ReGeo ISSN: 2177-3246

SEROPREVALENCE OF VISCERAL LEISHMANIASIS AMONG BLOOD DONORS IN A REGIONAL BLOOD CENTER IN AN ENDEMIC AREA OF NORTHEASTERN BRAZIL

SOROPREVALÊNCIA DA LEISHMANIOSE VISCERAL ENTRE DOADORES DE SANGUE EM UM CENTRO REGIONAL DE SANGUE EM UMA ÁREA ENDÊMICA DO NORDESTE DO BRASIL

SEROPREVALENCIA DE LA LEISHMANIASIS VISCERAL ENTRE DONANTES DE SANGRE EN UN CENTRO REGIONAL DE SANGRE EN UN ÁREA ENDÉMICA DEL NORDESTE DE BRASIL

https://doi.org/10.56238/revgeov17n7-113

Data de submissão: 02/06/2026 **Data de publicação:** 17/07/2026

Ricardo Parente Garcia Vieira[1], **Cláudio Gleidiston Lima da Silva**[2], **Terentia Batista Sá de Norões**[3], **Ana Cristina de Brito Gomes**[4], **Ana Carolina Carvalho Ferraz**[5], **Janaina Carvalho Braz Macedo**[6]

ABSTRACT

Visceral leishmaniasis (VL) is a potentially fatal infectious disease caused by protozoa of the genus Leishmania spp., with endemic presence in several countries, including Brazil, African and Asian regions. This study aimed to assess the seroprevalence of asymptomatic Leishmania infection among blood donors in an endemic area of a northeastern Brazilian state. In addition, it aimed to outline the sociodemographic profile of these donors and promote discussion about the potential inclusion of VL screening in blood donation routines in endemic zones. Using the immunochromatographic rapid test (K39ICT), 195 blood donors were evaluated, predominantly male (58%), mixed-race (63%), with a mean age of 31 years. Most participants were residents of the municipality housing the blood center (62%), from urban areas (68%), and had an average household income of BRL 2,895. The sample revealed a null seroprevalence for VL, diverging from findings reported in other endemic areas. These results suggest low cost-effectiveness for implementing VL screening in the studied center. Further studies with larger samples, longer duration, and different screening methodologies are necessary to support broader public health decisions.

Keywords: Visceral Leishmaniasis. Blood Donors. Seroprevalence.

[1] PhD in Medicine. School of Medicine, Federal University of Cariri (UFCA). E-mail: ricardopgv@gmail.com Orcid: https://orcid.org/0009-0004-3380-4491
[2] PhD in Medicine. School of Medicine, Federal University of Cariri (UFCA). E-mail: claudio.gleidiston@ufca.edu.br Orcid: https://orcid.org/0000-0001-5730-0512
[3] PhD in Medicine. School of Medicine, Regional University of Cariri. E-mail: terentia@leaosampaio.edu.br Orcid: https://orcid.org/0000-0001-5341-8783
[4] Specialist in Hematologia. Center for Hematology and Hemotherapy of Ceará (HEMOCE). E-mail: tidu7608@gmail.com Orcid: https://orcid.org/0009-0003-2476-8209
[5] PhD in Medicine. School of Medicine, Regional University of Cariri. E-mail: carolina.ferraz@urca.br Orcid: https://orcid.org/0009-0007-0484-8956
[6] PhD in Medicine. School of Medicine, Regional University of Cariri. E-mail: janacbraz@hotmail.com Orcid: https://orcid.org/0000-0002-2959-8371

RESUMO
A leishmaniose visceral (LV) é uma doença infecciosa potencialmente fatal causada por protozoários do gênero Leishmania spp., com presença endêmica em diversos países, incluindo Brasil, regiões da África e Ásia. Este estudo objetivou avaliar a soroprevalência da infecção assintomática por Leishmania entre doadores de sangue em área endêmica de estado do Nordeste brasileiro. Além disso, buscou delinear o perfil sociodemográfico desses doadores e promover discussão sobre a potencial inclusão de triagem de LV nas rotinas de doação de sangue em zonas endêmicas. Utilizando o teste rápido imunocromatográfico (K39ICT), foram avaliados 195 doadores de sangue, predominantemente do sexo masculino (58%), pardos (63%), com idade média de 31 anos. A maioria dos participantes era residente do município que abriga o centro de sangue (62%), de áreas urbanas (68%), e tinha renda média domiciliar de R$ 2.895. A amostra revelou soroprevalência nula para LV, divergindo dos achados relatados em outras áreas endêmicas. Estes resultados sugerem baixa custo-efetividade para implementação de triagem de LV no centro estudado. Estudos adicionais com amostras maiores, maior duração e metodologias de triagem diferentes são necessários para apoiar decisões mais amplas de saúde pública.

Palavras-chave: Leishmaniose Visceral. Doadores de Sangue. Soroprevalência.

RESUMEN
La leishmaniasis visceral (LV) es una enfermedad infecciosa potencialmente fatal causada por protozoos del género Leishmania spp., con presencia endémica en varios países, incluidos Brasil, regiones de África y Asia. Este estudio tuvo como objetivo evaluar la seroprevalencia de la infección asintomática por Leishmania entre donantes de sangre en un área endémica de un estado del Nordeste brasileño. Además, buscó delinear el perfil sociodemográfico de estos donantes y promover discusión sobre la posible inclusión del cribado de LV en las rutinas de donación de sangre en zonas endémicas. Utilizando la prueba rápida inmunocromatográfica (K39ICT), se evaluaron 195 donantes de sangre, predominantemente hombres (58%), mestizos (63%), con edad media de 31 años. La mayoría de los participantes eran residentes del municipio que alberga el centro de sangre (62%), de áreas urbanas (68%), y tenían un ingreso promedio del hogar de BRL 2.895. La muestra reveló seroprevalencia nula para LV, divergiendo de los hallazgos reportados en otras áreas endémicas. Estos resultados sugieren bajo costo-efectividad para implementar cribado de LV en el centro estudiado. Se necesitan estudios adicionales con muestras más grandes, mayor duración y diferentes metodologías de cribado para apoyar decisiones más amplias de salud pública.

Palabras clave: Leishmaniasis Visceral. Donantes de Sangre. Seroprevalencia.

1 INTRODUCTION

Leishmaniases are diseases caused by protozoan parasites of the genus *Leishmania*, which comprises more than twenty species. They are obligate intracellular parasites of the mononuclear phagocyte system. In the insect vector, the promastigote flagellated form predominates, while in vertebrate tissues, the parasite exists as the amastigote form. In the New World, *L. infantum* is the most commonly isolated species.

The insects responsible for disease transmission belong to the order *Diptera*, family *Psychodidae*, and subfamily *Phlebotominae*. These are winged, hematophagous insects that serve as vectors for *Leishmania* and may also carry other parasites such as *Bartonella* species and certain arboviruses. The main species involved in transmission are *Lutzomyia longipalpis*, *Lutzomyia migonei*, and *Lutzomyia whitmani*.

Three main clinical forms of leishmaniasis are described: cutaneous, mucocutaneous, and visceral. Among these, visceral leishmaniasis (VL), also known as kala-azar, is the most severe, with a fatality rate of approximately 95% if left untreated. It is characterized by intermittent fever, weight loss, hepatosplenomegaly, and anemia, with children under five, the elderly, immunocompromised individuals, and malnourished patients being particularly vulnerable to severe disease.

The majority of cases occur in Brazil, East Africa, and India. Global estimates suggest between 50,000 and 90,000 new cases annually, although only 25–45% are officially reported to the World Health Organization. In Europe, cumulative incidence between 2005 and 2020 was highest in Albania (2.15 per 100,000), followed by Montenegro, Malta, Greece, Spain, and North Macedonia (0.53–0.42), Italy (0.16), and Portugal (0.09), with lower rates in other endemic countries (0.07–0.002). Leishmaniasis is often associated with poverty, low literacy, immunosuppression, malnutrition, gender inequality, limited research, and substandard housing conditions.

Despite the known transmission cycle of *Leishmania*, hematogenous transmission via asymptomatic infected blood donors remains a gap in the literature. In Brazil, a study conducted in other northeastern regions found a significant prevalence (6.2%) among blood donors. In southern Spain, 129 out of 1,260 blood donors were found to have asymptomatic *Leishmania* infection. Similarly, a study in southern Thailand aimed at detecting asymptomatic infection among 500 blood donors found a prevalence of 19%.

Although Brazil is an endemic country for visceral leishmaniasis, the disease is not included in the mandatory testing panel for blood donors, which currently screens for HIV, HTLV, syphilis, hepatitis B and C, and Chagas disease.

This study is based on the hypothesis that endemic areas for visceral leishmaniasis may harbor a significant number of asymptomatic carriers. Understanding the seroprevalence of VL among blood donors can provide valuable data to support or reject the inclusion of VL screening in mandatory blood donation tests, especially in endemic zones, in order to ensure transfusion safety.

The objective of this study was to investigate the seroprevalence of visceral leishmaniasis among blood donors in an endemic region in southern Ceará, a state in northeastern Brazil, and to explore the feasibility of implementing VL screening in blood donation protocols in endemic countries.

2 MATERIALS AND METHODS

This is an observational, non-interventional, cross-sectional study conducted with blood donor users and approved by the Research Ethics Committee (CEP) in Brazil, under approval number 5.986.110, CAAE 67826123.0.0000.5055.

The study was carried out in the metropolitan region of Cariri, comprising nine municipalities in the southern part of Ceará, a state in northeastern Brazil, at the largest blood center in the region, located in the city of Crato. Laboratory analyses of the collected samples were performed at the Laboratory of Experimental Pathology (LAPEX) of the Federal University of Cariri (UFCA).

The collection of sociodemographic data and biological samples from the participants included in the study took place between April 2023 and January 2024. Among the blood donors who voluntarily presented themselves at the blood center during this period, individuals of both sexes, aged between 18 and 69 years, who agreed to participate in the study by signing the Informed Consent Form (ICF), were included. Individuals who either declined participation or initially consented but later withdrew before the end of data collection were excluded.

The sociodemographic data collected at the time of blood donation screening included: age, race, sex, household income, occupation, and city of residence. Regarding testing for *Leishmania*, the first test performed for all participants was the immunochromatographic rapid

test (k39ICT). For those with a positive rapid test result, blood samples were collected for culture and Polymerase Chain Reaction (PCR) assay.

The k39ICT rapid immunochromatographic test for Visceral Leishmaniasis, from the LSH Ab ECOTESTE® kit, is a qualitative immunoassay used to detect antibodies against VL in human serum, plasma, or whole blood. The sample for the k39ICT test was collected via digital pulp puncture using a lancet, after local asepsis with 70% alcohol. Following the puncture, 20 microliters of blood were applied to the test strip using a capillary tube. With the test strip held in a vertical position, 150 microliters of buffer solution were added. A test was considered positive when two dark lines appeared on the strip (one corresponding to the control and the other to the patient sample).

The membrane is pre-coated with rK39 in the test line region and with anti-chicken protein A in the control line region. During the test, the sample reacts with the conjugate dye (protein A – colloidal gold conjugate) that has been pre-coated on the nitrocellulose membrane of the test. The sample then migrates by capillary action along the membrane to react with the recombinant visceral leishmaniasis antigen, producing a red line. The presence of this red line indicates a reactive result, whereas its absence indicates a non-reactive result. Regardless of the presence of antibodies against rK39, the sample continues to migrate across the membrane until it is immobilized by the anti-chicken protein A in the control line region. A red line in the control region must always appear. The presence of this red line serves as a procedural control to indicate that the sample volume was sufficient, the flow was adequate, and the reagents functioned correctly.

Subjects who tested positive in the rapid test were invited to undergo additional diagnostic procedures. Both qualitative and quantitative data were tabulated for the construction of sociodemographic profile charts. The sample size was determined based on the total number of blood donors at HEMOCE Crato in 2022 (4,500 donors), considering a 95% confidence level and a 7% margin of error, resulting in a minimum required sample of 188 donors, according to the central limit theorem. The seroprevalence rate was calculated using the following formula: SP = (positive cases / studied population) × 100.

3 RESULTS AND DISCUSSION

Blood samples from 195 individuals attended at Hemoce Crato between April 2023 and January 2024 were analyzed.

In the sociodemographic analysis, the mean age of the donors was 31 years, ranging from 18 to 59, with a median of 30 years. There was a predominance of male participants, accounting for 58% of the cases. Most donors (62%) were from the municipality of Crato-CE, with 15% of them residing in other states. All donors were from the northeastern region of Brazil, and 68% lived in urban areas. The majority of participants (63%) self-identified as mixed race (pardo), while 23% identified as white and 12% as Black. The average household income was BRL 2,895, ranging from BRL 600 to BRL 25,000, with a median of BRL 2,000. Most donors were students or healthcare professionals.

In the laboratory analysis of the samples, all individuals tested negative for visceral leishmaniasis using the k39 ICT rapid test and, therefore, did not proceed to the next stage of the study, which involved PCR and culture methods.

Endemic regions for visceral leishmaniasis are particularly prone to the presence of asymptomatic carriers. These individuals may eventually become candidates for blood donation, which could pose a risk of hematogenous transmission of the disease. In a study conducted in the city of Salvador involving 700 blood donors, a seropositivity rate of 5.8% was observed using the ELISA method. Among the ELISA-positive samples, 21% were also positive by PCR, raising concerns about the potential for hematogenous transmission of the disease in blood donors. Similarly, a study in Thailand that employed the Direct Agglutination Test (DAT) and PCR as screening methods revealed a 19% incidence of asymptomatic *Leishmania* infection in a sample of 500 blood donors.

In a meta-analysis that evaluated 496 publications totaling more than 17,000 blood donors, seroprevalence for VL was found to be 4% by serological techniques. The possibility of making blood filtration compulsory in endemic areas has been suggested, with the aim of reducing the chance of the disease being transmitted via the hematogenous route.

Another study conducted in Bangladesh (an endemic area) observed an extremely low seroprevalence (0.3%) using the k39 ICT method, a result that is similar to the one found in the present study.

This study identified a null seroprevalence in an endemic area located in the southern region of the state of Ceará, in northeastern Brazil. The results differ from the average seroprevalence reported in most studies conducted in endemic zones. Based on these findings, we believe there is no justification for the implementation of routine visceral leishmaniasis screening tests in blood banks in the study region. However, we emphasize the

need for larger studies both in this region and in other endemic areas, as well as the need to evaluate alternative screening methods.

The findings of this study also suggest a possible shift in the epidemiological profile of VL in the study region, as the incidence of asymptomatic carriers was null in the population analyzed. These findings are consistent with epidemiological data reported by the Ceará State Health Department, which indicate a decreasing incidence of the disease in the Cariri region of Ceará since 2017.

The limitations of this study, we highlight the use of only the immunochromatographic rapid test as a screening method. Additionally, we faced constraints in the number of tests performed due to a nationwide shortage of test kits during the research period, which forced us to reduce the sample size and accept a 7% margin of error.

4 CONCLUSION

The results revealed that most blood donors in the studied region were male, self-identified as mixed-race, residents of Crato-CE, living in urban areas, with an average age of 31 years and a mean household income of BRL 2,895. The predominant occupations were students and healthcare professionals.

The study found zero seroprevalence of visceral leishmaniasis among blood donors in this endemic region. Therefore, we conclude that the cost-benefit ratio does not support implementing routine VL screening in local blood banks. Nonetheless, further studies with larger sample sizes, longer durations, and different screening methodologies are essential to evaluate this issue more thoroughly in this and other endemic zones.

This research contributes to characterizing the sociodemographic profile and VL seroprevalence among blood donors in southern Ceará and aims to foster discussion on the feasibility of implementing VL screening protocols in blood centers located in endemic areas of Brazil.

REFERENCES

Aliaga L, Ceballos J, Sampedro A, Cobo F, López-Nevot MÁ, Merino-Espinosa G, *et al.* Asymptomatic Leishmania infection in blood donors from the Southern of Spain. Infection. 2019 Mar 19. doi:10.1007/s15010-019-01297-3.

Brazil. Ministry of Health. Health Surveillance Secretariat. Department of Epidemiological Surveillance. Manual for surveillance and control of visceral leishmaniasis. Brasília: Ministry of Health Publishing House; 2006. 120 p.

Brazil. Ministry of Health. National Health Surveillance Agency. Resolution RDC No. 34, of June 11, 2014. Provides for Good Practices in the Blood Cycle [Internet]. Official Gazette of the Union; 2014 [cited 2025 Feb 17].

Ceará. State Health Secretariat. Health Surveillance Coordination. Epidemiological Surveillance Center. Epidemiological bulletin: Visceral Leishmaniasis – Ceará, 2007 to 2019 [Internet]. Fortaleza (CE): SESA; 2019 Dec 19 [cited 2025 Apr 13]. 14 p. Available from: https://saude.ce.gov.br

Cruz I, Cañavate C, Rubio JM, Morales MA, Chicharro C, Laguna F, *et al.* A nested polymerase chain reaction (Ln-PCR) for diagnosing and monitoring Leishmania infantum infection in patients co-infected with human immunodeficiency virus. Trans R Soc Trop Med Hyg. 2002 Apr;96 Suppl 1:S185-9. doi:10.1016/s0035-9203(02)90074-x.

Foroutan M, Dalvand S, Khademvatan S, Majidiani H, Khalkhali H, Masoumifard S, *et al.* A systematic review and meta-analysis of the prevalence of Leishmania infection in blood donors. Transfus Apher Sci. 2017 Aug;56(4):544–51. doi:10.1016/j.transci.2017.07.001.

Fukutani KF, Figueiredo V, Celes FS, Cristal JR, Barral A, Barral-Netto M, *et al.* Serological survey of Leishmania infection in blood donors in Salvador, Northeastern Brazil. BMC Infect Dis. 2014 Jul 30;14(1):422. doi:10.1186/1471-2334-14-422.

Huda MM, Rudra S, Ghosh D, Bhaskar KR, Chowdhury R, Dash AP, *et al.* Low prevalence of Leishmania donovani infection among the blood donors in kala-azar endemic areas of Bangladesh. BMC Infect Dis. 2013 Feb 2;13(1):62. doi:10.1186/1471-2334-13-62.

Maia C, Conceição C, Pereira A, Rocha R, Ortuño M, Muñoz C, *et al.* The estimated distribution of autochthonous leishmaniasis by Leishmania infantum in Europe in 2005–2020. PLoS Negl Trop Dis. 2023 Jul 19;17(7):e0011497. doi:10.1371/journal.pntd.0011497.

Okwor I, Uzonna J. Social and economic burden of human leishmaniasis. Am J Trop Med Hyg. 2016 Mar 2;94(3):489-93. doi:10.4269/ajtmh.15-0408.

Pan American Health Organization. Leishmaniasis [Internet]. Brasília: PAHO; 2024 [cited 2025 Feb 17]. Available from: https://www.paho.org/pt/topicos/leishmaniose

Piyaraj P, Bualert L, Kalrat A, Leelayoova S, Ruang-areerate T, Theprin N, *et al.* Asymptomatic Leishmania infection among blood donors in a Southern Province of Thailand. Am J Trop Med Hyg. 2024 Aug 13. doi:10.4269/ajtmh.24-0218.

Silva FA, Costa DA, Silva BHM, Alves AF, Souza SJ, Silva GMB, *et al.* Identification of phlebotomine sand fly (Diptera: Psychodidae) in Atlantic forest fragments and their dispersal to urban area. An Acad Bras Cienc. 2023;95(4):e20191596. doi:10.1590/0001-3765202320191596.

Silva LP, Montenegro S, Werkauser R, Sales KG, Soares FC, Costa VM, *et al.* Asymptomatic Leishmania infection in blood donors from a major blood bank in Northeastern Brazil: a cross-sectional study. Rev Inst Med Trop Sao Paulo. 2020;62:e92. doi:10.1590/s1678-9946202062092.

World Health Organization. Leishmaniasis [Internet]. Geneva: WHO; 2024 [cited 2025 Feb 17]. Available from: https://www.who.int/news-room/fact-sheets/detail/leishmaniasis