and of the other serological tests according to BLCA are presented as median and 95 % credible intervals in Table 2. The median and 95 % credible intervals of the negative and positive predictive values of the tests for the different prevalence scenarios are shown in Fig. 2. Serum-ICT showed the highest sensitivity and NPV, followed by Black-ICT, while the ELISA had the highest specificity and PPV.

The sensitivity analysis results are detailed in Table S3. A discrepancy was noted between the posterior distribution of the Western Blot sensitivity and the prior values derived from existing literature, suggesting a variance in the test's performance in our study compared to previous estimates. Despite this, the overall findings remained robust and qualitatively consistent regardless of the different priors chosen and the exclusion of data from individual sub-populations.

The agreement between the Black-ICT and the other serological methods was assessed; an overall substantial concordance was observed between the test under evaluation and the commercially available serological tests, with the highest agreement between Black-ICT and

Table 2
Accuracy of Black-ICT and other serological tests to diagnose schistosomiasis. Posterior medians and 95 % credible intervals for sensitivity and specificity of the Black-ICT on finger prick blood and of the other serologic tests for schistosomiasis calculated by Bayesian latent class analysis (BLCA).

	Black-ICT	ELISA	Serum-ICT	Western Blot	Microscopy
Sensitivity	86.6 % (76.9–94.7)	73.7 % (61.8–84.9)	91.0 % (84.7–96.4)	77.7 % (69.5–85.1)	38.8 % (30.8–47.2)
Specificity	88.4 % (82.0–94.3)	92.6 % (87.5–96.7)	82.0 % (77.2–86.7)	86.5 % (81.5–91.1)	95.6 % (91.9–98.5)

ICT, immunocromatographic test; ELISA, Enzyme-linked immunosorbent assay.

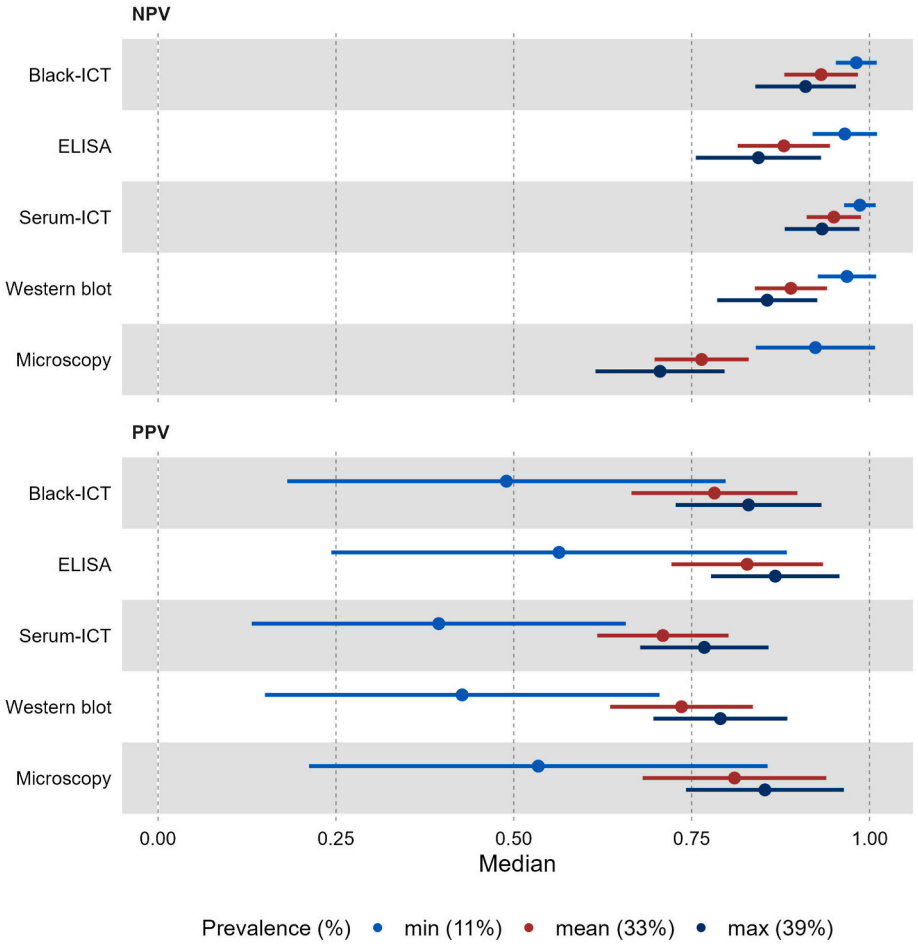

Fig. 2. Predictive values of serological tests for schistosomiasis according to the Bayesian latent class analysis for different prevalence scenarios. The highest negative predictive value (NPV) was revealed by Serum-ICT while the highest positive predictive value (PPV) by ELISA test. Estimated medians (dots) and 95 % credible intervals (lines) of PPV and NPV of each test for the estimated mean prevalence in the study area (33 %, red colored dot and line), minimum prevalence (11 %, light blue colored dot and line) and maximum prevalence (39 %, blue colored dot and line). Error bars show 95 % credible intervals.

ELISA (Cohen's kappa coefficient of 0.73 (95 % Confidence interval: 0.62–0.83), followed by a Cohen's kappa coefficient of 0.68 (95 % Confidence interval: 0.57–0.79) when comparing Black-ICT with serum-ICT and of 0.39 (95 % Confidence interval: 0.26–0.53) between Black-ICT and Western Blot.

The mean prevalence of the infection in the study population, calculated with BLCA, was 32.6 % (25.5, 40.0). True prevalence estimates for each geographical region are presented in Table S4.

4. Discussion

This is the first, prospective diagnostic study on a rapid ICT for the screening of schistosomiasis in immigrants, which was modified for use as a POC test on finger prick blood. The patented ICT for use on serum has proved to be the most sensitive among serologic tests, in line with previous findings in non-endemic settings, including an Italian study in African recent asylum seekers routinely screened for schistosomiasis [15] as well as a Spanish study in sub-Saharan migrants with confirmed schistosomiasis [23]. We observed that the new POC test exhibited a good sensitivity and specificity, with the potential to detect more infections than the predecessor, as the simpler and lab-free approach could greatly expand the target group.

Compared to previous, preliminary studies, i.e. the one on the use of the serum-ICT on blood obtained by finger prick [24] and the one comparing the serum-ICT with the Black-ICT testing sera [25], the improvement of the new version of the index test based on black latex matrix appears evident, with good concordance with all other serological tests and with excellent negative predictive value.

It is worth to highlight that the simple change in the latex color used for the test band in the index POC increased the usefulness of the ICT allowing its use also directly on finger prick blood. This aspect is very important particularly in a non-endemic setting where the ICT can be used also in first reception centers by non-healthcare personnel without requiring specialized laboratories. Overall, the licensed serological tests

employed in this prospective evaluation exhibited similar performances as in previous studies on schistosomiasis in immigrants [15], with ELISA proving again to be the most specific assay. Concerning Western Blot, results must be interpreted with some caution, as they could be partly affected by reading and interpretation problems.

The main strength of this study is the prospective design and the recruitment strategy, based on the screening of individuals at risk, regardless of the presence or absence of symptoms. Furthermore, the Black-ICT was carried out independently of the other analyses. In addition, the use of the BLCA model allowed to obtain robust estimates of the tests' accuracy, and in particular of the new Black-ICT, despite the lack of a gold standard.

This study has several limitations. First, the sample size was comparatively low, hence the quite ample confidence intervals. Using statistical methods to cope with the lack of a gold standard, although methodologically correct, is not a panacea and misclassification of some cases cannot be excluded. In addition, the low number of microscopically positive cases might have affected the calculated performances of the index test and of the other antibody-based tests. Moreover, microscopy examination was lacking in several cases. Serological tests for tissue invasive helminths are known to show some cross-reactivity with antibodies against other helminth infections [7,31]. However, relying on direct methods only would largely underestimate the true prevalence of schistosomiasis and bias specificity assessment [16]. The few invalid tests were not repeated due to logistical problems in the management of the subjects participating to this study.

Recent guidelines issued in low-endemic settings recommend the employment of serological tests for screening of schistosomiasis in individuals originating from endemic areas [6,10]. Even the most accurate serological test detecting *Schistosoma* spp. antibodies in the blood may still be positive for a fairly long time, not allowing to differentiate past and cured infections from active ones [32] and inevitably leading to treat people who do not have the active infection. On the other hand, as no sensitive direct test is currently available, we should continue to rely on antibody tests to be confident that cases of true infection do not escape treatment, which is effective, relatively inexpensive, and well-tolerated. The new Black-ICT could be a valuable screening tool enabling rapid and simple testing of at-risk individuals *via* finger prick, not only in immigration reception facilities, but also, potentially, in general healthcare settings.

In conclusion, the Black-ICT could play an important role in schistosomiasis screening, although, considering that this study was carried out in a hospital outpatient clinic, further studies are needed to confirm the clinical utility of the Black-ICT in other non-endemic settings, and the feasibility of its implementation in primary health care.

CRediT authorship contribution statement

Margherita Ortalli: Writing – review & editing, Writing – original draft, Supervision, Methodology, Data curation, Conceptualization. **Bianca Granozzi:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Data curation, Conceptualization. **Michele Bacchiega:** Writing – review & editing, Visualization, Investigation, Data curation. **Concettina Di Lillo:** Writing – review & editing, Investigation, Data curation. **Greta Roncarati:** Writing – review & editing, Investigation, Data curation. **Silvia Stefania Longoni:** Writing – review & editing, Writing – original draft, Conceptualization. **Cristina Mazzi:** Writing – review & editing, Formal analysis, Data curation. **Elisa Vanino:** Writing – review & editing, Conceptualization. **Zeno Bisoffi:** Writing – review & editing, Writing – original draft, Conceptualization. **Stefania Varani:** Writing – review & editing, Writing – original draft, Supervision, Project administration.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

LdBio Diagnostic kindly donated the Black-ICT test.

CM, ZB and SSL were partially supported by the Italian Ministry of Health, "Fondi Ricerca Corrente, project L3P2".

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tmaid.2025.102807.

References

[1] McManus DP, Dunne DW, Sacko M, Utzinger J, Vennervald BJ, Zhou XN. Schistosomiasis. Nat Rev Dis Prim 2018;4:13.
[2] McManus DP, Bergquist R, Cai P, Ranasinghe S, Tebeje BM, You H. Schistosomiasis-from immunopathology to vaccines. Semin Immunopathol 2020;42:355–71.
[3] WHO. Guideline on control and elimination of human schistosomiasis. https://www.who.int/publications/i/item/9789240041608. [Accessed 22 November 2023].
[4] Nelwan ML. Schistosomiasis: life cycle, diagnosis, and control. Curr Ther Res Clin Exp 2019;91:5–9.
[5] Carbonell C, Rodríguez-Alonso B, López-Bernús A, et al. Clinical spectrum of schistosomiasis: an update. J Clin Med 2021;10.
[6] Comelli A, Genovese C, Gobbi F, et al. Schistosomiasis in non-endemic areas: Italian consensus recommendations for screening, diagnosis and management by the Italian society of tropical medicine and global health (SIMET), endorsed by the committee for the study of parasitology of the Italian association of clinical microbiologists (CoSP-amcli), the Italian society of parasitology (SoIPa), the Italian society of gastroenterology and digestive endoscopy (SIGE), the Italian society of gynaecology and obstetrics (SIGO), the Italian society of colposcopy and cervico-vaginal pathology (SICPCV), the Italian society of general medicine and primary care (SIMG), the Italian society of infectious and tropical diseases (SIMIT), the Italian society of pediatrics (SIP), the Italian society of paediatric infectious diseases (SITIP), the Italian society of urology (SIU). Infection 2023;51:1249–71.
[7] Asundi A, Beliavsky A, Liu XJ, et al. Prevalence of strongyloidiasis and schistosomiasis among migrants: a systematic review and meta-analysis. Lancet Global Health 2019;7:e236–48.
[8] Barnett ED, Wheelock AB, MacLeod WB, et al. Infections with long latency in international refugees, immigrants, and migrants seen at GeoSentinel sites, 2016–2018. Trav Med Infect Dis 2023;56:102653.
[9] Marrone R, Mazzi C, Ouattara H, et al. Screening for Neglected Tropical Diseases and other infections in African refugees and asylum seekers in Rome and Lazio region, Italy. Trav Med Infect Dis 2023;56:102649.
[10] Teymur N. Public health guidance on screening and vaccination for infectious diseases in newly arrived migrants within the EU/EEA. European Centre for Disease Prevention and Control (ECDC); 2018.
[11] Colley DG, Bustinduy AL, Secor WE, King CH. Human schistosomiasis. Lancet 2014;383:2253–64.
[12] Stothard JR, Kabatereine NB, Tukahebwa EM, et al. Use of circulating cathodic antigen (CCA) dipsticks for detection of intestinal and urinary schistosomiasis. Acta Trop 2006;97:219–28.
[13] Vaillant MT, Philippy F, Neven A, et al. Diagnostic tests for human Schistosoma mansoni and Schistosoma haematobium infection: a systematic review and meta-analysis. Lancet Microbe 2024;5:e366–78.
[14] Graeff-Teixeira C, Favero V, Pascoal VF, et al. Low specificity of point-of-care circulating cathodic antigen (POCCCA) diagnostic test in a non-endemic area for schistosomiasis mansoni in Brazil. Acta Trop 2021;217:105863.
[15] Beltrame A, Guerriero M, Angheben A, et al. Accuracy of parasitological and immunological tests for the screening of human schistosomiasis in immigrants and refugees from African countries: an approach with Latent Class Analysis. PLoS Neglected Trop Dis 2017;11:e0005593.
[16] van Lieshout L, de Jonge N, Bassily S, Mansour MM, Deelder AM. Assessment of cure in schistosomiasis patients after chemotherapy with praziquantel by quantitation of circulating anodic antigen (CAA) in urine. Am J Trop Med Hyg 1991;44:323–8.
[17] Ochodo EA, Gopalakrishna G, Spek B, et al. Circulating antigen tests and urine reagent strips for diagnosis of active schistosomiasis in endemic areas. Cochrane Database Syst Rev 2015;2015. xCD009579.f.
[18] Tamarozzi F, Ursini T, Hoekstra PT, et al. Evaluation of microscopy, serology, circulating anodic antigen (CAA), and eosinophil counts for the follow-up of migrants with chronic schistosomiasis: a prospective cohort study. Parasites Vectors 2021;14:149.
[19] van Grootveld R, van Dam GJ, de Dood C, et al. Improved diagnosis of active Schistosoma infection in travellers and migrants using the ultra-sensitive in-house lateral flow test for detection of circulating anodic antigen (CAA) in serum. Eur J Clin Microbiol Infect Dis 2018;37:1709–16.

[20] Weerakoon KG, Gobert GN, Cai P, McManus DP. Advances in the diagnosis of human schistosomiasis. Clin Microbiol Rev 2015;28:939–67.
[21] Hinz R, Schwarz NG, Hahn A, Frickmann H. Serological approaches for the diagnosis of schistosomiasis - a review. Mol Cell Probes 2017;31:2–21.
[22] Kinkel HF, Dittrich S, Bäumer B, Weitzel T. Evaluation of eight serological tests for diagnosis of imported schistosomiasis. Clin Vaccine Immunol 2012;19:948–53.
[23] Luzón-García MP, Cabeza-Barrera MI, Lozano-Serrano AB, et al. Accuracy of three serological techniques for the diagnosis of imported schistosomiasis in real clinical practice: not all in the same boat. Trav Med Infect Dis 2023;8:73.
[24] Buonfrate D, Rodari P, Brunelli D, et al. Diagnostic study on an immunochromatographic rapid test for schistosomiasis: comparison between use on serum and on blood spot from fingerprick. BMJ Open 2018;8:e019228.
[25] Longoni SS, Piubelli C, Perandin F, et al. Preliminary evaluation of a new schistosoma immunochromatographic test. Acta Trop 2021;219:105893.
[26] Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030. https://www.who.int/publications/i/item/9789240010352. [Accessed 11 January 2024].
[27] Altman DG. Practical statistics for medical research. London: Chapman & Hall; 1991. p. 285–8.
[28] Denwood MJ. Runjags: an R Package providing interface utilities,model templates, parallel computing methods and additional distributions for MCMC models in JAGS. J Stat Software 2016;71(i09).
[29] Revelle W. Psych: procedures for psychological, psychometric, and personality research. Evanston, Illinois: Northwestern University; 2023. Package version 2.3.3, https://CRAN.R-project.org/package=psych. [Accessed 11 June 2024].
[30] Plummer M. JAGS: a programme for analysis of bayesian graphical models using Gibbs sampling. In: 3rd international workshop on distributed statistical computing; 2003. p. 20–2. March.
[31] Hoermann J, Kuenzli E, Schaefer C, et al. Performance of a rapid immunochromatographic test (Schistosoma ICT IgG-IgM) for detecting Schistosoma-specific antibodies in sera of endemic and non-endemic populations. PLoS Neglected Trop Dis 2022;16:e0010463.
[32] Utzinger J, Becker SL, van Lieshout L, van Dam GJ, Knopp S. New diagnostic tools in schistosomiasis. Clin Microbiol Infect 2015;21:529–42.