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ARTICLE

Budgetary impact of diagnostic tests for visceral leishmaniasis in Brazil

Impacto orçamentário dos testes diagnósticos para leishmaniose visceral no Brasil

Impacto presupuestario de las pruebas diagnósticas para la leishmaniosis visceral en Brasil

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Abstract

The aim of the present study was to estimate the financial costs of the incorporation and/or replacement of diagnostic tests for human visceral leishmaniasis (VL) in Brazil. The analysis was conducted from the perspective of the Brazilian Unified National Health System (SUS) over a period of three years. Six diagnostic tests were evaluated: the indirect immunofluorescence antibody test (IFAT), the IT LEISH rapid test, the parasitological examination of bone marrow aspirate, the direct agglutination test (DAT-LPC) standardized in the Clinical Research Laboratory, René Rachou Institute of the Oswaldo Cruz Foundation, the Kalazar Detect rapid test, and polymerase chain reaction (PCR). The assumptions used were the number of suspected cases of VL reported to the Brazilian Ministry of Health in 2014 and the direct cost of diagnostic tests. The costs to diagnose suspected cases of VL over three years using the IFAT and the DAT-LPC were estimated at USD 280,979.91 and USD 121,371.48, respectively. The analysis indicated that compared with the use of the IFAT, the incorporation of the DAT-LPC into the SUS would result in savings of USD 159,608.43. With regard to the budgetary impact of rapid tests, the use of IT LEISH resulted in savings of USD 21.708,72 over three years. Compared with a parasitological examination, diagnosis using PCR resulted in savings of USD 3,125,068.92 over three years. In this study, the replacement of the IFAT with the DAT-LPC proved financially advantageous. In addition, the replacement of the Kalazar Detect rapid test with the IT LEISH in 2015 was economically valuable, and the replacement of parasitological examination with PCR was indicated.

Budgetary Control; Visceral Leishmaniasis; Diagnosis

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Introduction

Visceral leishmaniasis (VL) is a neglected human disease that can be fatal if not diagnosed and treated early. It is estimated that 300,000 new cases of the disease occur annually, and 90% of these cases occur in six countries: Bangladesh, Ethiopia, India, Nepal, Sudan, and Brazil [1]. In Brazil, 26,112 cases of VL, with 1,599 deaths, were reported between 2007 and 2013 (Brazilian Health Informatics Department – DATASUS. http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sinannet/cnv/leishvbr.def, accessed on 27/Feb/2015). In addition to the high fatality rate, the disease is one of the leading causes of morbidity and has a significant economic impact on the Brazilian Unified National Health System (SUS). Between 2007 and 2013, there were 18,212 hospitalizations due to VL at a cost of USD 365.145,40 per year (DATASUS. Sistema de Informações Hospitalares do SUS. http://datasus.saude.gov.br/sistemas-e-aplicativos/hospitalares/sihsus, accessed on 27/Feb/2015).

Rapid and efficient diagnosis of VL is crucial for disease management. Until 2014, the Brazilian Ministry of Health provided two serological tests to public health care services: indirect fluorescence antibody test (IFAT) for human leishmaniasis, developed by Immunobiological Tecnology Institute (Biomanguinhos), Oswaldo Cruz Foundation, Brazil, and the Kalazar Detect rapid test (InBios International, USA). The IFAT has a sensitivity and specificity of 88%-92% and 83%-88%, respectively [2,3]. The advantage of the IFAT is that it is produced in Brazil, however, it requires a laboratory infrastructure of medium complexity and specialized professionals. The Kalazar Detect test is straightforward and easy to interpret, and its sensitivity and specificity are 84.0%-88.1% and 90.6%, respectively [4,5]; however, it is standardized for use in serum, which is an obstacle to rapid diagnosis in primary care services.

In 2015, the Brazilian Ministry of Health replaced the rapid test in use with the IT LEISH rapid test (Bio-Rad Laboratories, USA). The IT LEISH test is also simple and easy to interpret but has two advantages over previously available rapid tests: (1) improved performance (sensitivity of 92%-93% and specificity of 92%-98%) [3,4]; and (2) the test is standardized for use in serum or finger capillary blood. In this sense, the incorporation of the IT LEISH rapid test by the SUS improved VL diagnosis: the diagnosis became possible at bedside, and the results are available in 30 minutes.

In addition to the IFAT and the IT LEISH rapid test, the Brazilian Ministry of Health also supports performing a parasitological examination of bone marrow aspirate for confirmation of clinically suspected cases of VL [6]. The parasitological examination is considered the gold standard for VL diagnosis, however, it requires hospital or outpatient infrastructure of moderate complexity and specialized medical professionals. Furthermore, the procedure is invasive, and its sensitivity is 77% [3]. Molecular diagnosis using standard polymerase chain reaction (PCR) may be less invasive than parasitological examination of bone marrow, as it presents high performance in whole blood (sensitivity of 93.1% and specificity of 95.6%), according to a meta-analysis study by Ruiter et al. [7]. However, it also requires a complex infrastructure and specialized professionals and, thus, the technique is restricted to reference centres.

The introduction of rapid tests in 2010 as an alternative to IFAT in Brazil was critical, however, the IFAT, even with its limitations, was still the most widely used serological diagnostic test in Brazil until 2013, when 46% (1,586/3,470) of VL cases were confirmed using this test. In the same period, 1,881 (54%) patients did not undergo any serological examination, and 1,509 (43%) patients underwent bone marrow parasitological examination, of which 1,112 (74%) were positive cases[2].

In recent years, a direct agglutination test standardized in the Clinical Research Laboratory (DAT-LPC) of the René Rachou Institute at Oswaldo Cruz Foundation (CPqRR/Fiocruz) has shown high efficiency for the diagnosis of VL in immunocompetent patients (sensitivity of 99% and specificity of 98%) [8]. In immunocompromised patients, the estimated sensitivity of DAT is 89.7% and the specificity is 85.3% [9]. This test is simple and easy to interpret, requires a simple laboratory infrastructure with a centrifuge and pipettes, and can replace the IFAT in routine clinical laboratories, thereby increasing efficiency, operability, and speed.

Taking into account this diagnostic setting and the challenge of the SUS in reconciling budget constraints with the need to evaluate and incorporate new technologies, Machado de Assis et al. [10] performed a cost-effectiveness analysis of six strategies for the diagnosis of VL in Brazil, including the IT LEISH rapid test, the Kalazar Detect rapid test, the IFAT, the DAT-LPC, parasi-

tological examination, and PCR. At the time, the DAT-LPC was the most cost-effective method, and the authors recommended that it should replace the IFAT. Moreover, the IT LEISH proved to be cheaper and more efficient than the Kalazar Detect rapid test, and PCR was more effective than parasitological examination.

The budget impact analysis is a complement to the cost-effectiveness analysis, it assists in preparing the budget forecast over a defined time interval and enables the projection of costs incurred with the use of these technologies in population terms [11,12]. The aim of this study was to estimate the financial costs of the incorporation and/or replacement of diagnostic tests for human VL in Brazil.

Materials and methods

Study design

The budget impact analysis of diagnostic tests for human VL was performed on spreadsheets using a static model. This model consists of a simple multiplication of the individual cost of each technology per patient, multiplied by the number of subjects with an indication of use. The analysis was conducted from the perspective of the SUS with a three-year time horizon. The reference population consisted of patients with clinical suspicion of VL who sought medical care for VL in Brazil. This study followed the Brazilian Ministry of Health methodological guidelines for budget impact analysis [11].

Diagnostic methods included in the analysis/evaluation scenarios

Six diagnostic tests were included in the analysis: the IFAT, the IT LEISH rapid test in finger capillary blood, parasitological examination of bone marrow aspirate, the DAT-LPC, the Kalazar Detect rapid test, and PCR. The first three tests are diagnostic options available in Brazil at present (reference scenario), and the last three tests were alternatives for the strategies in use (alternative scenario).

Model inputs

The inputs used in our analyses were (1) number of suspected cases of VL reported by the Brazilian Ministry of Health in 2014, and (2) direct cost of diagnostic tests.

In 2014, 10,279 suspected cases of VL were reported to the Brazilian Ministry of Health (Tália Santana Machado de Assis, personal communication). The direct cost of the diagnostic tests was calculated via micro-costing analysis, which is a cost measurement methodology with a high degree of detailing, taking into account supplies and human resources required for processing, as previously described by Machado de Assis et al. [10]. The values estimated in 2014 were USD 11.39 for the IFAT, USD 6.57 for the IT LEISH in finger capillary blood, USD 159.40 for parasitological examination, USD 4.92 for the DAT-LPC, USD 7.45 for the Kalazar Detect rapid test, and USD 32.72 for PCR.

This budgetary impact analysis assumes that (1) the cost of the diagnostic tests and the average number of cases of VL will remain constant in the triennium – years 1, 2 and 3; (2) the diagnostic tests in the alternative scenario would be incorporated in 60% of health care services in the first year of implementation, 80% in the second year and 100% in the third year; and (3) the currently existing laboratory network in the SUS can fully meet the demand for diagnostic tests, with no additional costs for construction of new diagnostic testing facilities.

Budget impact and sensitivity analyses

The incremental budget impact, which indicates to the health manager the additional costs of incorporating a technology (i.e., the incremental cost) compared with the reference scenario, has been calculated taking into account the following comparisons: IFAT X DAT-LPC; IT LEISH X Kalazar Detect; and parasitological examination of bone marrow aspirate X PCR. The univariate sensitivity analysis was performed using the cost parameters (plus or minus a variation of 25%) of the diagnostic tests.

Results

Estimated annual costs of diagnosing an average of 10,279 suspected cases of VL (year 3) using the IFAT and the DAT-LPC in Brazil were USD 117,077.81 and USD 50,572.68, respectively. Budget impact analysis indicated that the incorporation of the DAT-LPC into the SUS would result in savings of USD 39,900.49 in the first year of implementation, USD 53.202,81 in the second year and USD 66,505.13 in the third year and USD 159,608.43 over three years compared with the use of the IFAT (Table 1).

Comparison of the budget impacts of the IT LEISH and Kalazar Detect rapid test indicated that the use of the IT LEISH would result in savings of USD 5,426.96 in the first year of implementation, USD 7,236.24 in the second year and USD 9,045.52 in the third year, corresponding to savings of USD 21,708,72 over three years. Furthermore, diagnosis using parasitological examination would result in incremental costs of USD 781,235.56 in the first year of implementation, USD 1,041,689.64 in the second year and USD 1,302,143.72 in the third year and USD 3,125,068.92 over three years compared with the diagnosis using PCR (Table 1).

Results of the univariate sensitivity analysis considering 100% coverage are shown in Table 2, considering the parameter "direct cost of diagnostic tests". Comparison of the budget impacts of the IT LEISH and Kalazar Detect rapid test, indicated that the use of the IT LEISH would result in savings

Table 1

Budget impacts of diagnostic tests for human visceral leishmaniasis in Brazil, considering the reference and alternative scenarios in the triennium.

Diagnostic test/Type of scenario/Direct cost *	Annual cost – year 1 60% coverage = 6.167 cases		Annual cost – year 2 80% coverage = 8.223 cases		Annual cost – year 3 100% coverage = 10.279 cases		Triennial cost (USD)	
	Annual cost (USD) **	Annual incremental budgetary impact (USD)	Annual cost (USD) **	Annual incremental budgetary impact (USD)	Annual cost (USD) **	Annual incremental budgetary impact (USD)	Triennial cost (USD)	Triennial incremental budgetary impact (USD)
IFAT/Reference/ USD 11.39	70,242.13	-39,900.49	93,659.97	-53,202.81	117,077.81	-66,505.13	280,979.91	-159,608.43
DAT-LPC/ Alternative/USD 4.92	30,341.64		40,457.16		50,572.68		121,371.48	
IT LEISH/ Reference/USD 6.57	40,517.19	5,426.96	54,025.11	7,236.24	67,533.03	9,045.52	162,075.33	21,708.72
Kalazar Detect/ Alternative/USD 7.45	45,944.15		61,261.35		76,578.55		183,784.05	
Bone marrow aspirate ***/ Reference/USD 159.40	983,019.80	-781,235.56	1,310,746.20	-1,041,689.64	1,638,472.60	-1,302,143.72	3,932,238.60	-3,125,068.92
PCR/Alternative/ USD 32.72	201,784.24		269,056.56		336,328.88		807,169.68	

DAT-LPC: direct agglutination test standardized in the Clinical Research Laboratory; IFAT: indirect fluorescence antibocy test;
PCR: polymerase chain reaction.

* Direct costs are available in Machado de Assis et al. [10];

** Number of cases X direct cost of the test;

*** Hospital-based parasitological examination of bone marrow aspirate.

Table 2

Sensitivity analysis of the budget impacts of diagnostic tests for human visceral leishmaniasis in Brazil, considering 100% coverage and a variation of 25% (plus or minus) in the cost of the tests.

Diagnostic test	Direct cost of the diagnostic test – 25% lower than the estimated value (USD)	Year 3		Direct cost of diagnostic test – 25% higher than the estimated value (USD)	Year 3	
		Cost (USD) *	Incremental cost (USD)		Cost (USD) *	Incremental cost (USD)
IFAT	8.54	87,782.66	49,853.15	14.24	146,372.96	83,157.11
DAT-LPC	3.69	37,929.51		6.15	63,215.85	
IT LEISH	4.93	50,675.47	6,784.14	8.21	84,390.59	11306.90
Kalazar Detect	5.59	57,459.61		9.31	95,697.49	
Bone marrow aspirate **	119.55	1,228,854.45	976,607.79	199.25	2,048,090.75	1,627,679.65

DAT-LPC: direct agglutination test standardized in the Clinical Research Laboratory; IFAT: indirect fluorescence antibocy test; PCR: polymerase chain reaction.

* Number of cases X direct cost of the test;

** Hospital-based parasitological examination of bone marrow aspirate;

varying from USD 6,784.14-USD 11,306.90; of the IFAT X DAT-LPC indicated that the use of the DAT-LPC would result in savings varying from USD 49,853.15-USD 83,157.11; and of the parasitological examination X PCR indicated that the use of the PCR would result in savings varying from USD 976,607.79-USD 1,627,679.65 per year.

Discussion

It is evident that public financial resources are limited, and their use to fund the diagnosis and treatment of patients with a disease makes it impossible to apply these resources to other potential uses. Therefore, it is important to maximize gains in health and, in this respect, decision-making based on careful evaluations is essential [13,14]. New technologies can significantly increase financial costs in the system, and these costs may or may not be offset by savings in resources from other procedures and by improvements in patient outcomes. These evaluations are of particular importance in developing countries, where neglected diseases are prevalent in the poorest regions and health care needs are urgent.

The diagnosis of VL has made little progress in recent decades, and the tools available to date are limited. Machado de Assis et al. [15] conducted a prospective study to validate diagnostic tests for VL in Brazil and found that the average period between symptom onset and confirmation of diagnosis was 53 days (ranging of 5 to 360 days). This finding indicates the need for awareness and training of health care professionals, as highlighted by Luz et al. [16], and the need to provide simple, accurate, and fast diagnostic tests. These actions, which have a direct impact on the period between patient diagnosis and treatment, can reduce the high rates of morbidity and mortality due to VL in Brazil.

In this study, it was determined that the replacement of the IFAT with the DAT-LPC would constitute a valid economic decision and would decrease costs by 57% considering 100% coverage (year 3) if all patients were diagnosed using the DAT-LPC. It is worth mentioning that the IFAT is a serologic test that requires laboratory infrastructure of moderate complexity, including an immunofluorescence microscope. This requirement delays diagnosis and often entails the transfer of biological samples to a central lab, increasing costs. The implementation of the DAT-LPC in health care services would be simple because the test requires minimal infrastructure (centrifuges and pipettes), consequently expediting diagnosis. In addition, the DAT-LPC is produced in Brazil [8].

The Brazilian Ministry of Health's decision in 2015 to replace the Kalazar Detect rapid test with the IT LEISH was economically viable and decreased costs, resulting in savings of USD 21,708.72 over three years. Unfortunately, there is no rapid test commercially available in the Brazilian domestic market for VL diagnosis. Therefore, new research and development of rapid diagnostic tests, particularly those standardized for use at the bedside, should be encouraged.

The replacement of parasitological examination with PCR performed in peripheral blood samples is economically indicated. Undeniably, both parasitological examination and conventional PCR require highly complex infrastructure, however, PCR should be used wherever possible because of its decreased invasiveness and lower cost.

A limitation of our study was the use of estimates based on suspected cases of VL reported to the Brazilian Ministry of Health, considering that there are no official data on the number of diagnostic tests used. Secondly, the cost of diagnostic tests evaluated were estimated at a reference centre for VL. In this sense, the results of the sensitivity analysis may be useful.

During the incorporation or replacement of new diagnostic tests in health care, it is important to know the tests' advantages and disadvantages regarding efficiency and cost, and the financial implications of decision-making in the short- and medium-term [17]. In this context, the budget impact analysis, an integral part of the health technology assessment process, is extremely relevant. In Brazil, this type of analysis has become a requirement with the enactment of *Law 12,401/2011*, which established new rules for the incorporation of health technologies [11].

In fact, in recent years the field of technology assessment in health, including production, systematization, and dissemination of studies, and the adoption of flow sheets for incorporation and replacement of new technologies by the SUS have expanded in Brazil. Since 2009, these processes have been part of the National Health Technology Management Policy, which aims to maximize the health benefits from resources available, ensuring the access of the population to safe and effective technologies, under fair conditions [18]. Other significant milestones are related to the creation of the Brazilian Network for Health Technology Assessment, the Institute for Health Technology Assessment, and the Commission for the Incorporation of Health Technologies in the SUS (Conitec) [18,19,20].

Economic studies focused on VL diagnosis are scarce. The results of this study suggest the incorporation of the DAT-LPC to replace the IFAT as an economically feasible alternative considering the Brazilian Ministry of Health budget currently allocated to diagnosis using the IFAT. Replacement of the Kalazar Detect rapid test with the IT LEISH in 2015 was an economically valuable change and the replacement of parasitological examination with PCR is indicated. Moreover, as tests in use would be replaced with tests with higher performance in the medium- and long-term, savings would be even greater because the repetition of tests with false-negative and false-positive results would not be required, thereby increasing the system efficiency and the allocation of available resources. The results of this study may contribute to the decision-making process regarding the different diagnostic strategies for VL available in Brazil.

Contributors

T. S. Machado de Assis, A. L. F. Azeredo-da-Silva, D. Oliveira, G. Cota, G. L. Werneck and A. Rabello participated in conception and design, acquisition, analysis, and interpretation of data; drafting the article and final approval of the version for publication.

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Resumo

O estudo teve como objetivo estimar os custos financeiros da incorporação e/ou substituição dos testes diagnósticos para a leishmaniose visceral (LV) humana no Brasil. A análise foi realizada na perspectiva do Sistema Único de Saúde (SUS) ao longo de três anos. Foram avaliados seis testes diagnósticos: reação de imunofluorescência indireta (RIFI), teste rápido IT LEISH, exame parasitológico de aspirado de medula óssea, teste de aglutinação direta DAT-LPC padronizado pelo Laboratório de Pesquisas Clínicas do Instituto René Rachou, Fundação Oswaldo Cruz, teste rápido Kalazar Detect e reação em cadeia da polimerase (PCR). Os parâmetros utilizados foram o número de casos suspeitos de LV notificados ao Ministério da Saúde em 2014 e o custo direto dos testes diagnósticos. Os custos do diagnóstico de casos suspeitos de LV ao longo de três anos usando o RIFI e DAT-LPC foram estimados em USD 280.979,91 e USD 121.371,48, respectivamente. De acordo com a análise, comparado ao uso do RIFI, a incorporação do DAT-LPC pelo SUS resultaria numa economia de USD 159.608,43. Com relação ao impacto dos testes rápidos, o uso do IT LEISH resultou em economia de USD 21.708,72 ao longo de três anos. Comparado ao exame parasitológico, o diagnóstico com PCR resultou em economia de USD 3.125.068,92 ao longo de três anos. Neste estudo, a substituição do RIFI pelo DAT-LPC mostrou ser financeiramente vantajosa. Além disso, a substituição do teste rápido Kalazar Detect com o IT LEISH em 2015 foi economicamente apropriada, e a substituição do exame parasitológico pela PCR está economicamente indicada.

Controle Orçamentário; Leishmaniose Visceral; Diagnóstico

Resumen

El objetivo del estudio fue estimar los costes financieros de la incorporación y/o sustitución de las pruebas diagnósticas para la leishmaniasis visceral (LV) humana en Brasil. El análisis se realizó desde la perspectiva del Sistema Único de Salud (SUS) a lo largo de tres años. Se evaluaron seis pruebas diagnósticas: reacción de inmunofluorescencia indirecta (RIFI), test rápido IT LEISH, examen parasitológico de aspirado de medula ósea, test de aglutinación directa DAT-LPC, estandarizado por el Laboratorio de Investigación Clínica del Centro de Investigación René Rachou, Fundación Oswaldo Cruz, test rápido Kalazar Detect y la reacción en cadena de la polimerasa (PCR). Los parámetros utilizados fueron el número de casos sospechosos de LV notificados al Ministerio de Salud en 2014 y el coste directo de los test diagnósticos. Los costes del diagnóstico de casos sospechosos de LV a lo largo de tres años, usando el RIFI y DAT-LPC, se estimaron en USD 280.979,91 y USD 121.371,48, respectivamente. De acuerdo con el análisis, comparado con el uso del RIFI, la incorporación del DAT-LPC por el SUS resultaría en un ahorro de USD 159.608,43. En relación con el impacto de los test rápidos, el uso del IT LEISH aportaba un ahorro de USD 21.708,72 a lo largo de tres años. Comparado con el examen parasitológico, el diagnóstico con PCR suponía un ahorro de USD 3.125.068,92 a lo largo de tres años. De acuerdo con el estudio, la sustitución del RIFI con el DAT-LPC mostró ser financieramente ventajosa. Asimismo, la sustitución del test rápido Kalazar Detect con el IT LEISH en 2015 representó un ahorro económico, y los resultados favorecieron la sustitución del examen parasitológico con PCR.

Control Presupuestario; Leishmaniasis Visceral; Diagnóstico

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