Field evaluation of a rapid, visually-read colloidal dye immunofiltration assay for *Schistosoma japonicum* for screening in areas of low transmission

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Objective To determine the validity of a recently developed rapid test — a colloidal dye immunofiltration assay (CDIFA) — used by health workers in field settings to identify villagers infected with *Schistosoma japonicum*.

Methods Health workers in the field used CDIFA to test samples from 1553 villagers in two areas of low endemicity and an area where *S. japonicum* was not endemic in Anhui, China. All the samples were then tested in the laboratory by laboratory staff using a standard parasitological method (Kato–Katz), an indirect haemagglutination assay (IHA), and CDIFA. The results of CDIFA performed by health workers were compared with those obtained by Kato–Katz and IHA.

Findings Concordance between the results of CDIFA performed in field settings and in the laboratory was high (kappa index, 0.95; 95% confidence interval, 0.93–0.97). When Kato–Katz was used as the reference test, the overall sensitivity and specificity of CDIFA were 98.5% and 83.6%, respectively in the two villages in areas of low endemicity, while the specificity was 99.8% in the non-endemic village. Compared with IHA, the overall specificity and sensitivity of CDIFA were greater than 99% and 96%, respectively. With the combination of Kato–Katz and IHA as the reference standard, CDIFA had a sensitivity of 95.8% and a specificity of 99.5%, and an accuracy of 98.6% in the two areas of low endemicity.

Conclusion CDIFA is a specific, sensitive, and reliable test that can be used for rapid screening for schistosomiasis by health workers in field settings.

Keywords Schistosomiasis japonica/diagnosis; Immunoassay/methods; Colloids; Dyes; Hemagglutination tests; Parasite egg count/methods; Sensitivity and specificity; Comparative study; Evaluation studies; China (*source: MeSH, NLM*).

Mots clés Schistosomiase artérioveineuse/diagnostic; Dosage immunologique/méthodes; Colloïde; Colorants; Réaction hémagglutination; Numération œuf parasite/méthodes; Sensibilité et spécificité (Epidémiologie); Etude comparative; Etude évaluation; Chine (*source: MeSH, INSERM*).

Palabras clave Esquistosomiasis japonica/diagnóstico; Inmunoensayo/métodos; Coloides; Tinturas; Tests de hemaglutinación; Recuento de huevos de parásitos/métodos; Sensibilidad y especificidad: Estudio comparativo; Estudios de evaluación; China (*fuente: DeCS, BIREME*).

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Introduction

Schistosomiasis remains a public health problem in China, although great advances in schistosomiasis control have been achieved during the past five decades (*1*). It has been estimated that in 2002 more than 0.8 million people were infected, and about 30 million people were at risk of infection (*1, 2*). At present, selective chemotherapy is the main strategy for control of schistosomiasis in China because the prevalence and the morbidity of the disease are low after many years of mass chemotherapy (*1, 3*). Thus the "test-treat" approach is probably the most cost-effective strategy for identifying individuals

to be targeted for repeated treatments (*4*). For this approach to be adopted by the schistosomiasis control programme in China, there is an essential need for a simple, rapid, sensitive and inexpensive screening technique.

Some indirect methods, including interpretation of clinical symptoms, ultrasound examination, measurement of markers of biochemical or morbidity, and the application of questionnaires, have been proved useful in screening for *Schistosoma haematobium* in Africa and are cost-effective in areas where the infection is highly endemic (*5, 6*). However, these methods are of very limited usefulness in screening for intestinal

schistosomiasis caused by *S. mansoni* or *S. japonicum*, especially in areas of low or declining prevalence, because of their lack of specificity (7, 8).

Direct parasitological techniques, apart from being labour-intensive and time-consuming, have become relatively insensitive owing to the widespread use of chemotherapy resulting in generally lower worm burdens per individual. A definitive diagnosis of infection with *S. japonicum* still relies on the identification of eggs or miracidia in the faeces. In order to improve the identification of individuals to be targeted for treatment, however, immunodiagnostic methods such as the circumoval precipitin test (COPT), indirect fluorescence assay (IFA) and enzyme-linked immunosorbent assay (ELISA), which have a high sensitivity, specificity, and reliability, and high compliance compared with parasitological techniques, have been integrated into the control programme in China since the early 1980s when the safe and effective anti-schistosomiasis drug (praziquantel) was introduced (4, 9). These immunodiagnostic tests share drawbacks, however, including cost, requirements for laboratory equipment and specific expertise, electricity, refrigeration, and incubation periods that cause a delay in diagnosis, which make them unsuitable for direct use in field settings. The lack of effective tools for screening has been recognized as a major barrier to the prevention and control of this infection in areas of low transmission.

We have recently developed a novel method for rapid screening for infection with *S. japonicum* — a colloidal dye immunofiltration assay (CDIFA) that is based on the detection of antibody to the heat-resistant, soluble egg antigen of *S. japonicum*. Laboratory studies have shown that CDIFA is a rapid, convenient and reliable method for screening for schistosomiasis infection (10). In the study reported here, we further evaluated the performance and acceptability of CDIFA in field situations and compared it with the indirect haemagglutination test (IHA) and Kato–Katz method.

Materials and methods

Study site and participants
The study was conducted between August and November 2003 in three widely separated areas of Anhui, China: Dongliang village (village A) in Wuhu City, Puxi village (village B), in Lanling County, and Dayao village (village C, a non-endemic area) in Shouxian County. All the subjects were asymptomatic villagers who were self-selected to participate in a mass screening survey on parasitic diseases. All participants in the three villages were included in this study, except those people in village C who had ever visited an endemic area (Fig.1). Age, sex, schistosomiasis history and data on treatment were recorded for all participants.

Specimen collection and handling
In all three studies, field health workers were blinded to the schistosomiasis status of the subject to be tested. Samples of 250 µl of ear lobe blood were collected using the heparinized plastic capillary tubes (2 mm in diameter) provided with the CDIFA kit, sealed at one end. The tubes were then maintained in a vertical position for about 1 h to allow the spontaneous separation of the plasma and red blood cells. Plasma was removed by cutting the tubes with scissors. The plasma was tested immediately with the CDIFA kit on the spot, and the residual plasma, as well as a faecal sample obtained from the

Fig. 1. **Profile of the schistosomiasis trial** (numbers of subjects at each stage)
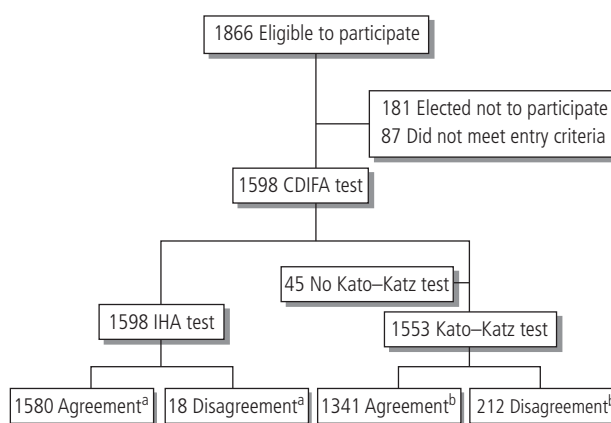
[a] Refers to agreement or disagreement of results of CDIFA with those of IHA.

[b] Refers to agreement or disagreement of results of CDIFA with those of Kato–Katz.

CDIFA = colloidal dye immunofiltration assay; IHA = indirect haemagglutination assay.   *WHO 05.44*

same subject, was taken to local schistosomiasis stations where CDIFA, IHA and Kato–Katz tests were performed by laboratory staff within 24 h of sample collection.

Stool examinations
The Kato–Katz thick smear stool examination (11) was performed to identify and quantify *S. japonicum* eggs in the faeces of each subject. The stool examination was based on three slides (41.7 mg per smear) prepared from a single stool specimen, resulting in a total sample weight of 125 mg. Slides were read 12–48 h after their initial preparation by two experienced technicians who were unaware of the subject's medical status or immunological test result. *S. japonicum* egg counts were expressed in eggs per gram (EPG).

Repeat stool examination
In village B, 40 randomized individuals all with a negative result by initial Kato–Katz test and half of them with a positive result by CDIFA were selected for repeat stool examination. Three repeated faecal samples from each person on three separate days were collected and tested by Kato–Katz technique (10 slides from a single stool sample) and egg hatching test (12, 13).

Indirect haemagglutination test
IHA was performed as described in previous reports (12, 14). The titre in the test plasma was recorded as one dilution before that which yielded a clear, sharp dark spot similar to that in the negative control wells. Titres were expressed as reciprocal values. Titres of ⩾ 10 were considered to indicate a positive result (12, 14).

CDIFA
CDIFA was performed as described previously (10). Standard operating procedures are as follows: (i) add two drops of washing buffer from the buffer bottle to a well on the test card; (ii) add one drop of plasma taken directly from the blood collecting tube to the same well, and allow it to be absorbed completely; (iii) add two drops of dye-labelled soluble egg antigen conjugate from the detecting bottle to the well, and

Table 1. **Characteristics of the villages included in the study and the results of the three different diagnostic assays**

Village[a]	No. of subjects	Average age (range)	Sex (M/F[b])	No. of subjects (%) with a positive result according to:			
				Kato–Katz	CDIFA[c] by laboratory staff	CDIFA by health workers	IHA[d]
A	501	36.4 (5–77)	257/244	2 (0.4)	41 (8.2)	42 (8.4)	43 (8.6)
B	625	39.6 (5–84)	321/304	66 (10.6)	233 (37.3)	235 (37.6)	240 (38.4)
C	427	31.3 (5–71)	228/199	0 (0.0)	1 (0.2)	1 (0.2)	3 (0.7)

[a] A, Dongliang village; B, Puxi village; C, Dayao village.
[b] M/F = male/female.
[c] CDIFA = colloidal dye immunofiltration assay.
[d] IHA = indirect haemagglutination assay.

allow to soak in; (iv) add two drops of washing buffer to the well to remove the unbound conjugate, and then read the result immediately. The appearance of two red dots in the well indicates a positive reaction, and the appearance of a single red dot indicates a negative reaction. The assay is performed at room temperature without incubation and the whole procedure can be completed within 2 min.

Training

The CDIFA kits were stored at room temperature (12–30 °C) during the study. Five laboratory technicians, five medical doctors and 12 health workers participated in running and reading CDIFAs over the 12 weeks of the study. All received 2 h of training on site from one of the authors (*X.X.* or *W.T.*) in how to obtain samples and to use, read, and archive the assay.

CDIFA was performed on fresh plasma in the field. Two aliquots (one for CDIFA and one for IHA) were made from the residual plasma and each aliquot was assigned a randomly-generated code to ensure that the technicians taking part in the study in laboratory could not trace the identity of the subject giving the sample.

Questionnaire

To assess ease of use of the three assays, the technicians and health workers involved were asked to complete a questionnaire on their impressions of test presentation, simplicity of the test procedure, and ease of interpretation of test results.

Data analysis

Only data from subjects who accepted all three tests was used for the analyses, which were performed using the SPSS Statistical Package for Social Sciences, Version 11.5 software (SPSS Inc., Chicago, IL, 2002). To measure test agreement between field health workers and laboratory staff, the kappa index was calculated. Owing to the fact that the test was expected to be performed mainly by field health workers rather than by laboratory staff in the future, only the results by field health workers were use to calculate sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), with microscopy and/or IHA results being used as the "reference standards". The variables measured were the number of true positives (TP), number of true negatives (TN), number of false positives (FP), and number of false negatives (FN). Sensitivity was calculated as $TP/(TP + FN)$, specificity was calculated as $TN/(TN + FP)$, the PPV was calculated as $TP/(TP + FP)$, and the NPV was calculated as $TN/(FN + TN)$. Test accuracy — the proportion of all tests that gave a correct result — was defined as $(TP + TN)/($number of all tests$)$. Reliability was expressed as the Youden index (sensitivity + specificity −1).

Results

Test results

Of the 1598 participants, 45 were excluded from the analysis owing to incomplete data (they were not able to offer stool

Table 2. **Performance characteristics of CDIFA[a] compared with microscopy**

Criterion assessed	Endemic villages[b]			Non-endemic village[c]
	A (*n* = 501)	B (*n* = 625)	Total (*n* = 1126)	C (*n* = 427)
No. of true positives	2	65	67	0
No. of true negatives	459	389	848	426
No. of false positives	40	170	210	1
No. of false negatives	0	1	1	0
Sensitivity [% (95% CI[d])]	100 (16–100)	98.5 (95.5–100)	98.5 (95.6–100)	–
Specificity [% (95% CI)]	92.0 (89.6–94.4)	69.6 (65.8–73.4)	80.2 (77.8–82.6)	99.8 (99.3–100)
PPV[e] [% (95% CI)]	4.8 (1–16)	27.7 (22–33.4)	24.2 (19.2–29.2)	–
NPV[f] [% (95% CI)]	100	99.7 (99.2–100)	99.9 (99.8–99.9)	100
Accuracy [% (95% CI)]	92.0 (89.7–94.4)	72.6 (69.2–76.1)	81.3 (79–83.6)	99.8 (99.3–100)
Youden index	0.92	0.68	0.79	–

[a] CDIFA = colloidal dye immunofiltration assay.
[b] A, Dongliang village; B, Puxi village.
[c] C, Dayao village.
[d] CI = confidence interval.
[e] PPV = positive predictive value.
[f] NPV = negative predictive value.

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Table 3. **Performance characteristics of IHA[a] compared with microscopy**

Criterion assessed	Endemic villages[b]			Non-endemic village[c]
	A (*n* = 501)	B (*n* = 625)	Total (*n* = 1126)	C (*n* = 427)
No. of true positives	2	65	67	0
No. of true negatives	458	384	842	424
No. of false positives	41	175	216	3
No. of false negatives	0	1	1	0
Sensitivity [% (95% CI[d])]	100 (16–100)	98.5 (95.5–100)	98.5 (95.6–100)	–
Specificity [% (95% CI)]	91.8 (89.4–94.2)	68.7 (64.9–72.5)	80.0 (77.6–82.4)	99.3 (98.5–100)
PPV[e] [% (95% CI)]	4.7 (1–16)	27.1 (21.9–32.3)	23.7 (18.7–28.7)	–
NPV[f] [% (95% CI)]	100	99.7 (99.2–100)	99.9 (99.7–100)	100
Accuracy [% (95% CI)]	91.8 (89.4–94.2)	71.8 (68.3–75.3)	80.7 (78.4–83.0)	99.3 (98.5–100)
Youden index	0.92	0.67	0.79	–

[a] IHA = indirect haemagglutination assay.
[b] A, Dongliang village; B, Puxi village.
[c] C, Dayao village.
[d] CI = confidence interval.
[e] PPV = positive predictive value.
[f] NPV = negative predictive value.

samples) (Fig.1). The vast majority of the subjects excluded were from village C, with only four being from village A and one from village B. All the excluded subjects had negative results for both CDIFA and IHA. The initial test results and the characteristics of the remaining 1553 subjects are shown in Table 1. The geometric mean egg count for infected persons was 8 eggs per gram (EPG) in village A, and 15.6 EPG (range, 8–280 EPG) in village B.

Concordance between results obtained by field health workers and laboratory staff
The agreement between the results of CDIFA tests performed by field health workers or by laboratory staff was excellent. Only 21 (1.4%) of the results of 1553 tests by both groups were discordant; of these, 12 positive results obtained by field health workers were declared to be negative by laboratory staff, and the remaining 9 negative results were declared to be positive by laboratory staff. For all 1553 samples, the kappa index was 0.95 (95% confidence interval (CI), 0.93–0.97).

Performance of CDIFA and IHA compared with microscopy
The results of CDIFA and IHA compared with those of microscopy are shown in Table 2 and Table 3.

In the population of village A, CDIFA had a sensitivity of 100% and a specificity of 92% compared with microscopy. The PPV of this test was 4.8% and the NPV was 100%. In comparison, IHA had a sensitivity of 100% and a specificity of 91.8%, with a PPV of 4.7% and NPV of 100%.

In the population of village B, CDIFA performed with a sensitivity of 98.5% and a specificity of 69.6% compared with microscopy, with PPV 27.7% and NPV 99.7%. In comparison, IHA showed a sensitivity of 98.5% and a specificity of 68.7%, while the PPV was 27.1% and the NPV was 99.7%.

In the population of village C, a non-endemic area, both CDIFA and IHA showed excellent specificity (99.6% and 98.79%, respectively). The agreement between CDIFA and microscopy was 92.0% in village A, 72.6% in village B and 99.8% in village C.

Performance of CDIFA compared with IHA
The results of screening for *S. japonicum* using CDIFA compared with IHA (the most commonly used immunological method for schistosomiasis screening in China) are shown in Table 4. In the two villages in which *S. japonicum* was endemic, CDIFA had a sensitivity of 96.1% and a specificity of 99.4% compared with IHA, while the PPV was 98.2% and the NPV was 98.7%. The agreement between CDIFA and IHA was 99% in village A, 98.2% in village B and 99.5% in village C.

Performance of CDIFA compared with the combination of microscopy and IHA
If the combination of microscopy and IHA was taken as the "reference standard" (which was not the case), the overall sensitivity and specificity of CDIFA were 95.8% (95% CI, 93.4–98.1%) and 99.5% (95% CI, 99.1–100%) in the two villages of low endemicity, respectively, while the PPV was 98.2% (95% CI, 96.6–99.8%) and the NPV was 98.6% (95% CI, 97.1–100%), with an accuracy of 98.6% (95% CI, 97.9–99.4%).

Performance of CDIFA compared with repeat stool examination
Of the 20 subjects who had positive results by CDIFA, 10 were finally confirmed as positive for schistosomiasis by three repeat stool examinations; 6 of these subjects had no history of schistosomiasis and 4 had reported recent treatment (8 months previously) with praziquantel. Of the other 20 subjects who had negative results by CDIFA, none was finally confirmed as having a positive result.

Assay characteristics and ease of use
Minimal equipment, such as an incubator, microplate shaker and precision pipettes are needed to perform IHA. CDIFA, however, requires no specialist instruments or electricity, because the kit contains all the necessary equipment and reagents, and the reagents are stable at room temperature for more than 6 months (*10*). The testers' impressions of the presentation of the test, simplicity of the operating procedure, and ease of

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Table 4. **Performance characteristics of CDIFA[a] compared with IHA[b]**

Criterion assessed	Endemic village[c]			Non-endemic village[d]
	A (*n* = 501)	B (*n* = 625)	Total (*n* = 1126)	C (*n* = 427)
No. of true positives	40	232	272	1
No. of true negatives	456	382	838	424
No. of false positives	2	3	5	0
No. of false negatives	3	8	11	2
Sensitivity [% (95% CI[e])]	93.0 (81–98)	96.7 (94.4–98.9)	96.1 (93.9–98.4)	33.3 (1–91)
Specificity [% (95% CI)]	99.6 (99–100)	99.2 (98.3–100)	99.4 (98.9–99.9)	100
PPV[f] [% (95% CI)]	95.2 (84–99)	98.7 (97.3–100)	98.2 (96.6–99.7)	100
NPV[g] [% (95% CI)]	99.3 (98.6–100)	98.0 (96.5–99.4)	98.7 (98–99.4)	99.5 (98.9–100)
Accuracy [% (95% CI)]	99.0 (98.1–99.9)	98.2 (97.7–99.3)	99.5 (98.9–100)	99.5 (98.9–100)
Youden index	0.92	0.96	0.96	0.33

[a] CDIFA = colloidal dye immunofiltration assay.
[a] IHA = indirect haemagglutination assay.
[c] A, Dongliang village; B, Puxi village.
[d] C, Dayao village.

[e] CI = confidence interval.
[f] PPV = positive predictive value.
[g] NPV = negative predictive value.

interpretation of results for CDIFA, IHA and the Kato–Katz test are shown in Fig. 2. CDIFA was reported to be the best presented, and easiest to use and to interpret of these three tests.

Discussion

The term "ASSURED" ("affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end-users") has been coined to describe the ideal characteristics of a diagnostic test for use in developing countries (*15*). For a screening test to be used in areas where schistosomiasis is of low endemicity, sensitivity is of course given top priority (*4, 9*). The present study showed that the sensitivity of CDIFA is excellent, being greater than 98% in the two villages of low endemicity (villages A and B) studied. However, the specificity of CDIFA in village B (about 70% compared with the Kato–Katz test) may not be adequate, since large numbers of uninfected persons (but who had a positive test result by CDIFA) would be given chemotherapy. The low specificity of CDIFA was not caused by cross-reaction with intestinal nematodes, which is often the case with other routine serological tests such as enzyme-linked immunoabsorbent assay (ELISA) tests that use crude antigen (*9*); for example, in the non-endemic village, the specificity of CDIFA was excellent despite the fact that 24% of residents were infected with *Ascaris*, 12% with hookworm and 9% with *Trichuris* (data not shown). In addition, the prevalence of intestinal nematodes was similar in the three villages (data not shown) and no cases of infection with *Paragonimus* or *Clonorchis* were found in this study. This is in agreement with the results of studies with CDIFA in the laboratory that show no cross-reaction with intestinal nematodes (*10*).

In our experience with sero-epidemiological studies in different regions of China, we have found that rates of sero-prevalence of *S. japonicum* are 2–4 times higher than rates of prevalence determined by methods relying on faecal parasitology. This difference seems to be caused mainly by the poor sensitivity of the parasitological methods and thus failure to detect infection in some patients with low egg counts (*4, 9, 16, 17*). The high sensitivity of CDIFA and the capacity to detect very low-level infections that would not be detected by faecal examination might explain the difference observed between

the serological and parasitological methods investigated in this study. Yu et al. (*18*) reported that more than half of the infected people in endemic areas (i.e. areas with a *S. japonicum* prevalence of at least 26%) would fail to be detected by duplicate Kato–Katz smears (41.7 mg of faecal sample each). Many epidemiological studies carried out in areas of low endemicity in China (*19*), or other countries (*20–22*), have given similar results. In this study, half of the 20 randomized subjects with a positive result by CDIFA but a negative result by Kato–Katz test in the first survey were finally confirmed as infected by three repeated stool examinations. It is clear that the true specificity and PPV of CDIFA for the detection of schistosomiasis is higher than that obtained when using a single Kato–Katz stool examination as the gold standard.

The seroprevalence of *S. japonicum* may also be higher than the prevalence determined by methods relying on faecal parasitology because of the inability of the serological tests to discriminate between present and past infections (*4, 9*). Many

Fig. 2. **Testers' impressions of the three assays used**
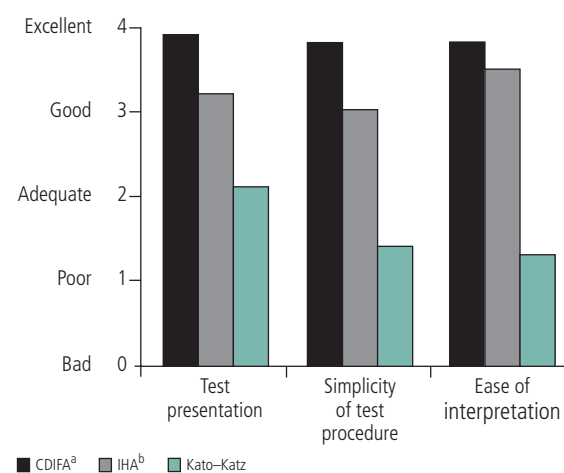
[a] CDIFA = colloidal dye immunofiltration assay.
[b] IHA = indirect haemagglutination assay.

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studies suggest that, in areas of low endemicity, results obtained by serology more closely approximate the true situation than do results obtained by parasitology (*9, 19, 23, 24*). For schistosomiasis control programmes, it is important to use the method that most accurately estimates the true prevalence of schistosomiasis. This is important not only for a better epidemiological understanding, but also for more efficient coverage with chemotherapy in control programmes. Specific antibodies to schistosomiasis may disappear within 1 to 3 years, or after a period 5 or 7 years, depending on the technique and antigen used (*9, 25, 26*). However, the antigen used in CDIFA — purified heat-resistant soluble egg antigen — differs from crude soluble egg antigen and the antigens used in conventional immunological methods, and the question of at what time-point the results of CDIFA become negative in successfully treated patients needs to be addressed.

For instrument-independent tests, reproducibility is another intrinsic factor that may affect performance. Operator variability for CDIFA was 1.4% between qualified laboratory staff and minimally trained field health workers, illustrating its excellent performance. The results of the questionnaire demonstrated the preference of the operators for CDIFA (Fig. 2).

In addition to sensitivity, specificity, simplicity and stability, some other factors, such as kit costs, should also be considered in the choice of a screening assay for application in field settings. The cost per test for CDIFA is very low, about US$ 0.12; however, many other factors can also affect cost-effectiveness. Therefore CDIFA should be incorporated into community control programmes to analyse its cost-effectiveness in areas where *S. japonicum* is endemic at different levels of prevalence.

Whether a screening test is suitable for a specific task depends on its predictive value in given settings, in particular, according to the prevalence of the condition to be detected. On the basis of the sensitivity and specificity as determined by field health workers, we showed that, with the testing strategies applied, CDIFA had a PPV and NPV both of greater than 98% in areas of low endemicity, compared with the combination of Kato–Katz and IHA. This is particularly important in selective chemotherapy strategies in areas of low endemicity where a negative test result needs to predict a true negative case with a probability of close to 100%. Considering the fact that the work described here was carried out independently in remote villages by field health workers with minimal training, the performance of CDIFA was excellent, suggesting that CDIFA can usefully be employed as a sensitive and reliable screening test for *S. japonicum*. ∎

Résumé

Évaluation sur le terrain d'un test diagnostique rapide, à lecture visuelle, utilisant la technique d'immunofiltration et un colorant colloïdal, pour le dépistage de la schistosomiase sino-japonaise dans les zones de faible transmission

Objectif Déterminer la validité d'un test diagnostique rapide (CDIFA) récemment mis au point, faisant appel à un colorant colloïdal et à la technique d'immunofiltration et destiné au dépistage sur le terrain par des agents de santé de *Schistosoma japonicum* chez les villageois .

Méthodes Des agents de santé présents sur le terrain ont appliqué le test CDIFA à des prélèvements effectués sur 1553 villageois provenant de deux zones de faible endémicité de la schistosomiase sino-japonaise et d'une zone où cette maladie n'est pas endémique, appartenant à la province d'Anhui, en Chine. Tous ces prélèvements ont ensuite été analysés en laboratoire par du personnel spécialisé utilisant une technique de diagnostic parasitologique classique (technique de Kato), la technique d'hémagglutination indirecte (IHA) et le test CDIFA. Les résultats des tests CDIFA effectués par les agents de santé ont été comparés à ceux obtenus par la technique de Kato et par hémagglutination indirecte.

Résultats Le taux de concordance entre les résultats des tests CDIFA effectués sur le terrain et en laboratoire est élevé (indice kappa : 0,95, intervalle de confiance à 95 % : 0,93- 0,97). Si l'on utilise la technique Kato comme référence, on parvient à une sensibilité et à une spécificité globales pour le test CDIFA de 98,5 % et de 83,6 % respectivement dans les deux villages situés en zones de faible endémicité, ainsi qu'à une spécificité de 99,8 % dans le village exempt de schistosomiase sino-japonaise à l'état endémique. Par comparaison avec la technique d'hémagglutination indirecte (IHA), la spécificité et la sensibilité globales du test CDIFA sont respectivement supérieures à 99 et 96 %. Si l'on se réfère à une combinaison de la technique KATO et de la technique d'hémagglutination indirecte, on obtient pour le test CDIFA une sensibilité de 95,8 % et une spécificité de 99,5 %, ainsi qu'une précision de 98,6 % dans les deux zones d'endémicité.

Conclusion Le test CDIFA offre une méthode spécifique, sensible et fiable permettant le dépistage rapide sur le terrain de la schistosomiase par les agents de santé.

Resumen

Evaluación sobre el terreno de una prueba visual rápida de inmunofiltración con colorante coloidal para *Schistosomiasis japonica* con fines de cribado en zonas de baja transmisión

Objetivo Determinar la validez de una prueba rápida desarrollada recientemente -prueba de inmunofiltración con colorante coloidal (PICC)- y empleada por agentes de salud sobre el terreno para identificar a los lugareños infectados por *Schistosoma japonicum*.

Métodos Agentes de salud sobre el terreno utilizaron la PICC para analizar muestras de 1553 lugareños en dos zonas de baja endemicidad y una zona sin *S. japonicum* endémica de Anhui, China. Todas las muestras fueron analizadas en el laboratorio por personal técnico utilizando un método parasitológico estándar (Kato-Katz), una prueba de hemaglutinación indirecta (IHA) y la PICC. Los resultados de la PICC llevada a cabo por los agentes de salud fueron comparados con los obtenidos mediante las técnicas de Kato-Katz e IHA.

Resultados Se observó una elevada concordancia entre los resultados de la PICC aplicada sobre el terreno y la practicada en el laboratorio (índice kappa = 0,95; intervalo de confianza del 95% = 0,93–0,97). Cuando se utilizó el método Kato-Katz como prueba de referencia, la sensibilidad y la especificidad generales de la PICC fueron de un 98,5% y un 83,6%, respectivamente, en las dos aldeas de las zonas de endemicidad baja, mientras que la especificidad fue del 99,8% en la aldea sin endemicidad. En comparación con la IHA, la especificidad y la sensibilidad generales de la PICC superaron el 99% y el 96%, respectivamente. Utilizando la combinación de Kato-Katz e IHA como referencia, la PICC presentó una sensibilidad del 95,8% y una especificidad del 99,5%, con una precisión del 98,6%, en las dos zonas de endemicidad baja.

Conclusión La PICC constituye una prueba específica, sensible y fiable, que se presta a ser utilizada por los agentes de salud sobre el terreno para el cribado rápido de la esquistosomiasis.

ملخص

تقييم ميداني للمقايسة السريعة المقروءة بالعين للارتشاح المناعي للصباغ الكولوئيدي لتحري البلهارسيات اليابانية في مناطق السراية المنخفضة

الهدف: تعيين مدى صحة اختبار سريع مؤخراً هو مقايسة الارتشاح المناعي للصباغ الكولوئيدي الذي يستخدمه العاملون الصحيون في المواقع الميدانية لكشف القرويين المصابين بعدوى البلهارسيات اليابانية.

الطريقة: استخدم العاملون الصحيون الميدانيون طريقة مقايسة الارتشاح المناعي للصباغ الكولوئيدي لفحص العينات المأخوذة من 1553 قروياً من منطقتين تنخفض فيهما درجة توطن العدوى بالبلهارسيا اليابانية وفي منطقة لا تتوطن فيها العدوى بها في آنهوي في الصين. وقد فحصت جميع العينات في المختبر باستخدام الطريقة المعيارية في علم الطفيليات (كاتو كاتز) وهي مقايسة غير مباشرة للراصة الدموية، وباستخدام مقايسة الارتشاح المناعي للصباغ الكولوئيدي، ثم أجريت المقارنة بين النتائج التي حصل عليها العاملون الصحيون في الطريقتين.

الموجودات: لقد لوحظ توافق بعيد المدى بين النتائج التي حصل عليها العاملون الصحيون باستخدام الطريقتين (فقد كان منسب كابا 0.95 وفاصلة الثقة 95%، إذ تراوح منسب كابا بين 0.93 و0.97)، وعند استخدام طريقة كانو كاتز كاختبار مرجعي فإن الحساسية الإجمالية لمقايسة الارتشاح المناعي للصباغ الكولوئيدي بلغت 98.5% فيما بلغت النوعية 98.6% في القريتين التي ينخفض فيهما مستوى التوطن فيما بلغت النوعية 99.8% في القرى غير الموطونة. وعند مقارنة النتائج بالمقايسة غير المباشرة للراصة الدموية كانت النوعية لاختبار مقايسة الارتشاح المناعي للصباغ الكولوئيدي تزيد عن 99% فيما كانت الحساسية تزيد عن 96%. وعند الجمع بين الاختبارين واعتبارهما مرجعاً، وصلت حساسية اختبار مقايسة الارتشاح المناعي للصباغ الكولوئيدي 95.8% ونوعيته 99.5% فيما بلغت الدقة 98.6% في المنطقتين التي ينخفض فيهما مستوى التوطن.

الاستنتاج: يتمتع اختبار المقايسة للارتشاح المناعي للصباغ الكولوئيدي بالنوعية والحساسية والموثوقية، ويمكن للعاملين الصحيين استخدامه للتحري السريع لداء البلهارسيات في المواقع الميدانية.

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Research

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