ESC HEART FAILURE
ESC Heart Failure (2024)
Published online in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/ehf2.14965

ORIGINAL ARTICLE

American registry of ambulatory and acute decompensated heart failure (AMERICCAASS registry): Rationale and design

Juan Esteban Gómez-Mesa[1,2,3,4]*, Juliana María Gutiérrez-Posso[2], Manuela Escalante-Forero[2], David Esteban Eraso-Bolaños[2], Mark H. Drazner[5], Daniel Quesada-Chaves[4,6], Alexander Romero-Guerra[4,7], Eduardo R. Perna[4,8], Amada Álvarez-Sangabriel[4,9], Víctor Rossel[4,10,11], Walter Alarco[4,12] and Mario Speranza[4,13]

[1]*Department of Cardiology, Fundación Valle del Lili, Cali, Colombia;* [2]*Department of Investigation and Innovation, Fundación Valle del Lili, Cali, Colombia;* [3]*Department of Health Sciences, Universidad Icesi, Cali, Colombia;* [4]*Consejo Interamericano de Falla Cardíaca e Hipertensión Pulmonar (CIFACAH) de la Sociedad Interamericana de Cardiología (SIAC), Mexico City, Mexico;* [5]*Department of Cardiology, University of Texas Southwestern Medical Center, Dallas, TX, USA;* [6]*Department of Cardiology, Hospital San Vicente de Paul, Heredia, Costa Rica;* [7]*Department of Cardiology, Hospital Santo Tomas, Panama City, Panama;* [8]*Department of Heart Failure and Pulmonary Hypertension, Instituto De Cardiología J. F. Cabral, Corrientes, Argentina;* [9]*Emergency Department and Coronary Care Unit, Instituto Nacional de Cardiología Ignacio Chávez, Mexico City, Mexico;* [10]*Department of Cardiology, Instituto Nacional del Tórax, Santiago, Chile;* [11]*Faculty of Medicine, Universidad de Chile, Santiago, Chile;* [12]*Department of Cardiology, Instituto Nacional Cardiovascular INCOR, Lima, Peru; and* [13]*Department of Cardiology, Hospital Clínica Bíblica, San José, Costa Rica*

Abstract

Aims Heart failure (HF) is a highly prevalent and progressive condition associated with significant morbidity and mortality rates. Acute decompensated HF precipitates millions of hospitalizations each year. Despite therapeutic advances, the overall prognosis of HF is poor. The varying clinical courses and outcomes of patients with this disease may be due to region-specific gaps and since most HF studies are conducted in developed countries, the participation of Latin American and Caribbean countries is low. Considering this, the American Registry of Ambulatory and Acute Decompensated Heart Failure (AMERICCAASS) aims to characterize the population with ambulatory and acute decompensated HF in the American continent and to determine rehospitalization and survival outcomes during the 12 months of follow-up.

Methods and results AMERICCAASS Registry is an observational, prospective, and hospital-based registry recruiting patients with ambulatory or acute decompensated HF. The registry plans to include between two and four institutions per country from at least 20 countries in the Americas, and at least 60 patients recruited from each participant institution regardless of their ambulatory or acutely decompensated condition. Ambulatory patients with confirmed HF diagnosis or inpatients presenting with acute decompensated HF will be included. Follow-up will be performed at 12 months in ambulatory patients or 1, 6, and 12 months after hospital discharge in acutely decompensated HF patients. This ongoing study began on 1 April 2022, with recruitment scheduled to end on 30 November 2023, and follow-up on 31 January 2025. Ethics approval was obtained from the Biomedical Research Ethics Committee of Fundación Valle del Lili. Data collected in the AMERICCAASS registry is being stored on the electronic platform REDCap (Research Electronic Data Capture), which allows different forms for patient groups to enable unbiased analyses. For quantitative variables comparison, we will use the Student's *t*-test or non-parametric tests accordingly. Categorical variables will be presented as proportions, and groups will be compared with Fisher's exact test. The significance level will be <0.05 for comparisons. Readmissions and post-discharge mortality will be calculated as proportions at 1, 6, and 12 months, with a survival analysis by conditional probability and the Kaplan–Meier method.

Conclusions AMERICCAASS Registry is intended to be the most important registry of the continent for obtaining important information about demographics, aetiology, co-morbidities, and treatment received, either ambulatory or hospitalized. This registry may contribute to the optimization of national and regional evidence and public policies for the diagnosis and treatment of HF disease.

Keywords America; Heart failure; Latin America; Registries

Received: 23 June 2023; Revised: 12 June 2024; Accepted: 24 June 2024

*Correspondence to: Juan Esteban Gómez-Mesa, Department of Cardiology, Fundación Valle del Lili, 98 N. 18-49, Cali, Colombia; Department of Health Sciences, Universidad Icesi, Cali, Colombia. Email: juan.gomez.me@fvl.org.co
Trial registration number: NCT05295641

Introduction

Heart failure (HF) is a clinical syndrome due to a structural and/or functional abnormality of the heart that is highly prevalent in the adult population, around 1% to 2% worldwide and among >10% in patients with >70 years of age; however, the true prevalence is likely to be higher.[1] The prevalence of HF could vary among countries due to differential risk factors and the effect of the epidemiological transition of age.[2,3] HF is a progressive condition associated with substantial morbidity and mortality that makes it a significant public health problem.[4,5]

Acute HF (AHF) precipitates millions of hospitalizations each year.[6] Despite therapeutic advances, the prognosis of AHF is poor, the in-hospital mortality ranges from 4% to 7%, and the 28 to 90-day mortality ranges from 9% to 27%[7] (*Table 1*). Important differences in timing and type of treatment exist in HF; the REPORT-HF registry identified region-specific gaps in medical management that may be associated with patient outcomes as the length of stay and early readmissions.[7] Length of hospitalization seems to be longer in Latin America (LA) compared with Asian-Pacific countries and the United States: 6 days (range: 4 to 10 days) versus 4 days (range: 4 to 7 days), and the mortality is heterogeneous among countries (0.5% to 8.5%).[8] In the REPORT-HF, LA had the highest in-hospital mortality compared with the overall AHF population (4.4% vs. 2.4%).[6]

AHF is a significant cause of mortality and hospitalization in America, mainly in the elderly population.[8] Bocchi et al.[8] found variability in the high prevalence of HF risk factors such as high blood glucose, high systemic blood pressure, obesity, tobacco abuse, and life expectancy among LA countries. In the CARMELA study (Cardiovascular Risk Factor Multiple Evaluation in Latin America), data suggested that some countries in LA may have HF risk factors such as diabetes that are comparable with developed countries.[9] Based on that, LA is a heterogeneous region that has HF risk factors and HF epidemiology of developed countries with the added factors of arterial hypertension, Chagas' disease (ChD), and rheumatic fever (RF)[8,10,11] of developing countries (*Table 2*). The knowledge about risk factors for HF in LA is essential because there are factors more frequent in LA than in other countries or regions worldwide.[8]

Socioeconomic deprivation is a powerful independent predictor of HF development and adverse outcomes.[12] The per capita income of LA countries (US $8.555) in comparison with Canada (US $38.370) and the United States (US $47.320) indicates a lower economic status in LA and an increased HF risk.[8] The significant economic and social differences among American countries have an impact on the treatment and prognosis of HF. The essential registries about AHF have a low number of countries representative from Central and South America that may help to explore the differential risk factors, treatment, and patient outcomes of AHF (*Table 2*).

Based on the previously mentioned information, and to obtain reliable information about demographics, aetiology, treatment, and outcomes of HF patients from different countries and regions of the American continent, we planned the AMERICCAASS Registry (American Registry of Ambulatory and Acute Decompensated Heart Failure). The aim of this registry is to be a source of reliable and safe data about the implementation of diagnostic and therapeutic options recommended in the different guidelines for the management of acute decompensated HF and during outpatient management in the American continent and different countries.

Study design

The AMERICCAASS registry is an ongoing observational, longitudinal, prospective, and hospital-based registry that includes patients enrolled from institutions in American countries with a confirmed clinical diagnosis of HF (defined as having a previous/current history of this pathology and receiving pharmacological management for this condition), in the ambulatory setting (patients who attend a cardiology or internal medicine follow-up visit), or those presenting with acutely decompensated HF admitted to the hospitalization service (emergency, general ward, specialized care, coronary care, and intensive care) or another in-hospital care service. HF diagnosis relies on information included in clinical records of recruited patients and implies patients receiving HF treatment. Ethics approval was obtained from the Biomedical Research Ethics Committee of the Fundación Valle del Lili under act number 313-2018. This study started on 1 April 2022. The estimated completion date of recruitment is 30 November 2023, and the estimated completion date of follow-up is 31 January 2025.

The registry is being coordinated and supervised by the Board of Directors of the Consejo Interamericano de Falla Cardíaca e Hipertensión Pulmonar (CIFACAH) of the Sociedad Interamericana de Cardiología (SIAC). This Board will act as the Scientific Committee/Steering Committee of the registry. All members of the Scientific Committee/Steering Committee must be cardiologists linked to the Cardiovascular Scientific Societies or Associations that are members of the SIAC.

The Cardiovascular Scientific Societies and Associations from the countries of the American continent and Caribbean region (both Hispanic and English speaking) that are members of the SIAC (*Figures 1*, *2*, and *3*) have a cardiologist

Table 1 Clinical outcomes among registries

	ADHERE[15] (*N* = 187 565)	US OPTIMIZE[16] (*N* = 48 612)	EFICA[17] (*N* = 581)	ESC-HF Pilot[18] (*N* = 1892)	ATTEND[19] (*N* = 4841)	PERNA et al.[20] (*N* = 2974)	BREATHE[21] (*N* = 1261)	RENAIC CR[22] (*N* = 695)	REPORT HF[6] (*N* = 18 553)	Lee et al.[23] (*N* = 4031)
Hospital stay, days	-	4 (3–7)	14 ± 15	8 (5–11)	21 (14–32)	9 ± 8	-	-	8 (5–12)	-
In-hospital mortality (%)	4	4	-	4	6	8	13	5	2	9
Post-discharge mortality (%)	-	9 (60–90 days)	27 (28 days)-		-	-	-	-		11 (30 days)
Readmission (%)	-	30 (60–90 days)	-	-	-	-	-	-		-

Population limited to the intensive care unit.

who acts as their delegate to CIFACAH. This delegate will act as national coordinator for the AMERICCAASS registry for each scientific entity and, based on that, will coordinate the selection of participating institutions and will supervise the adequate development of this registry in their respective country.

All participant countries will be grouped based on their geographical location, and based on that, each country will have assigned a member of the Scientific Committee as a regional coordinator (Data S1).

The Research Center from the Fundación Valle del Lili [blinded] will provide the technical, logistical and epidemiological support required to develop this registry. The data collected in the AMERICCAASS will be stored on the electronic platform REDCap (*Table 3*).

The main outcomes to be evaluated in this registry are adherence to optimal medical treatment (at recruitment and during follow-up), rehospitalization, and mortality (in-hospital or ambulatory).

Data collection and follow-up

The study will have a recruitment phase and a follow-up phase. The recruitment phase will last 12 months, and each institution must recruit at least 60 patients during that period. Each institution has the flexibility to determine the number of ambulatory and acutely decompensated patients they recruit. There is no maximum number of institutions to participate per country nor a maximum number of patients to be recruited by institutions. The follow-up phase will last 12 months, starting from the date of the first patient recruited and ending at 12 months from the date of the last patient recruited. This registry does not involve pharmacological interventions or specialized activities other than those performed routinely within hospital treatment and outpatient follow-up of patients with HF, and because of that, informed consent is not required.

An initial evaluation of the patient will be made at the moment of recruitment. The clinician-investigator will collect information about demographic characteristics, medical history, previous admissions, heart failure history (aetiology information, functional status, and echocardiographic data including ejection fraction, severe valvular disease, and pulmonary artery pressure, among other echocardiographic variables), vital signs (including weight, height, blood pressure, and heart rate), procedures performed during follow-up (including diagnostic and therapeutic cardiovascular procedures), laboratory values (including renal, hepatic and haematological profile, as well as natriuretic peptides), pharmacological treatment (including beta-blockers, mineralocorticoid receptor antagonist, renin-angiotensin-aldosterone system inhibitor, neprilysin inhibitor, and sodium-glucose contransporter-2 inhibitor), and vital status

Table 2 Acute HF characteristics among registries

		ADHERE[15] (*N* = 187 565)	US OPTIMIZE[16] (*N* = 48 612)	EFICA[17] (*N* = 581)	ESC-HF Pilot[18] (*N* = 1892)	ATTEND[19] (*N* = 4841)	PERNA et al.[20] (*N* = 2974)	INTER-CHF[24] (*N* = 858)	BREATHE[21] (*N* = 1261)	RENAIC CR[22] (*N* = 695)	REPORT HF[6] (N = 18 553)	Lee et al.[23] (*N* = 4031)
		USA	USA	France	Europe	Asia	Argentina	South America	Brazil	Costa Rica	Worldwide	Canada
		2001–2009	2003–2004	2001	2009–2010	2007–2009	1992–2004	2012–2014	2011–2012	2016–2017	2014–2017	1997–2001
Demographics	Age (years), mean ± SD; median (IQR)	72 ± 14	73 ± 14	73 ± 13	70 ± 13	73 ± 14	68 ± 14	67 ± 0.5	64 ± 16	-	67 (57–77)	76 ± 11
	Male, %	48	48	59	63	58	59	61	40	58	61	49
LVEF	LVEF <40 (%)	47	49	73∼	61	53	72	71	-	81∼	40	50
	LVEF%, mean ± SD	-	39 ± 18	38 ± 15	38 ± 14	-	-	-	39 ± 16	-	40 ± 16	-
Aetiology (%)	Hypertensive	-	23	15[b]	-	-	23	20	20	43	15	-
	Ischaemic	57	46	61	51	31	31	26	30	58	33	-
	Valvular	-	-	21	-	-	19	13	12	14	11	-
	Other	-	-	4	-	-	12	26	37	26[a]	8	-
Co-morbidities (%)	Coronary artery disease	57	50	46	51	-	23	18	27	34	34	37
	Previous HF	76	87	66	75	36	52	27	-	28	57	
	Arterial Hypertension	74	71	60	62	69	66	74	71	81	64	-
	Dyslipidaemia	36	32	30	-	36	25	49	37	54	-	-
	Chronic kidney disease	30	20	10	26	-	10	12	24	18	20	-
	Diabetes mellitus	44	42	27	35	34	23	22	34	38	37	34
	CRT/ICD	21	15	-	9	11	-	-	-	8	10	-
	Atrial arrhythmia	31	31	25	44	40	28	-	27	23	31	29

CRT/ICD, cardiac resynchronization therapy/implantable cardioverter; HF, heart failure; LVEF, left ventricular ejection fraction.
[a]Could have more than one aetiology.
[b]Combination with hypertrophic aetiology, preserved LVEF as >45%.

Figure 1 Cardiovascular Societies or Associations from North America that are members of SIAC.

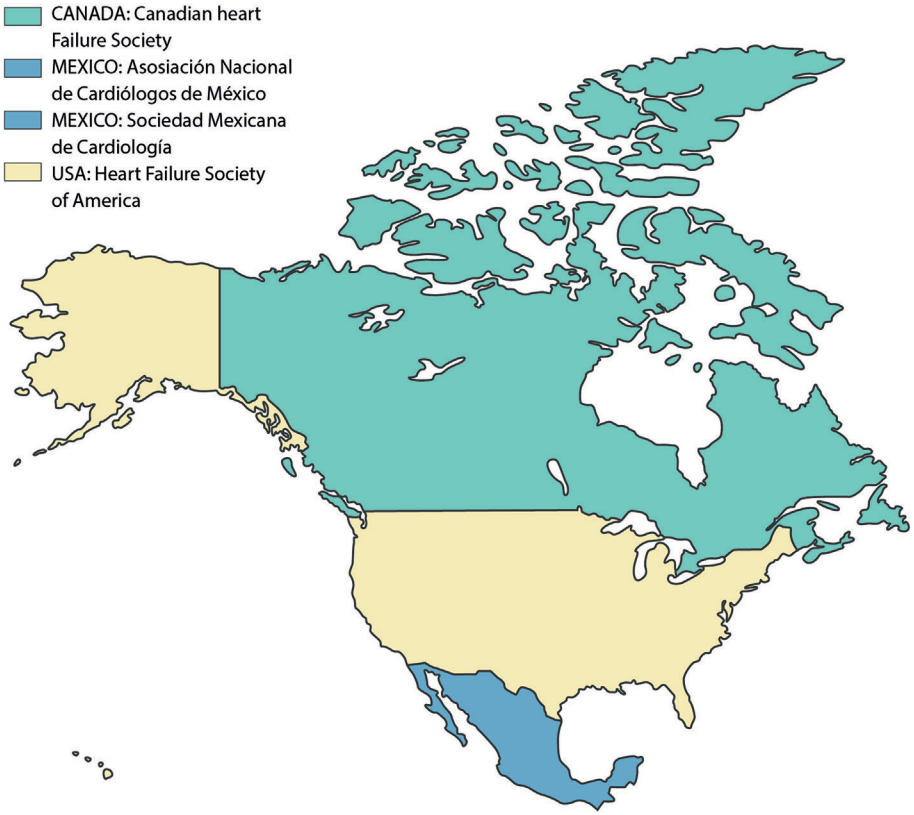

Figure 2 Cardiovascular Societies or Associations included from Central America and Caribbean countries that are members of SIAC.

Figure 3 Cardiovascular Societies or Associations included from South America that are members of SIAC.

Table 3 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Patients over 18 years old	• Patients hospitalized for another cardiovascular or non-cardiovascular condition and during hospitalization develop ADHF
• In-hospital patients with an admission diagnosis of ADHF	• Patients on a waiting list for heart transplantation
• Ambulatory patients with a confirmed diagnosis of HF	• Patients who have a long-term ventricular assist device implanted or are in the process of implanting (e.g., HeartMate II and HeartMate III) as destination therapy
	• Patients with palliative care, previously defined by their cardiac condition (e.g., HF) or by another medical condition (cancer, COPD, etc.) • Patients who are discharged or referred to another institution within less than 48 h of hospital stay. • The inability to comply with scheduled follow-ups (telephone or face-to-face) due to social, personal, or other conditions according to the principal investigator. • Life expectancy of less than 6 months due to a condition different from HF (cancer, COPD, etc.)

ADHF, acute decompensated heart failure (principal or complementary diagnosis); COPD, chronic obstructive pulmonary disease; HF, heart failure.

during follow-up. A pre-specified data collection point will occur at 12 months after recruitment in ambulatory patients and will occur at 1, 6, and 12 months after recruitment in hospitalized patients; these follow-ups can be done by face-to-face or by telephone interview. If the patient cannot schedule an appointment for follow-up or cannot be transported to the participating institution for any reasons, the follow-up that corresponds (1, 6, or 12 months) must be done by telephone or virtually. The window period for these follow-ups is 30 days for the 1-month follow-up and 60 days for the 6- and 12-month follow-up. Given the above, the AMERICCAASS Registry will have a maximum duration of 24–26 months (a window period of 2 months for the last 12-month follow-up visit). According to the follow-up objectives, at each data collection point, the study staff will obtain an updated medication history, vital status, re-hospitalization data, functional class, review of symptoms, procedures performed, and laboratory values.

For recruitment and follow-ups, a standardized interview must be performed and registered in the virtual database to control memory bias. Additionally, to control patient lost during follow-up (information bias), each participant will be asked to provide contact information that includes cell phone or landline numbers from the patient and a family member or friend.

Statistical analysis plan

The sample size estimated for the registry is a minimum of 60 patients per institution and at least two to four institutions per country. Expecting to include at least 20 countries, we plan to recruit between 2400 and 4800 patients. The population for initial data analysis will be composed of all recruited patients (those who met the selection criteria and have correctly filled out the information at the recruitment moment). All the information will be stored on the REDCap platform, creating different forms based on the patient selection group (ambulatory or acutely decompensated). We propose to perform stratified sampling with proportional allocation given that not all institutions will have the same number of patients with HF. The global population data analysis will be composed of all the recruited patients who complete follow-up at 12 months. Quality control will be carried out in patients from each country, taking a random sampling of 10% of the cases to verify the integrity of the data collected. In case of inconsistencies, another 10% of cases will be reviewed, and if the discrepancies persist, the entire country database will be reviewed.

For the statistical analysis, a univariate analysis will be performed to determine the behaviour of the numerical variables. The normality for continuous variables will be evaluated through a Shapiro–Wilk test, those with a $P > 0.05$ are considered a normal distribution and will be presented as means and standard deviation, those with abnormal distribution will be presented as median and interquartile range (IQR). For the comparison of quantitative variables, in case of a normal distribution, the Student's *t*-test will be used, in case there is no normal distribution, non-parametric tests will be used. The categorical variables will be presented as proportions, and the groups will be compared with Fisher's exact test. The significance level will be <0.05 for comparisons.

The readmissions and post-discharge mortality will be calculated as proportions at 1, 6, and 12 months, with a survival analysis by conditional probability and the Kaplan–Meier method. The death cause will be categorized as a cardiovascular, non-cardiovascular, or unidentified origin.

Ethics

All information collected will be stored in the REDCap platform. A username and password will be assigned to each participating institution and research group to access the electronic data collection format in REDCap. This registration information is unique and belongs to each institution. Before the registry initiation, the registry protocol must be approved by the ethics committee of all the participant institutions.

This study will be conducted in accordance with the Declaration of Helsinki. The protocol was submitted and approved by the Institutional Review Board and/or Ethics Committee and must be submitted and approved by the Institutional Review Board and/or Ethics Committee of each participating institution.

Based on the methodology of the registry (to registry the current treatment and follow-up of HF patients) and following the classification of 'no risk for patients' made by the Institutional Review Board and the Ethics Committee, no informed consent is required. However, the application of informed consent was left to the discretion of each participating institution.

Discussion

Population-based studies from LA report that the epidemic of cardiovascular diseases keeps on rising, and this is related to demographic and lifestyle changes attributed to the epidemiological transition, which will lead to a higher number of cardiovascular events (including HF).[3,8] Differences in economic growth, genetic susceptibility, cultural practices, disposition of risk factors, and treatments contribute to intercontinental and continental differences in HF evolution.[13] The demographic and clinical characteristics of HF are widely described in Europe and the United States. They tend to differ considerably according to the populations enrolled and the definitions of HF adopted.[2] Besides that, there is variability in AHF aetiologic factors and precipitants in America, especially in

LA and the Caribbean region, where there are differential risk factors such as obesity, arterial hypertension, ChD and RF.[6,8]

HF aetiology, severity, and management differ between North, Central, and South America.[13] Main described aetiologies of HF in LA are idiopathic dilated cardiomyopathy (from 1.3% to 37%), ChD (from 1.3% to 21%), ischaemic (from 17% to 68%), arterial hypertension (from 14% to 76%), valvular (from 3% to 22%), and alcohol-related (from 1.1% to 8%).[8] The prognosis of ChD HF is worse than other aetiologies.[8]

AHF represents a quick development or change of signs and symptoms in HF patients that require medical attention, which usually leads to hospitalization, and this is the leading cause of cardiovascular hospitalization of HF patients.[1] AHF is a major problem of public health and has a poor prognosis.[7] In the REPORT-HF registry, LA had the highest in-hospital mortality compared with the overall population (4.4% vs. 2.4%).[6] These outcomes could be related in part to the significant economic and social differences among American countries that impact the treatment and prognosis of HF.

The development of a continental registry (AMERICCAASS) must lead to better characterization of the differential risk factors in America in comparison with other continents or other registries. It also could guide the management for primary (early diagnosis and treatment of cardiovascular risk factors) and secondary (optimization of HF overall therapy and development of an effective transition and follow-up plan) prevention for HF and thus establish a solid base that allows an improvement in the healthcare of these patients.

While the heterogeneity of underlying aetiologies of HF has been the focus of much prior investigation, continental and country-specific differences in HF are additional and critically important reasons for HF heterogeneity.[13] An American registry could be an important resource of real-world data on a chronic medical condition such as HF and therefore be fundamental to modify or implement public health policies at all levels (national, regional, and continental) and guide future research.

Disease-based registries could be used to compare disease management between several countries and regions and derive estimates of morbidity, mortality, and resource utilization.[14] With the implementation of the AMERICCAASS registry, it is expected to contribute to the knowledge of epidemiology, sociodemographic, and clinical characterization of the population that is barely descriptive for most of the American countries in the scientific literature. It is also expected to have reliable and safe data about the implementation of the diagnostic and therapeutic options recommended in the different international guidelines for the management of acute decompensated HF and during outpatient management.

There are limitations regarding collecting data on an international registry due to the challenging clinical diagnosis of HF. There will inevitably be missing data and patients lost to follow-up even though the protocol is designed to facilitate data collection and minimize the missing data. However, this registry aims to generate information about the reality of HF in the American continent and by regions (North, Central and South America, and the Caribbean region). Also, it could allow the generation of national and regional public policies for the diagnosis and timely treatment of the disease. Finally, the development of this registry can serve as a foundation for subsequent projects, allowing us to deepen our understanding of this important pathology, including quality of life (QoL) outcomes.

Strengths and limitations of this study

- The implementation of the AMERICCAASS registry, is expected to contribute to the knowledge of epidemiology, sociodemographic, and clinical characterization of the population that is barely descriptive for most of the American countries in the scientific literature.
- This registry will be a source of reliable and safe data about the implementation of the diagnostic and therapeutic options recommended in the different guidelines for the management of acute decompensated HF and during outpatient management.
- There are limitations regarding collecting data on international registries due to the challenging clinical diagnosis of HF.
- There will be (inevitably) missing data and loss to follow-up patients even though the protocol is designed to facilitate data collection and minimize the missing data and missing patients.

Conclusions

AMERICCAASS registry is intended to be the most important HF registry of the continent, mainly because we plan to obtain important information about demographics, aetiology, co-morbidities, and treatment received, either ambulatory or hospitalized from most of the countries. This registry will also be a source of reliable and safe data that will help to implement and/or improve national and regional guidelines to optimize the treatment of these patients.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Conflict of interest

There are no competing interests to be declared.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Data S1. Supplementary Information.

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