Revista da Sociedade Brasileira de Medicina Tropical 49(2):241-244, Mar-Apr, 2016
http://dx.doi.org/10.1590/0037-8682-0247-2015

Short Communication

Acceptance and potential barriers to effective use of diagnostic tests for visceral leishmaniasis in an urban area in Brazil

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ABSTRACT

Introduction: Acceptance of the IT LEISH® and direct agglutination test- made in the Laboratório de Pesquisas Clínicas (DAT-LPC) by healthcare professionals and patients suspected of visceral leishmaniasis (VL) in Ribeirão das Neves was evaluated. **Methods:** Ninety-two patients and 47 professionals completed three questionnaires. **Results:** Eighty-eight (96%) patients considered fingertip blood collection a positive test feature, and 86% (37) and 91% of professionals considered the IT LEISH® easy to perform and interpret, respectively. All professionals classified the DAT-LPC as simple and easy. **Conclusions:** Patients and healthcare professionals in Ribeirão das Neves demonstrated a high degree of acceptance of the IT LEISH® and DAT-LPC.

Keywords: Acceptance. Diagnostic tests. Visceral leishmaniasis.

Rapid tests and the direct agglutination test (DAT) are the most appropriate serological tests available for visceral leishmaniasis (VL) diagnosis in the field[1], because they are performed and decentralized easily. In Brazil, two serological tests, the indirect fluorescence antibody test (IFAT) [Bio-Manguinhos, *Fundação Oswaldo Cruz* (FIOCRUZ), Rio de Janeiro, Brazil] and the rapid test, Kala-Azar Detect™ (InBios International, Seattle, USA), are available via the public health system and have been standardized for use with serum. The IFAT requires a complex infrastructure and trained technicians, limiting access. The Kala-Azar Detect® requires blood centrifugation for serum preparation and presents a drawback for the point-of-care objective.

The introduction of the IT LEISH® (Bio-Rad Laboratories, Marnes-la-Coquette, France) at the bedside and the DAT in local laboratories could advance the diagnostic approach to VL in Brazil. These advances are operational, technical, and performance and access related. Both tests have been validated in Brazil, showing satisfactory performance[2] [3]. Despite improvement, the DAT-LPC [DAT made in the *Laboratório de Pesquisas Clínicas* (LPC), *Centro de Pesquisas René Rachou* (CPqRR), *Fundação Oswaldo Cruz* (FIOCRUZ)] requires pipetting and several hours of incubation, making it less suitable for use in the field.

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Received 20 July 2015
Accepted 3 November 2015

Introduction of new technologies in health services requires evaluation of each implementation step[4] [5]. These assessments allow program activity monitoring and aim to identify possible strong or weak points and perform corrections. In this context, health professionals and patients can collaborate[6].

The study aimed to evaluate the acceptability of the IT LEISH® and DAT-LPC for healthcare professionals, and patients with suspected VL, in Brazil.

The study was conducted in Ribeirão das Neves, Minas Gerais, Brazil. The city contains 62 health units, 53 of which are part of the Family Health Program; an outpatient clinic for infectious and parasitic diseases; two emergency units, five basic referral units, and a hospital.

The LPC research team offered training in performing the IT LEISH® and DAT-LPC for primary healthcare professionals in the municipality and the application of the IT LEISH® acceptance questionnaire. In addition, the IT LEISH® was provided for all health services in the municipality, and the DAT-LPC was provided to the Municipal Laboratory.

The patient group included individuals of both sexes, aged 17 years or older, who sought assistance in any health unit in Ribeirão das Neves during the study period. Patients displayed clinical features considered suggestive of VL by the attending physician, or a fever lasting more than two weeks with no defined etiology or duration. The healthcare-professional group included all healthcare professionals working at the municipality and participating in LPC training during the study period.

Any healthcare professional at a health unit could request rapid tests for patients. To manage the established flowchart and existing VL diagnosis routine in the municipality according to

Ministry of Health recommendations, patients were referred to the Municipal Laboratory for blood collection and the Kala-Azar Detect® after completing the IT LEISH® at health units.

Data collection was performed by healthcare professionals from Ribeirão das Neves and researchers from CPqRR using three questionnaires based on those of Okamura et al.[7]. A health professionals administered the first questionnaire to patients immediately after the rapid test at the local health service. A researcher administered the second and third questionnaires to the health professionals who performed the IT LEISH® and the DAT-LPC in the Municipal Laboratory.

This study was conducted between November 2011 and July 2014. In total, 92 patients and 47 healthcare professionals participated in the study; of these, four worked in the Municipal Laboratory exclusively. Patients' mean age was 46 years (range: 18-84 years), and 51% (47/92) were male. Most of the rapid tests were requested by physicians (19/43, 44%), followed by nurses (16/43, 37%), nursing technicians (5/43, 12%) and others (3/43, 7%). Once the IT LEISH® was requested, 89 (97%) patients received the rapid test the same day, three returned to the service location once for testing, and one returned twice.

Eighty-eight (96%) patients considered fingertip blood collection a positive feature of the rapid test. Four (4%) patients disagreed with this; of these, three justified their responses, reporting that fingertip blood collection was difficult. The result of the rapid test was considered reliable by 90 (98%) patients **(Table 1)**. The two patients who considered the results unreliable also considered fingertip blood collection difficult.

Table 1 shows that five (12%) healthcare professionals reported difficulty in performing fingertip blood collection. Thirty-seven (86%), five (12%), and one (2%) healthcare professionals considered the test easy to perform, a little complex, and very complex, respectively. Visual interpretation of the test was considered easy and quite easy by 91% (39/43) and 9% (4/43) of healthcare professionals, respectively. Thirty-eight (88%) professionals relied on the test results, and five (12%) did not rely on the results for the following reasons: they did not rely on diagnostic tests generally, because they produce numerous false-positive and false-negative results (1); it is a new test for which biological material collection is difficult (3); and it has numerous steps and is very fast (1). Eight (19%) healthcare professionals felt that performing the test was not their responsibility for the following reasons: they were not full-time employees (2), there were more qualified professionals to perform the test (4), the nurse responsible for the unit should perform the test (1), and the test should be performed by the professional who conducted the patient's initial consultation (1).

All professionals from the Municipal Laboratory (4/4, 100%) relied on the results of the DAT-LPC; they experienced no difficulty in performing the test, classified the technical complexity of the test as simple and easy to read, and believed that the implementation of the DAT-LPC in the health service could benefit VL patients **(Table 2)**.

The use of a rapid test of digital capillary blood allows VL diagnosis during a single medical consultation, eliminates the need for another visit to the health service to obtain results, and allows immediate access to results. Nevertheless, in this study, three patients did not receive the IT-LEISH® rapid test on the day on which it was requested.

TABLE 1 - Evaluation of acceptance of the rapid IT LEISH® test by patients and healthcare professionals in Ribeirão das Neves, Minas Gerais.

Patients	**Answer**		
Question 1. Do you consider fingertip blood collection a positive feature of the test?	Yes 88 (96%)		No 4 (4%)
Question 2. How do you classify the result of the test performed?	Reliable 90 (98%)		Unreliable 2 (2%)
Health professionals			
Question 1. Did you have any problems or difficulty in performing the test?	Yes 5 (12%)		No 38 (88%)
Question 2. How do you classify the technical complexity of the test?	Easy 37 (86%)	A little complex 5 (12%)	Very complex 1 (2%)
Question 3. What is your opinion regarding the visual interpretation of the test result?	Easy 39 (91%)	Quite easy 4 (9%)	Difficult 0 (0%)
Question 4. How do you classify the result of the test performed?	Reliable 38 (88%)		Unreliable 5 (12%)
Question 5. Do you consider performing rapid testing in your service your responsibility?	Yes 35 (81%)		No 8 (19%)

TABLE 2 - Evaluation of acceptance of DAT-LPC by healthcare professionals in Ribeirão das Neves, Minas Gerais.

Patients	Answer		
Question 1. How do you classify the result of the test performed?	Reliable 4 (100%)		Unreliable 0 (0%)
Question 2. Did you have any problems or difficulty in performing the test?	Yes 0 (0%)		No 4 (100%)
Question 3. How do you classify the technical complexity of the test?	Easy 4 (100%)	A little complex 0 (0%)	Very complex 0 (0%)
Question 4. What is your opinion regarding the visual interpretation of the test result?	Easy 4 (100%)	Quite easy 0 (0%)	Difficult 0 (0%)
Question 5. Do you believe that the implementation of the DAT-LP C in this service will benefit the diagnosis of patients with suspected VL?	Yes 4 (100%)		No 0 (0%)

DAT-LPC: direct agglutination test DAT made by the *Laboratório de Pesquisas Clínicas.*

This study is also linked to the current diagnostic context of VL in Brazil, because the Ministry of Health's goal for 2015 is to replace the current rapid test (Kala-Azar Detect™) with the IT-LEISH® rapid test.

There are currently four rapid tests for VL diagnosis registered at the Brazilian national regulatory agency: Kala-Azar Detect®, IT LEISH®, OL Leishmaniose Visceral Humana (Orangelife Comércio e Indústria Ltda), and Leishmaniose Visceral Rápido (Vida Biotecnologia Ltda)[7]. Of these, only the Kala-Azar Detect® and IT LEISH®, which are imported from other countries, have been validated in Brazil.

The Kala-Azar Detect™ has been available in Brazil since 2009. The sensitivity and specificity of the Kala-Azar Detect™ in Brazil vary from 72.4% to 90% and from 90.6% to 100%, respectively[8] [9] [10] [11]. The IT LEISH® rapid test was also validated in Brazil, with sensitivity and specificity estimated at 92-93% and 92-98%, respectively[2] [9].

One of the advantages of the IT LEISH® is the possibility of performing the test at patients' bedsides, using capillary blood. Replacing the Kala-Azar Detect® with a kit that uses capillary blood, such as the IT LEISH®, could increase access to diagnosis.

Patients reported a high degree of acceptance of the IT LEISH® rapid test; 98% expressed confidence in the result, and 88% considered the fingertip blood collection a positive feature of the test. Healthcare professionals also exhibited elevated degrees of acceptance of the rapid test and DAT-LPC, because more than 85% reported confidence in the results and considered the test complexity and reading the results easy.

One limitation of this study was the small size of the sample of health professionals included in assessment of acceptance of the DAT-LPC (four professionals); therefore, the results concerning this test should be evaluated with caution. Studies evaluating acceptance of rapid tests and the DAT for VL are lacking; however, increased acceptance of diagnosis via rapid tests has been demonstrated in HIV patients[6].

One important report from 12% of healthcare professionals who executed the IT LEISH® described difficulty in performing fingertip blood collection. They also suggested that fingertip blood collection and the capillary kit supplied should be replaced.

All of the health professionals in the Municipal Laboratory reported that the implementation of the DAT-LPC in the health service would benefit patient diagnosis. The DAT-LPC's operational superiority, superior performance, and lower cost, relative to those of the IFAT, are clear[3]; see too Machado de Assis TS: unpublished data. However, the DAT-LPC is not currently commercially available.

Patients and healthcare professionals demonstrated a high degree of acceptance of the IT LEISH® rapid test and DAT-LPC in health services in Ribeirão das Neves, Minas Gerais. Incorporation of these two tests into decentralized services would reduce workloads at central laboratories.

Evaluation of diagnostic algorithms, including those of the two assessed tests, is timely. However, introduction of one of these methods should account for effectiveness, cost, and potential sustainability. These results represent a series of studies conducted by our research team and contribute to the expansion of access to simple diagnostic tests that are not currently used in Brazil.

Ethical considerations

The study received approval from the ethical review board at the CPqRR, number 21/2011.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

FINANCIAL SUPPORT

The study received funding from National Counsel of Technological and Scientific Development and Foundation for Research Support of the State of Minas Gerais.

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