Prevalence of Chagas Disease among Solid Organ–Transplanted Patients in a Nonendemic Country

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Abstract. Reactivation of Chagas disease in the chronic phase may occur after solid organ transplantation, which may result in high parasitemia and severe clinical manifestations such as myocarditis and meningoencephalitis. The aim of the present study is to describe the prevalence of Chagas disease among solid organ–transplanted patients in a tertiary hospital from a nonendemic country. A cross-sectional study was performed at Vall d'Hebron University Hospital (Barcelona, Spain) from April to September 2016. Chagas disease screening was performed through serological tests in adult patients coming from endemic areas that had received solid organ transplantation and were being controlled in our hospital during the study period. Overall, 42 patients were included, 20 (47.6%) were male and median age was 50.5 (23–73) years. Transplanted organs were as follows: 18 kidneys, 17 lungs, and 7 livers. Three patients had Chagas disease, corresponding to a prevalence among this group of solid organ–transplanted patients of 7.1%. All three patients were born in Bolivia, had been diagnosed with Chagas disease and received specific treatment before the organ transplantation. We highly recommend providing screening tests for Chagas disease in patients with or candidates for solid organ transplantation coming from endemic areas, early treatment with benznidazole, and close follow-up to prevent clinical reactivations.

INTRODUCTION

Chagas disease is a parasitic infection caused by the hemoflagellated protozoan *Trypanosoma cruzi*, and is estimated that 6–7 million people are infected worldwide.¹ Although Chagas disease is an endemic disease of Latin America affecting rural population, progressive urbanization and the increase of population mobility during the last decades have made Chagas disease a global disease outside endemic countries, Spain being one of the most affected countries.^{2,3}

After the acute phase of the infection, which is either asymptomatic or presents with nonspecific symptoms (fever, malaise, and lymphadenopathy), a subsequent, usually asymptomatic, indeterminate form takes place for years. After 10–30 years, up to 30–40% of patients will develop the symptomatic chronic phase, with cardiac and/or digestive involvement.⁴ Reactivation in the chronic phase may occur when immunosuppression is established, sometimes resulting in high parasitemia and severe clinical manifestations, such as meningoencephalitis, acute myocarditis, and skin lesions.^{5,6}

One of these immunosuppressant conditions is solid organ transplantation. Information about the reactivation of Chagas disease in transplanted patients mainly comes from kidney and heart transplantation in endemic countries for Chagas disease.^{7,8} However, migration flows from endemic areas to nonendemic areas have contributed that Chagas disease patients increasingly participate in transplantation programs, and consequently reactivation and transmission of Chagas

disease in nonendemic areas due to organ transplantation have been described.^{9–11} Taking into account all of these facts, transplantation expert groups have published consensus documents to address these situations, stressing the importance of screening for Chagas disease in donors and recipients from endemic areas.^{12–14} The current Spanish consensus document regarding the prevention of donor to recipient infection transmission recommends screening all donors being born or residing in endemic countries for Chagas disease through serological tests. Organ donation is absolutely contraindicated in acute infection, heart donation is absolutely contraindicated in chronic infection, and a relative contraindication is established for other organs.¹⁵ However, there is scarce data regarding prevalence of Chagas disease in solid organ transplantation outside endemic areas.

The aim of the present study is to describe the prevalence of Chagas disease among solid organ–transplanted patients in a tertiary hospital from a nonendemic country, where kidney, liver, and lung transplantation programs are implemented.

MATERIALS AND METHODS

This is a cross-sectional study performed at the Vall d'Hebron University Hospital, a tertiary hospital included in the International Health Program of the Catalan Health Institute (PROSICS Barcelona, Barcelona, Spain), from April to September 2016. The inclusion criteria were as follows: should be adult patients (more than 18 years old), should have undergone solid organ transplantation and been controlled at Vall d'Hebron University Hospital (Department of Nephrology, Department of Pulmonology and Lung Transplant Unit, and Department of Hepatopancreatobiliary Surgery and Transplants), should have been born or lived for more than 1 year in an endemic country for Chagas disease. Chagas disease screening was performed through serological techniques in

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routine blood tests (no extra blood extraction was necessary), and clinical and epidemiological information from patients was recorded.

Diagnosis of Chagas disease was performed through two positive different serological tests according to World Health Organization recommendations¹⁶: an enzyme-linked immunosorbent assay (ELISA) that uses recombinant antigen (Bioelisa Chagas; Biokit, Lliçà d'Amunt, Spain) and an ELISA that uses crude antigen (Ortho *T. cruzi* ELISA; Johnson & Johnson, High Wycombe, United Kingdom). When serological tests were discordant, both serological tests were repeated, and a real-time polymerase chain reaction (RT-PCR) to detect *T. cruzi* DNA in peripheral blood was performed according to the method described by Piron et al.¹⁷

Patients with a positive result were assessed for cardiac and digestive involvement through clinical symptoms questionnaire, physical examination, 12-lead electrocardiography, chest radiography, echocardiogram, and barium enema. Subsequently, treatment with benznidazole 5 mg/kg/day divided into two or three doses for 60 days was provided.

The study protocol was approved by the Ethical Review Board of the Vall d'Hebron University Hospital (Barcelona, Spain), and oral informed consent was obtained from all patients. Procedures were performed in accordance with the ethical standards laid down in the Declaration of Helsinki as revised in 2013.

SPSS software for Windows (Version 19.0; SPSS Inc., Chicago, IL) was used for statistical analyses. Categorical data are presented as absolute numbers and proportions, and continuous variables are expressed as medians and ranges.

RESULTS

Overall, 47 transplanted patients met the inclusion criteria; however, five patients did not go to the control visit and Chagas disease screening could not be performed. Of the 42 included patients, 20 (47.6%) were male and median age was 50.5 (23–73) years. Median time since transplantation to Chagas disease screening was 48 (1–204) months, and transplanted organs were as follows: 18 kidney transplantations, 17 lung transplantations, and 7 liver transplantations. Clinical and epidemiological data of these 42 patients are summarized in Table 1.

Three patients had been diagnosed with Chagas disease before the organ transplantation. Hence, *T. cruzi* serology was performed in 39 patients, yielding the following results: 38 patients with negative serology and one patient with discordant result. This patient was an Argentinean 48-year-old man who underwent orthotopic liver transplantation 10 years ago; serological tests were repeated and a *T. cruzi* RT-PCR in peripheral blood was performed and all the tests resulted negative. Therefore, prevalence of Chagas disease among this group of solid organ-transplanted patients was 7.1% (95% confidence interval: 2.5–19.1).

Clinical information of the three Chagas disease patients is summarized in Table 2. Briefly, patient 1 was a Bolivian 36-year-old woman with a perineuclear antineutrophil cytoplasmic antibodies-associated renal vasculitis who underwent kidney transplantation; patient 2 was a Bolivian 48-year-old woman with pulmonary bronchocentric granulomatosis who underwent single-lung transplantation; and patient 3 was a Bolivian 54-year-old human immunodeficiency virus (HIV)–

TABLE 1
Clinical and epidemiological characteristics of patients with solid organ transplantation coming from Chagas disease–endemic areas in Vall d'Hebron University Hospital, Barcelona, Spain

Characteristics	Number of patients (N = 42)
Age, years	50.5 (23–73)
Gender, male	20 (47.6%)
Country of origin	
Ecuador	10 (23.8%)
Bolivia	7 (16.7%)
Argentina	5 (11.9%)
Peru	4 (9.5%)
Colombia	4 (9.5%)
Honduras	3 (7.1%)
Venezuela	3 (7.1%)
Chile	2 (4.8%)
Uruguay	2 (4.8%)
Spain*	2 (4.8%)
Transplanted organ	
Kidney	18 (42.9%)
Lung	17 (40.5%)
Liver	7 (16.7%)
Time since transplantation, months	48 (1–204)
Immunosuppressive therapy	
Tacrolimus	40 (95.2%)
Corticosteroids	35 (83.3%)
Mycophenolate	30 (71.4%)
Everolimus	4 (9.5%)
Sirolimus	4 (9.5%)
Azathioprine	2 (4.8%)

Data are reported as number (%) of patients or median (range).

* These two patients were born in Spain, but they lived for more than 1 year in Venezuela and Mexico, respectively.

infected man with high blood pressure, dyslipidemia, and diabetic nephropathy who underwent kidney transplantation. All of them received Chagas disease treatment before transplantation. Patients 1 and 2 received benznidazole 5 mg/kg/day divided into three doses for 60 days, and clinical and microbiological (through *T. cruzi* RT-PCR determination in peripheral blood every 6 months) follow-up revealed no reactivation of Chagas disease. Patient 3 received benznidazole at the same doses for 60 days, but 5 years later, *T. cruzi* RT-PCR determination in peripheral blood was positive and treatment with nifurtimox was initiated, although it had to be stopped because of adverse events at day 35 of the treatment; subsequently, *T. cruzi* RT-PCRs of peripheral blood were negative. During the follow-up after transplantation, none of them showed clinical signs of reactivation.

DISCUSSION

The present study showed a Chagas disease prevalence of 7.1% (three patients) among solid organ-transplanted patients coming from endemic countries in a teaching hospital placed in a nonendemic country. The three patients were born in Bolivia and were diagnosed and received specific treatment before organ transplantation.

Information about the prevalence of *T. cruzi* infection among solid organ-transplanted population is scarce, comes from endemic areas of Latin America, and is mainly focused on kidney transplantation recipients. Table 3 summarizes key information of most relevant studies addressing this issue. Prevalence of Chagas disease in these studies ranged from 0% to 10.7% depending on the country where the study was performed, the study period, and the serological test used for the diagnosis.^{7,18–21} Although our study is performed in a

TABLE 2
Epidemiological and clinical characteristics of Chagas disease patients with solid organ transplantation

Patients	Country of origin	Age (years)	Gender	Diagnosis of CD	CD clinical stage	CD treatment	Organ transplantation	Transplanted organ	Immunosuppressive therapy
1	Bolivia	36	F	2010	Indeterminate stage	2011	2016	Kidney	Corticosteroids, tacrolimus, mycophenolate mofetil
2	Bolivia	48	F	2009	Indeterminate stage	2009	2010	Lung	Corticosteroids, tacrolimus, mycophenolate mofetil
3	Bolivia	54	M	2009	CCC (KI)	2009/2014	2016	Kidney	Corticosteroids, tacrolimus, mycophenolate mofetil

CCC (KI) = chronic cardiac disease (Kuschnir stage I: abnormal electrocardiogram with normal chest X-ray and without cardiac failure symptoms); CD = Chagas disease; F = female; M = male.

smaller number of patients compared with these studies, it has been carried out in a nonendemic country and included different types of transplanted organs, providing important information on the topic.

The three patients with Chagas disease in our study were coming from Bolivia, yielding Chagas disease prevalence in the screened Bolivian population of the study of 42.8% (three out of seven). These results are in accordance with the Chagas disease patients profile in our area, where the percentage of patients coming from Bolivia is around 97%, as previously assessed in a study of 1,274 Chagas disease patients performed by our group.³ In a study performed by Basile et al.,²² based on migrant information in European countries and Chagas disease prevalence in Latin American countries, it was estimated that 120,000 people with Chagas disease were living in Europe and 80,000 of them were coming from Bolivia, although 95% of them remain undiagnosed.

Reactivation of Chagas disease has been mainly described in cases of hematopoietic stem cell transplantation (especially allogeneic bone marrow and umbilical cord blood transplantation), where the reactivation has been reported in up to 40% of the patients.^{23,24} Regarding solid organ transplantation, reactivation of Chagas disease is less common, although case reports are increasingly being reported, mainly after heart and kidney transplantation, both in endemic and nonendemic areas. Moreover, in addition to common clinical presentation of Chagas disease reactivation (myocarditis and meningoencephalitis), it may present with skin lesions such as panniculitis and erythema nodosum-like lesions.^{7,8,25–27}

The migration flows from rural endemic areas to urban areas and nonendemic areas have contributed that Chagas disease patients increasingly participate in transplantation programs.² Furthermore, since Chagas disease is usually asymptomatic, patients awaiting organ transplantation are often unaware of

the diagnosis. Taking into account the underdiagnosis rate and the potential reactivation when the immunosuppression is established, different expert groups (both in infectious diseases and transplantation areas) have elaborated consensus documents to address this issue. The most important recommendations of these consensus documents try to stress the importance of screening for Chagas disease in donors and recipients coming from endemic areas. Besides this, providing early specific treatment (preferably before organ transplantation) and a close follow-up with highly sensitive tests, such as PCR, are recommended to reduce the risk of Chagas disease reactivation.^{12–14} Most proposed follow-up schedules after transplantation (both in *T. cruzi*-infected recipient and in uninfected recipient receiving an organ from a *T. cruzi*-infected donor) include parasitological studies (PCR, Strout method, microhematocrit) weekly for 2 months, bi-monthly between the second and sixth months, and annually thereafter.¹⁴ Treatment with benznidazole in patients with impending immunosuppression is recommended; however, when the immunosuppression is established and the patient has the indeterminate form of the disease, the treatment is controversial because of benznidazole adverse events and the scarce information available.¹⁴ However, based on previous studies, which show high reactivation rates of Chagas disease in transplant recipients, and our own experience in immunosuppressed patients with Chagas disease, in whom treatment was well tolerated, we provide treatment with benznidazole at the time of Chagas disease diagnosis, before reactivation is detected.^{7–9,11}

Some Brazilian studies have shown higher risk of Chagas disease reactivation in heart transplant recipients receiving mycophenolate mofetil as a part of the immunosuppression protocol. Therefore, it is recommended not to use mycophenolate mofetil (or at least use reduced doses) in

TABLE 3

Information about most relevant studies about Chagas disease prevalence among solid organ-transplanted population coming from endemic areas

Reference and year of publication	Thambo, 1989 ¹⁸	Riarte, 1999 ⁷	Boin, 2010 ¹⁹	Fitzpatrick, 2010 ²⁰	Rodríguez-Romo, 2013 ²¹	Salvador, 2018
Country	Chile	Argentina	Brazil	United States	Mexico	Spain
Study period	1975–1986	1989–1996	1997–2007	2006–2008	2009–2010	2016
Number of patients	84	238	236	48	375	42
Chagas disease prevalence	10.7%	9.6%	0.4%	0%	2.13%	7.1%
Time of screening	Pretransplantation	Pretransplantation	Pretransplantation	Pretransplantation	Posttransplantation	Pre- and posttransplantation
Transplanted organs	Kidney	Kidney	Liver	Kidney	Kidney	Kidney, lung and liver
Diagnostic test	IHA	IFA, IHA, and ELISA	Serological test (not described)	IFA	ELISA and IFA	ELISA

ELISA = enzyme-linked immunosorbent assay; IFA = indirect immunofluorescence assay; IHA = indirect hemagglutination.

Chagas disease patients receiving heart transplantation.^{28,29} Nevertheless, no information in other organ transplantations is available. In our study, the three Chagas disease patients (receiving two kidney and one lung transplantation, respectively) received mycophenolate mofetil at normal doses without evidence of Chagas disease reactivation.

Despite these recommendations, no national directive or legislation regarding solid organ transplantation in European countries includes Chagas disease as a specific topic; only three national transplant organizations from Italy, Spain, and the United Kingdom have included a specific section regarding how to control transmission of Chagas disease through donor screening.³⁰ However, less attention is paid to solid organ transplantation recipients, and most of them remain unscreened for Chagas disease.

This study has some limitations, because it was carried out in a single center and screened population was limited. Moreover, our center has no cardiac transplantation program, which has more clinical implications in patients with Chagas disease. Serological tests have been performed in patients receiving immunosuppressive therapies; hence, the sensitivity of the tests could be lower than expected. Even so, this study, as mentioned previously, has also some strengths: it is performed in a nonendemic area and includes different types of transplanted organs. Moreover, as a consequence of this study, a screening protocol for Chagas disease in candidates for solid organ transplantation coming from endemic areas has been established in our hospital.

In summary, in this study, we have observed a 7.1% prevalence of Chagas disease among solid organ-transplanted patients in a teaching hospital outside an endemic area. All patients with Chagas disease were from Bolivia and had been diagnosed and received specific treatment before to organ transplantation. We highly recommend providing screening tests for Chagas disease in patients with or waiting for solid organ transplantation coming from endemic areas, early treatment with benznidazole, and close follow-up to prevent clinical reactivations.

Received September 20, 2017. Accepted for publication November 5, 2017.

Published online February 5, 2018.

Financial support: This study was supported by the 6th National Plan (PN) of Research + Development + Innovation (I+D+I) 2008–2011, ISCIII-General Division Networks and Cooperative Research Centres + FEDER funds + Collaborative Research Network on Tropical Diseases (RICET): RD12/0018/0020 and RD12/0018/0010.

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