I Brazilian Registry of Heart Failure - Clinical Aspects, Care Quality and Hospitalization Outcomes

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Abstract

Background: Heart failure (HF) is one of the leading causes of hospitalization in adults in Brazil. However, most of the available data is limited to unicenter registries. The BREATHE registry is the first to include a large sample of hospitalized patients with decompensated HF from different regions in Brazil.

Objective: Describe the clinical characteristics, treatment and prognosis of hospitalized patients admitted with acute HF.

Methods: Observational registry study with longitudinal follow-up. The eligibility criteria included patients older than 18 years with a definitive diagnosis of HF, admitted to public or private hospitals. Assessed outcomes included the causes of decompensation, use of medications, care quality indicators, hemodynamic profile and intrahospital events.

Results: A total of 1,263 patients (64 ± 16 years, 60% women) were included from 51 centers from different regions in Brazil. The most common comorbidities were hypertension (70.8%), dyslipidemia (36.7%) and diabetes (34%). Around 40% of the patients had normal left ventricular systolic function and most were admitted with a wet-warm clinical-hemodynamic profile. Vasodilators and intravenous inotropes were used in less than 15% of the studied cohort. Care quality indicators based on hospital discharge recommendations were reached in less than 65% of the patients. Intrahospital mortality affected 12.6% of all patients included.

Conclusion: The BREATHE study demonstrated the high intrahospital mortality of patients admitted with acute HF in Brazil, in addition to the low rate of prescription of drugs based on evidence. (Arq Bras Cardiol. 2015; 104(6):433-442)

Keywords: Heart Failure/mortality; Epidemiology; Hospitalization; Inappropriate Prescribing.

Introduction

Heart failure (HF) has been pointed to as an important public health problem and regarded as a new epidemic with high mortality and morbidity, in spite of the advances in current therapeutics. Updated data from the American Heart Association (AHA) estimated a prevalence of 5.1 million individuals with HF in the United States alone between 2007 and 2012. Projections show that the prevalence of HF will increase 46% between 2012 and 2030, resulting in more than 8 million individuals above the age of 18 years with HF². The rising prevalence is probably due to the increase in life expectancy, since HF affects predominantly older age groups².

HF is the leading cause of hospitalization, based on data available from about 50% of the population in South America. The most comprehensive portrait of the situation of hospitalizations for HF in Brazil can be obtained through analyses of DATA-SUS records, with the inherent limitations of a database of an administrative nature. Data show that in 2012 alone there were 26,694 deaths in Brazil due to HF. Of 1,137,572 admissions due to circulatory diseases in that same year, around 21% were due to HF⁴.

The burden becomes even more significant when we consider that almost 50% of all hospitalized patients with this diagnosis are readmitted within 90 days after hospital discharge, and that hospital readmission is one of the main risk factors for death in this syndrome⁵-⁷. Several studies have focused on identifying the factors associated with frequent readmissions⁸-¹⁰. Those usually described in the international literature are inadequate therapy, lack of adherence to treatment, social isolation, or worsening cardiac function. However, in approximately 30-40% of the cases it is not possible to identify the cause of clinical decompensation⁹.

Data on morbidity and consequent costs associated with decompensated HF are undeniable all over the world. In Brazil, there are only a few studies comprehensively and prospectively assessing the demographic, clinical and prognostic characteristics of patients who are admitted with a clinical diagnosis of HF. Isolated initiatives suggest the existence of significant regional differences in several characteristics of patients who are admitted...
with HF in Brazil, but these comparisons are methodologically
limited by often divergent guidelines and inclusion criteria\textsuperscript{3,4}. Thus, the establishment of a national registry which incorporates
a group of public and private hospitals from different Brazilian
regions can portray more accurately which patients are admitted
with a diagnosis of HF, how these patients are treated in their
institutions and what are their short- and long-term prognoses.

The BREATHE study is the first national and multicenter
registry of acute HF that includes all regions of the country, involving 51 public and private hospitals in 21 cities in Brazil.
The aim of this analysis is to describe the clinical features, treatment and prognosis of hospitalized patients admitted with
acute HF in Brazil.

Methods

Delineation

Cross-sectional, observational study (registry) with
longitudinal follow-up.

Hospital Selection

The public and private hospitals that participated in the
Registry of Decompensated Heart Failure of the Department of Heart Failure of the Brazilian Society of Cardiology were
chosen by the research committee. A fixed number of institutions
was allocated for each one of the five regions of the country, and the number of patients per region was defined based on the absolute number of hospitalizations by region in the year 2004 according to the IBGE (Supplement II).

Inclusion and Exclusion Criteria

The methods of BREATHE, as well as its inclusion and exclusion criteria, have been previously described\textsuperscript{11}. Patients older than 18 years, admitted to public or private hospitals with a definitive clinical profile of HF confirmed by
the Boston criteria were considered eligible for the study\textsuperscript{12}. Those patients undergoing myocardial revascularization procedures (coronary angioplasty or surgery) in the last month of the selection and who presented signs of HF secondary to sepsis were excluded from the study.

Definitions of the Study:

a) Clinical and Hemodynamic Profile:
The clinical and hemodynamic profile was defined according to
the classification of Stevenson\textsuperscript{13}, in four hemodynamic profiles according to the findings on physical examination of pulmonary congestion and peripheral perfusion. Patients with acute HF are generally in one of the following subgroups: 1) presence of pulmonary congestion without signs of hypoperfusion (wet and warm); 2) presence of pulmonary congestion associated with hypoperfusion (wet and cold); and 3) hypoperfusion without pulmonary congestion (dry and cold).

b) HF Treatment Targets Doses:
Target doses for the treatment of acute HF, for purposes of evaluation of the data from this study, were the same as those
recommended by the II Guideline of Acute Heart Failure of
the Brazilian Society of Cardiology\textsuperscript{14}.

c) Causes of HF Decompensation:
The main causes of decompensation analyzed included
infection, decompensation from acute valvular disease, poor adherence to drug therapy, excessive sodium intake in the last week, arrhythmias and pulmonary embolism. The classification was determined by the clinical judgment of the local investigator according to the patient’s report.

Follow-up

For the present analysis, in addition to hospital admission
data, data were collected during hospitalization until the date of
medical discharge or intrahospital death.

Outcomes of Interest

The primary outcome of this study was the all-cause
intrahospital mortality. Secondary outcomes included the
proportion of patients who received interventions with
proven benefit demonstrated by care quality indicators (use of angiotensin converting enzyme inhibitors [ACEI] / angiotensin
II receptor blockers [ARB] and use of beta-blockers), readmissions due to HF and cardiovascular mortality.

Ethical Aspects

The protocol was approved by the Research Ethics
Committee (Comitê de Ética em Pesquisa, CEP) of the Hospital
do Coração de São Paulo, SP (HCor) on February 1st, 2011,
under the registration number 144/2011, and following that,
each participating center also had their protocols approved
by their own CEPs. All patients signed a Free and Informed
Consent Form and the clinical study was conducted in
accordance with the principles of the current revision of the
Declaration of Helsinki.

Data Management

The management of the data was performed using the
EDC (Electronic Data Capture) system. Medical charts were
transcribed by Web-charts, sent to the central coordinating
center, and incorporated into a database for validation.
Quality control of the data of the study occurred mainly by
central checking in search of possible inconsistencies (data
without biological plausibility) or incomplete data, and was
reported to the participating centers for confirmation and/or
correction. The Department of Heart Failure of the Brazilian
Society of Cardiology was responsible for the management
of the data of the study.

Sample Size

The first phase of the Brazilian Registry of Decompensated HF predicted the evaluation of 1,200 admissions to the
public and private network in different regions of Brazil. This sample size was determined to represent the largest
Brazilian prospective study of decompensated HF, involving all regions of the country, allowing identification of regional
differences in intrahospital mortality.
Results

Between February 2011 and December 2012, 1,263 patients were included in 51 centers from different Brazilian regions (2 centers in the Northern region [164 patients], 13 centers in the Northeast [209 patients], 5 centers in the Midwest [66 patients], 33 centers in the Southeast [652 patients] and 5 centers in the South [172 patients]). Two patients were excluded from the analysis for meeting exclusion criteria. The flow diagram can be found in Supplement II.

The average age of the patients was 64 ± 16 years, with 73.1% above the age of 75 years and 60% women. Most patients were self-reportedly white (59%), admitted to the public network/Unified Health System (Sistema Único de Saúde, SUS; 64.8%) and from the South/Southeast regions (65.2%). Slightly over half of the patients included had left ventricular systolic dysfunction (58.7%), and the vast majority (70.8%) was hypertensive. Table 1 shows the baseline characteristics of the studied sample, including demographics and prior medical history.

The average age distribution by region showed a statistically significant difference with the inclusion of patients of more advanced age in the Southeastern and Southern regions of Brazil; 2) poor drug adherence was the factor most frequently associated with the studied population, affecting 30.1% and 20.3% of the patients, respectively. Around 11% of the patients had a diagnosis of Chagas disease (Figure 1).

In the analysis of the etiologies by region, patients from the South, Southeast and Northeast showed a predominance of the ischemic etiology (33.6%, 32.6%, and 31.9%, respectively). In patients in the Northern region the hypertensive etiology (37.2%) predominated, while among patients in the Northern region the Chagasic etiology predominated (42.4%) (Table 2).

The main causes of HF decompensation were poor adherence to medication (30%), followed by infections (23%) and inadequate control of water and sodium intake (9%), as shown in Table 3.

As for the clinical and hemodynamic profile on hospital admission, the prevalence was for the wet-warm profile, totaling 67.4% of the cases, whereas the wet-cold and dry-cold profiles accounted for 17.8% and 5.2%, respectively (Figure 2).

Table 4 lists the main procedures performed during hospitalization, as well as the mortality rate during hospitalization. The sum of the deaths in the first 24 hours (17 patients) and after this period (140 patients) totaled 12.6% of the studied cohort. Valve replacement prevailed among the procedures during hospitalization, occurring in 156 patients.

For the treatment of acute HF during hospitalization the use of loop diuretics prevailed (89.8%), followed by beta-blockers (57.1%). The use of intravenous vasodilators (6.6%) and inotropic agents (13.6%) represented a small portion of the therapy in this population (Figure 3).

According to the indicators of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 63.7% of the patients received guidelines on hospital discharge about the correct use of medications, whereas only 34.9% and 16.2% were advised about the diet to be followed at home and prescription of physical activity, respectively (Figure 4).

Discussion

The main findings of this analysis of the study BREATHE are: 1) baseline characteristics show a populational profile of predominantly elderly patients, mainly in the Southern and Southeastern regions of Brazil; 2) poor drug adherence was the factor most frequently associated with

Table 1 – Baseline characteristics of the cohort

| Variables                                      | BREATHE (n = 1,261) |
|------------------------------------------------|---------------------|
| Age (mean+/−SD)*                                | 64.1 ± 15.9         |
| Male gender (%)                                 | 40.0                |
| Prior acute myocardial infarction (%)           | 26.6                |
| Hypertension (%)                                | 70.8                |
| Dyslipidemia (%)                                | 36.7                |
| Prior stroke /TIA†                               | 12.6                |
| Atrial fibrillation (%)                         | 27.3                |
| Depression (%)†                                 | 13.5                |
| Occlusive peripheral arterial disease (%)†      | 10.8                |
| Chronic renal failure (%)†                      | 24.1                |
| Diabetes mellitus (%)                           | 34.0                |
| Chronic obstructive pulmonary disease (%)       | 12.7                |
| Left ventricular ejection fraction (average+/−SD)| 38.8 ± 16.5        |
| Sodium (mean+/−SD)                              | 137 ± 16            |
| Creatinine (mean+/−SD)                          | 1.7 ± 4.8           |
| BNP (median [IQR])§                             | 1,075 (518; 1,890)  |

* SD: standard deviation; † Values calculated on a total of 1,255 patients with complete information; †TIA: transient ischemic attack; BNP: brain natriuretic peptide; ‡IQR: interquartile range.
decompensation; 3) the prescription of drugs, mainly vasodilators, according to current evidence was below the expected rate for this population; and 4) high intrahospital mortality rate.

Patients with advanced age accounted for an important segment of the sample studied in BREATHE and predominated in the South and Southeast regions, where the ischemic etiology was also more prevalent.

Among patients with chronic diseases, approximately 50% do not take medications as prescribed. This poor drug adherence leads to increased morbidity, mortality and costs. In addition to that, advanced age is a risk factor for poor adherence which increases even more with polypharmacy, increasing the likelihood of adverse events.

Studies about drug adherence demonstrate highly variable rates of adherence among patients with HF. A study reported adherence rates of 79% for ACEi/ARB, 65% for beta-blockers and 56% for spironolactone after five years from the first hospitalization for HF. In contrast, the noncompliance rate based on pill count was much lower.

![Figure 1 – Distribution of etiologies of heart failure in the BREATHE registry.](image)

* DCM: dilated cardiomyopathy; † QT: secondary to chemotherapy.

### Table 2 – Distribution of etiologies according to Brazilian regions

| Etiology                        | South          | Southeast       | Midwest         | Northeast       | North          | Total         |
|---------------------------------|----------------|-----------------|-----------------|-----------------|----------------|---------------|
|                                 | n   | %   | n   | %   | n   | %   | n   | %   | n   | %   | n   | %   |
| Ischemic                        | 58  | 33.6| 213 | 32.6| 15  | 22.8| 67  | 31.9| 27  | 16.5| 380 | 30  |
| Idiopathic dilated cardiomyopathy| 12  | 7   | 93  | 14.3| 4   | 6.1 | 41  | 19.6| 33  | 20.1| 183 | 14.5|
| Hypertensive                    | 56  | 32.6| 98  | 15  | 7   | 10.6| 34  | 16.3| 61  | 37.2| 256 | 20.3|
| Chagas disease                  | 4   | 2.3 | 80  | 12.3| 28  | 42.4| 13  | 6.2 | 11  | 6.7 | 136 | 10.8|
| Valvular disease                | 24  | 14  | 80  | 12.3| 2   | 3   | 30  | 14.4| 20  | 12.2| 156 | 12.4|
| Secondary to chemotherapeutic agents | 1   | 0.6 | 2   | 0.3 | 0   | 0   | 2   | 1   | 0   | 0   | 5   | 0.4 |
| Myocarditis                     | 2   | 1.2 | 5   | 0.8 | 2   | 3   | 1   | 0.5 | 0   | 0   | 10  | 0.8 |
| Others                          | 15  | 8.7 | 74  | 11.3| 8   | 12.1| 20  | 9.6 | 12  | 7.3 | 129 | 10.2|
| Missing                         | 0   | 0   | 7   | 1.1 | 0   | 0   | 1   | 0.5 | 0   | 0   | 8   | 0.6 |
| **Total**                       | 172 | 100 | 652 | 100 | 66  | 100 | 209 | 100 | 164 | 100 | 1,263| 100 |
in the CHARM study, in which 11% of the patients took less than 80% of the prescribed pills. Adherence is associated with several factors and should not be regarded as the sole responsibility of the patient. The BREATHE study pointed out that only slightly more than 50% of the patients received guidelines for correctly taking the medications, and only 43.5% were advised about the recognition of worsening of symptoms and future appointments. Preliminary evidence shows that around 35% of the inpatients with acute HF receive appropriate instructions on hospital discharge, with academic centers showing worse performance in this indicator of the JCAHO.

Of still greater relevance and impact on the prescription of medication on discharge is the medication introduced during the hospital phase. This analysis demonstrates that there are still considerable gaps in the treatment of acute HF in Brazil. The treatment frequently does not follow current published guidelines, which may contribute to the high morbidity, mortality and economic cost of this syndrome. The IMPROVE-HF study showed that the addition of each evidence-based therapy was associated with a decreased risk of mortality in 24 months, with incremental benefit. This strong positive association between the use of evidence-based therapies and improved risk-adjusted survival reached a plateau after 4-5 therapies included in the therapeutic armamentarium of the patient with HF.

Despite the fact that the clinical hemodynamic profile wet-warm was the most common in the present study, only 6.6% of the population received intravenous vasodilators, whereas 42.2% of the patients received ACEi during the hospital phase. Around 18% of the patients showed a wet-cold profile on hospital admission, but only 13.6% received

| Decompression cause               | % (n = 1,250) |
|-----------------------------------|--------------|
| Infection                         | 22.7         |
| Poor medication adherence         | 29.9         |
| Increased ingestion of sodium and water * | 8.9         |
| Acute valvular disease            | 6.6          |
| Cardiac arrhythmia                | 12.5         |
| Pulmonary embolism                | 0.4          |
| Others                            | 32.4         |

*Total with complete information 1,242 patients.

| Decompensation cause               | % (n = 1,250) |
|-----------------------------------|--------------|
| Infection                         | 22.7         |
| Poor medication adherence         | 29.9         |
| Increased ingestion of sodium and water * | 8.9         |
| Acute valvular disease            | 6.6          |
| Cardiac arrhythmia                | 12.5         |
| Pulmonary embolism                | 0.4          |
| Others                            | 32.4         |

*Total with complete information 1,242 patients.

Table 4 – Events and procedures during hospitalization

| Events/procedures                  | % (n/total) |
|------------------------------------|-------------|
| Intrahospital mortality            | 12.6 (1,57/1,245) |
| Coronary artery bypass grafting    | 0.7 (9/197)  |
| Valve replacement                  | 12.4 (156/197) |
| Heart transplantation              | 1.2 (15/197)  |
| Coronary angioplasty               | 1.5 (19/197)  |
| Implantable defibrillator/Resynchronizer | 1.2 (15/197) |
| Cardiac pacemaker                  | 1.7 (22/197)  |

* Of the total, only 197 patients had procedures performed during hospitalization.

Figure 2 – Hemodynamic profile on hospital admission.
inotropes. Beta-blockers were prescribed to only 57.1% of the studied sample. In contrast, loop diuretics were prescribed to approximately 90% of the patients.

Results from the analysis of the ADHERE registry suggest that starting vasodilator therapy in the emergency department correlates with shorter hospital stays and fewer transfers to the intensive care unit, as well as higher percentages of asymptomatic patients at hospital discharge. Additionally, there was a substantial improvement in the survival rate of patients receiving intravenous vasodilators (nitroglycerin or nesiritide), compared with those who received intravenous inotropes (dobutamine...
or milrinone)\textsuperscript{24-26}. However, it is possible that patients requiring inotropic therapy have a more advanced form of HF than patients who receive vasodilators.

Analysis of the Euro Heart Survey clearly showed that patients included in randomized clinical trials are a highly selected group and that only a small proportion of the patients in this registry would be eligible. However, beta-blockers and ACEi were prescribed for less than half of the eligible patients and the doses used were below those which have proven to be effective. Therefore, the lack of similarity between patients with HF in clinical practice and those in clinical trials does not adequately explain the underutilization of the therapy\textsuperscript{27-29}.

Intrahospital treatment invariably has a direct impact on clinical events during hospitalization. The prognosis of HF is reserved and directly related to the loss of functional capacity. Data from the Framingham study showed a median survival rate after diagnosis of 1.7 years for men and 3.2 years for women. The high mortality, morbidity and impairment of quality of life related to HF affects primarily the elderly. Although we may observe a consistent and significant survival benefit in patients with HF with use of aggressive pharmacological strategies, the annual mortality of this disease remains high\textsuperscript{30-31}. The CONSENSUS (Cooperative North Scandinavian Enalapril Survival Study)\textsuperscript{32} and PROMISE (Prospective Randomized Milrinone Survival Evaluation)\textsuperscript{33} studies, for example, identified a high proportion of patients with annual mortality exceeding 30%. In more recent studies, the mortality of patients with functional class III-IV after 1 year of optimized treatment, including the routine use of ACEi and beta-blockers, was approximately 10-15\textsuperscript{o}. Although these values are encouraging, such mortality rates are also similar to those observed in many neoplastic diseases.

As for intrahospital mortality, it affects between 3% to 4% of the patients admitted for acute HF in prior studies\textsuperscript{34}, whereas the mortality rate in the BREATHE registry exceeds in two times the rates from American and European registries. In the ADHERE study, intrahospital mortality was 4.0%, and the average hospital stay was 4.3 days\textsuperscript{35}. Similar to the American registry, the Euro Heart Survey presented an overall intrahospital mortality rate of 3.8%, with 90.1% due to a cardiovascular cause. Higher mortality rates were observed in the presence of cardiogenic shock\textsuperscript{36}.

Some limitations inherent to the design of BREATHE should be considered in the interpretation of its results. The diagnosis of acute HF was based only on the Boston criteria and the date of onset of symptoms was not defined, therefore it was not possible to differentiate new acute HF from exacerbation of chronic HF. Consequently, since the population is heterogeneous, the analysis of treatment and prognosis will require appropriate adjustment. In addition, the number of missing data was elevated due to some variables whose completion was not mandatory, interfering with the results found.

**Conclusion**

BREATHE is the first Brazilian registry of acute HF and its results point to the high rate of intrahospital mortality related to low rates of evidence-based therapy prescribed during hospitalization, as well as low percentage of medical guidelines on hospital discharge of patients hospitalized for acute HF in different regions of Brazil. New strategies must be adopted to ensure improvement in the quality of hospital care of this disease.

**Author contributions**

Conception and design of the research: Albuquerque DC, Souza-Neto JD, Bacal F, Rohde LEP. Acquisition of data: researchers BREATHE, Albuquerque DC, Souza-Neto JD, Rohde LEP, Bernardez- Pereira S, Almeida DR. Analysis and interpretation of the data: Albuquerque DC, Rohde LEP, Bernardez-Pereira S, Berwanger O. Statistical analysis: Bernardez-Pereira S. Obtaining financing: Albuquerque DC. Writing of the manuscript: Albuquerque DC, Souza-Neto JD, Bacal F, Rohde LEP, Bernardez-Pereira S, Almeida DR. Critical revision of the manuscript for intellectual content: Albuquerque DC, Souza- Neto JD, Bacal F, Rohde LEP, Bernardez-Pereira S, Almeida DR.

**Potential Conflict of Interest**

No potential conflict of interest relevant to this article was reported.

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**Study Association**

This study is not associated with any thesis or dissertation work.
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