

Assessment of Adherence to Drug Therapy in Patients with Heart Failure Followed at a Specialized Outpatient Clinic

Breno Gabriel Araújo Sampaio de Jesus,¹ Felipe Barros Oliveira,¹ Felipe Caires Araújo Meira,¹ Livia Brito Oliveira,² Fabio Figueirêdo Costa,² Adriana Lopes Latado¹

Universidade Federal da Bahia,¹ Salvador, BA – Brazil

Hospital Universitario Professor Edgard Santos,² Salvador, BA – Brazil

Abstract

Background: Heart failure (HF) is a severe syndrome with high global prevalence. Despite safe and effective pharmacological therapies, its prognosis remains unfavorable, and low treatment adherence is the leading cause of rehospitalizations and worse outcomes.

Objective: To assess treatment adherence and its determinants in patients with HF followed at cardiology outpatient clinics of a specialized hospital.

Methods: A single-center, cross-sectional, observational study was conducted, with data collection via in-person interviews. Treatment adherence was measured using the Brief Medication Questionnaire (BMQ). Variables associated with adherence with $p < 0.10$ were included in a multivariate model, considering a significance level of 5%.

Results: A total of 200 patients were included; 79.6% showed low adherence according to the BMQ, and 52.6% showed low adherence in the “regimen” domain. Only 3 (1.6%) patients presented no barriers to adherence. In multivariate analysis, being married (odds ratio [OR] 0.40; 95% confidence interval [CI] 0.16–0.96; $p = 0.042$), prior acute coronary syndrome (ACS) (OR 0.21; 95% CI 0.08–0.51; $p < 0.001$), education level (OR 0.90; 95% CI 0.82–0.98; $p = 0.018$), higher number of prescribed medications (OR 1.44; 95% CI 1.03–2.05; $p = 0.037$), and HF with improved ejection fraction (OR 2.76; 95% CI 1.06–7.63; $p = 0.042$) were independent predictors of low adherence.

Conclusion: Low therapeutic adherence among patients with HF is prevalent and influenced by socioeconomic factors, social support, polypharmacy, and clinical characteristics. The results reinforce the need for health education and the simplification of therapeutic regimens.

Keywords: Heart Failure; Medication Adherence; Ambulatory Care.

Introduction

Heart failure (HF) is a severe syndrome affecting more than 23 million people worldwide.¹ In spite of robust evidence demonstrating the efficacy and safety of pharmacological treatment, including different medication classes,^{1,2} prognosis remains poor, particularly in advanced stages of the disease, with a 5-year survival below 35%.¹

Treatment adherence is defined as the extent to which patient behavior corresponds to healthcare professionals' recommendations.^{3–5} It is a crucial factor in the management of chronic conditions such as HF, where low adherence

is associated with increased rehospitalizations and worse outcomes.^{1,2,5–7} Treatment adherence is multifactorial, and it is influenced by socioeconomic factors, patient characteristics, healthcare systems, clinical conditions, and therapeutic regimens.⁴

Despite the recognized importance of appropriate medication use, gaps remain in the characterization of adherence levels across different HF populations.⁸ Furthermore, it is essential to identify modifiable factors that impact adherence in order to develop effective strategies to improve it.^{6,7} Therefore, the objective of this study was to describe medication adherence levels among patients with HF followed at cardiology outpatient clinics of a specialized hospital.

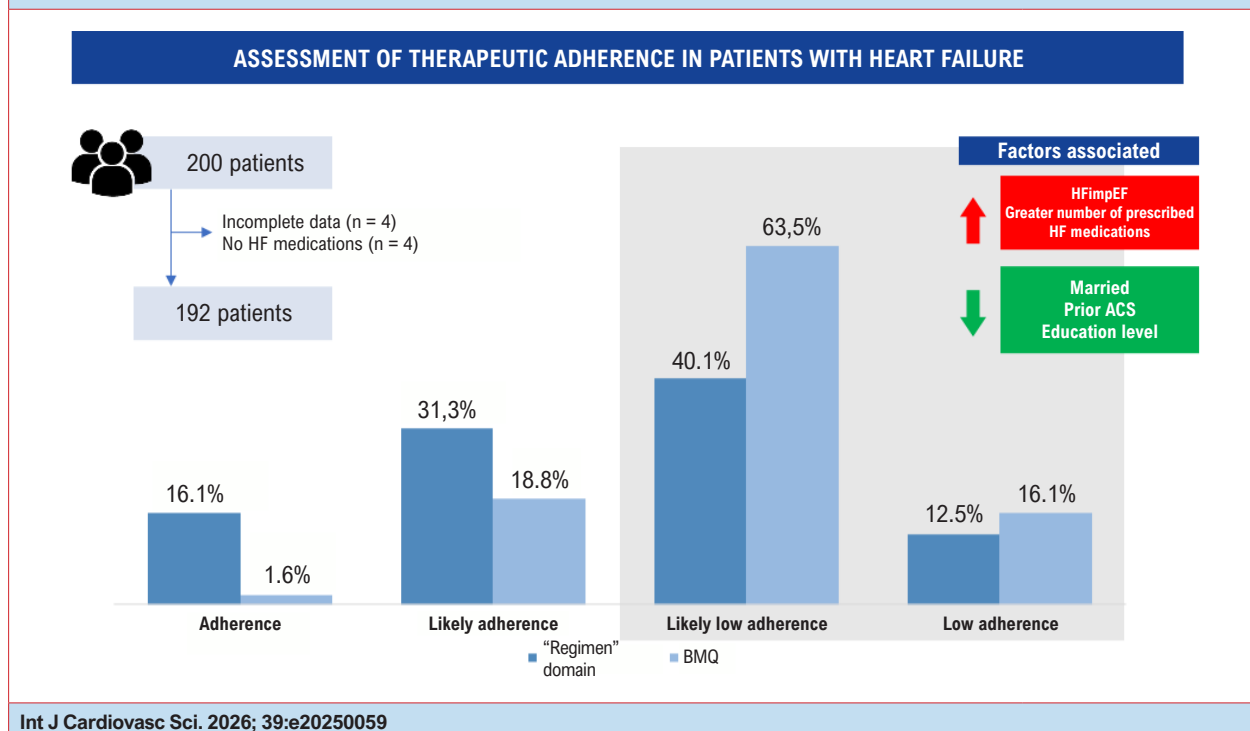
Methods

Study design and sampling

This single-center, descriptive, cross-sectional, observational study was conducted at a specialized outpatient clinic of a university hospital in the Northeast Region of Brazil. Adult patients (≥ 18 years old) with a confirmed diagnosis

Mailing Address: Breno Gabriel Araújo Sampaio De Jesus •
Universidade Federal da Bahia. Av. Reitor Miguel Calmon, S/N. Postal Code:
40110-909. Vale do Canela, Salvador – Brazil
E-mail: brenogabrieldejesus@gmail.com
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Central Illustration: Assessment of Adherence to Drug Therapy in Patients with Heart Failure Followed at a Specialized Outpatient Clinic

Assessment of Adherence to Medication Therapy in Patients with Heart Failure. ACS: acute coronary syndrome; BMQ: Brief Medication Questionnaire; HF: heart failure; HFimpEF: heart failure with improved ejection fraction.

of HF who were treated at cardiology outpatient clinics between September 2023 and May 2024 were included. Diagnosis confirmation was obtained by reviewing patient medical records, considering clinical history and results of complementary tests (electrocardiogram, echocardiogram, cardiac magnetic resonance imaging, and myocardial scintigraphy). Patients who refused to sign the free and informed consent form were excluded from the study.

Study procedures

Participants were recruited via in-person interviews during pre-scheduled clinical visits at the cardiology outpatient clinics. A treatment adherence questionnaire and a data collection form were applied, and electronic medical records were reviewed.

Variables included age, sex, race, marital status, education level, monthly income, comorbidities, medical history, functional assessment of HF, left ventricular ejection fraction (LVEF), and prescribed drug therapy. LVEF was used to classify patients into the following categories: heart failure with reduced ejection fraction (HFrEF) for LVEF $\leq$ 40%; heart failure with mildly reduced ejection fraction (HFmrEF) for LVEF between 40% and 50%; heart failure with preserved ejection fraction (HFpEF) for LVEF $\geq$ 50%; and heart failure with improved ejection fraction (HFimpEF), if a patient with prior HFrEF showed an improvement of $\geq$ 10 percentage points, with a second LVEF measurement $>$ 40%.^{9,10}

Treatment adherence was determined using the Brief Medication Questionnaire (BMQ), an instrument validated in Portuguese that identifies barriers related to the medication regimen over the past week, beliefs (perceived effectiveness and discomfort), and recall.^{11,12} Answers were compared against the medical prescription to calculate the score for each domain. A positive answer in any domain indicated a positive screen for that specific adherence barrier. Patients were classified into the following four categories: adherence (no positive domains), likely adherence (one positive domain), likely low adherence (two positive domains), and low adherence (three positive domains). In the Brazilian validation study, the authors recommended using the "regimen" domain to classify adherence, given that it showed the best balance between sensitivity (77%) and specificity (58.3%), notwithstanding its limited performance.¹²

Additionally, the 2022 Brazil Criterion was used to classify socioeconomic strata (A, B1, B2, C1, C2, or DE).¹³ Data were recorded using Research Electronic Data Capture (REDCap®) software by means of study-specific data collection instruments.

Statistical analysis

Statistical analyses were performed using R software, version 4.3.1 (R Foundation for Statistical Computing,

Vienna, Austria). Categorical variables were described as proportions, and continuous variables were described as means (standard deviation) or medians (interquartile range). The normality of continuous variables was assessed using the Shapiro–Wilk test and distribution characteristics (kurtosis and skewness). Bivariate analyses between clinical-demographic variables and adherence outcomes (assessed via the BMQ and the “regimen” domain) were conducted using Pearson’s chi-square test or Fisher’s exact test for categorical variables, and the unpaired Student’s t-test or Mann–Whitney U test for continuous variables, as appropriate. For these analyses, adherence levels were recategorized into two strata: “good adherence” (adherence and likely adherence) and “low adherence” (likely low adherence and low adherence). 12,14 Variables associated with the outcomes at $p < 0.10$ were selected for multivariate logistic regression models. The measure of association obtained was the odds ratio (OR), with respective 95% confidence intervals (95% CI). The significance level adopted was 5%.

Ethical aspects

In accordance with Resolution 466/2012 of the Brazilian National Health Council, this study received approval from the local Research Ethics Committee (CAAE 73034723.0.0000.0049).

Results

Sample characteristics

This study included 200 patients, 8 of whom were excluded from the outcome analysis due to incomplete data ($n = 4$) or absence of HF medication use at recruitment ($n = 4$). A predominance of female sex (56.5%) was observed, with a mean age of 62.8 (12.9) years, and the majority self-identified as mixed race or Black (86.5%). Regarding education level, 67.8% reported fewer than 12 years of formal schooling, indicating an educational level below completed high school. Median monthly income was 1.5 (1–2) times minimum wage, with 93.4% belonging to socioeconomic classes C1, C2, or DE (Table 1).

Regarding clinical characteristics, 42.5% of patients had HFrEF. The median values for the lowest recorded LVEF and the most recent LVEF were 37% (28%–49%) and 46% (36%–60%), respectively. The most prevalent comorbidities were systemic arterial hypertension (82%), dyslipidemia (75%), and diabetes mellitus (44%). Half of the patients had a history of hospitalization for HF decompensation, and 71.4% had been hospitalized for other causes.

The most advanced stages (III and IV) of the New York Heart Association functional classification for HF had been reached by 53% of the sample. Overall, 89% had current or previous HF symptoms, and 4.5% were refractory to clinical treatment (Table 1).

Table 1 – Patients’ baseline sociodemographic and clinical characteristics

Characteristics	N = 200
Age (years)*	62.8 (12.9)
Sex†	
Female	113 (56.5%)
Race†	
White	7 (13.5%)
Mixed race or Black	173 (86.5%)
Marital status†	
Unmarried	117 (58.5%)
Married	83 (41.5%)
Years of education‡	7 (5 – 12)
Monthly income (times minimum wage)‡	1.5 (1 – 2)
Socioeconomic class†	
A	1 (0.5%)
B1	1 (0.5%)
B2	11 (5.6%)
C1	44 (22.2%)
C2	65 (32.8%)
DE	76 (38.4%)
LVEF (%)‡	46 (36 – 60)

HF classification[†]

HFrEF	85 (42.5%)
HFmrEF	32 (16%)
HFpEF	50 (25%)
HFimpEF	33 (16.5%)

Most recent NYHA functional classification[†]

NYHA I	61 (30.5%)
NYHA II	107 (53.5%)
NYHA III	24 (12%)
NYHA IV	8 (4%)

Comorbidities[†]

Systemic arterial hypertension	64 (82%)
Dyslipidemia	150 (75%)
Diabetes mellitus	88 (44%)
Mood and/or anxiety disorder	62 (31%)
Chronic kidney disease	56 (28%)
Prior ischemic stroke	55 (27.5%)
Prior ACS	45 (22.5%)
Atrial fibrillation or flutter	31 (15.5%)
Use of permanent pacemaker	19 (9.5%)
Chronic obstructive pulmonary disease or asthma	16 (8%)

Prior hospitalization for decompensated HF[†]

101 (50.8%)

HF: heart failure; HFimpEF: heart failure with improved ejection fraction; HFmrEF: heart failure with mildly reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; NYHA: New York Heart Association; LVEF: left ventricular ejection fraction; ACS: acute coronary syndrome. * Mean (standard deviation); [†] n (%); [‡] median (interquartile range).

Pharmacological treatment and adherence

The characteristics of pharmacological treatment are detailed in Table 2. Regarding the “regimen” domain, only 31 (16.1%) patients showed no barriers to good adherence. Barriers related to “beliefs” and “recall” were identified in 19.3% and 91.1% of the sample, respectively. Considering all three BMQ domains, only 3 patients (1.6%) had a negative screen (Central Illustration). When dichotomizing the outcome, the prevalence of low adherence was 79.6% according to the BMQ and 52.6% based on the “regimen” domain. Furthermore, 43.9% reported some difficulty reading medication packaging; 25.5% reported difficulty remembering to take their medications; and 55.6% faced barriers to accessing the medications.

Comparison between good and low adherence groups

Bivariate analyses were conducted between clinical and sociodemographic characteristics (Tables 1 and 2) and adherence as assessed by the BMQ. Low adherence was more frequent among unmarried patients ($p = 0.036$) and those with HFrEF or HFimpEF ($p = 0.006$), whereas a history of acute coronary syndrome (ACS) was associated with a lower prevalence of this outcome ($p = 0.004$).

Additionally, patients with low adherence had fewer years of formal schooling (6 [5–12] vs. 11 [6–12] years; $p = 0.008$), lower monthly income (1 [1–2] vs. 1 [1–3] times minimum wage; $p = 0.024$), lower LVEF (43% [35–60] vs. 57% [38.5–62]; $p = 0.037$), and a higher number of HF medications (4 [3–5] vs. 3 [2–4]; $p = 0.002$).

In the “regimen” domain, low adherence was associated with lower education level (6 [4–11] vs. 9.5 [6–12] years; $p < 0.001$), lower income (1 [1–2] vs. 2 [1–2.5] times minimum wage; $p = 0.010$), and a higher number of medications (4 [3–5] vs. 3 [2–5]; $p < 0.001$). More advanced age (65 [13] vs. 61 [12] years; $p = 0.032$) and the presence of more than two comorbidities ($p = 0.016$) were also associated with low adherence.

In the multivariate model for low adherence based on the BMQ (Table 3), being married and a history of ACS maintained an independent association with better adherence. LVEF was excluded from the model due to potential collinearity with HF classification. In the analysis of the “regimen” domain (Table 4), higher education level was associated with higher adherence, whereas a higher number of prescribed HF medications was associated with lower adherence. Additionally, patients with HFimpEF showed lower adherence than those with HFrEF.

Table 2 – Medication therapy prescribed for patients with HF

Characteristics	N = 200
Medications*	
ACEI, ARB, or ARNI	178 (89%)
Beta-blocker	167 (83.5%)
Aldosterone antagonist	121 (60.5%)
Loop diuretic	107 (53.5%)
SGLT2 inhibitor	83 (41.5%)
Thiazide diuretic	38 (19%)
Digitalis	26 (13%)
Hydralazine/isosorbide dinitrate	26 (13%)
Ivabradine	1 (0.5%)
Number of medications†	7 (5–9)
Number of HF medications†	4 (3–5)
Daily frequency of medication (times/day)†	3 (2–3)
Dosing regimen*	
Regimen with 1 daily dose	26 (13.5%)
Regimen with ≥ 2 daily doses	166 (86.5%)
Monthly drug treatment costs (Brazilian reais)†	200 (70–350)
Source of funding for medication treatment*	
Exclusively out-of-pocket	28 (14.1%)
Out-of-pocket and via SUS	136 (68.7%)
Exclusively via SUS	34 (17.2%)

ACEI: angiotensin-converting enzyme inhibitor; ARB: angiotensin receptor blocker; ARNI: angiotensin receptor-neprilysin inhibitor; SGLT2: sodium-glucose cotransporter 2; SUS: Brazilian Unified Health System; HF: heart failure. *n (%); †median (interquartile range).

Discussion

This study identified a high prevalence of low adherence among patients with HF, reaching 52.6% in the “regimen” domain and 79.6% on the overall BMQ. Nearly all patients faced barriers to adherence, with the “recall” domain being the most frequently affected. Marital status (married), a history of ACS, and higher education levels were observed to be factors associated with better adherence. Additionally, in the “regimen” domain, adherence levels declined as prescription complexity increased and among patients with HFimpEF, compared to those with HFrEF.

Assessment of treatment adherence is essential to planning interventions that improve outcomes in chronic conditions.⁷ Low adherence poses an important challenge, especially in developing countries like Brazil,^{4,14,15} due to resource scarcity and healthcare access inequalities.¹⁶ Reported medication adherence levels among patients with HF vary widely in the literature, ranging from 9% to 98%,^{8,17} reflecting a lack of standardized measurement methods. In Brazil, few studies

have been designed to describe adherence in patients with non-decompensated HF. In 2020, Farah reported a low adherence rate of 24.7%, measured via questionnaire, in 400 patients with HF using implantable electronic cardiac devices.¹⁸ In 2024, Lima et al. identified low adherence in 9.4% of a sample of 340 patients.¹⁹ Another publication with sociodemographic characteristics similar to those of the present study found a low adherence rate of 72.8%.²⁰

Better socioeconomic conditions and higher education levels have been associated with improved medication adherence across both measurement methods, suggesting that higher socioeconomic status plays a relevant and consistent role in adherence behavior. HF treatment requires multiple medications and lifestyle changes.^{1,2} Patients with lower education levels are expected to face greater difficulties in understanding the complexity of the treatment and the guidance provided by healthcare professionals, which impacts appropriate self-care decision-making.^{14,15,17,21–23} In a previous study assessing the health literacy of HF patients, the majority

Table 3 – Multivariate model for predicting low adherence to HF medication therapy according to the BMQ*

Predictor variable	OR (95% CI)	p value
Married	0.40 (0.16–0.96)	0.043
Prior ACS	0.21 (0.08–0.50)	< 0.001
Race		
White	Reference	Reference
Mixed race or Black	1.86 (0.62–5.34)	1.86 (0.62–5.34)
LVEF classification		
HFrEF	Reference	-
HFpEF	0.41 (0.13–1.23)	0.113
HFmrEF	0.40 (0.12–1.29)	0.122
HFimpEF	2.59 (0.54–20.35)	0.285
Any comorbidity in addition to HF	7.14 (0.90–56.82)	0.056
Income	0.80 (0.60–1.04)	0.109
Number of HF medications prescribed	1.27 (0.91–1.80)	0.168
Education level	0.94 (0.85–1.05)	0.279

CI: confidence interval; HF: heart failure; HFimpEF: heart failure with improved ejection fraction; HFmrEF: heart failure with mildly reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; LVEF: left ventricular ejection fraction; OR: odds ratio; ACS: acute coronary syndrome.

* Multivariate binomial logistic regression.

Table 4 – Multivariate model for predicting low adherence to HF medication therapy based on the “regimen” domain of the BMQ*

Predictor variable	OR (95% CI)	p value
Socioeconomic class		
A, B1, or B2	Reference	-
C1, C2, or DE	3.19 (0.55–22.12)	0.210
Diabetes mellitus	1.51 (0.74–3.09)	0.261
Atrial fibrillation	1.81 (0.72–4.85)	0.216
LVEF classification		
HFrEF	Reference	-
HFpEF	1.23 (0.49–3.13)	0.655
HFmrEF	0.83 (0.30–2.28)	0.709
HFimpEF	2.76 (1.06–7.63)	0.042
More than 2 comorbidities in addition to HF	1.66 (0.72–3.90)	0.235
Age	1.01 (0.98–1.04)	0.453
Income	0.97 (0.73–1.26)	0.806
Education level	0.90 (0.82–0.98)	0.015
Number of HF medications prescribed	1.35 (1.01–1.83)	0.045

CI: confidence interval; HF: heart failure; HFimpEF: heart failure with improved ejection fraction; HFmrEF: heart failure with mildly reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; LVEF: left ventricular ejection fraction; OR: odds ratio. * Multivariate binomial logistic regression.

of those facing barriers in the “regimen” domain of the BMQ had inadequate health literacy, highlighting an association between lower education level and low adherence, possibly due to a lack of understanding of the disease.^{22,23} Accordingly, educational interventions are essential for both preventing adverse clinical outcomes and promoting self-care in the management of chronic diseases, particularly among patients with low health literacy.^{5,24,25} A multidisciplinary team comprising physicians, pharmacists, nurses, and other healthcare professionals should be central to the care strategy; furthermore, this appears to be a cost-effective approach in diverse countries.^{5,7,8,22,24}

Difficulties in obtaining medications were reported by more than half of the patients in our sample, which was predominantly characterized by lower socioeconomic classes and lower monthly household income. Cost-related non-adherence is the most common cause of low adherence, influenced by monthly income and the need to pay for treatment out-of-pocket.²⁶ Large population-based studies in the United States have found a high prevalence of cost-related non-adherence, especially among individuals with chronic diseases.^{27,28} In 2021, Kherallah et al. reported that this behavior was independently associated with female sex, low monthly income, and the presence of comorbidities; these characteristics were predominant in our sample. The expansion of public policies subsidizing healthcare costs proved effective in reducing low adherence rates in the United States.²⁷ Similarly, data from a population-based survey conducted in Brazil involving 11,842 individuals showed that patients with chronic conditions who received medication through the Brazilian Unified Health System (SUS) demonstrated higher adherence to drug therapy, highlighting the impact of costs on patient adherence in Brazil.¹⁴

The presence of comorbidities was associated with a higher prevalence of low adherence, although this relationship did not retain statistical significance in multivariate analyses. In patients with multiple comorbidities, polypharmacy and increased treatment complexity and costs exacerbate low adherence.^{14,27,29} In an analysis of the CHARM trial involving 7,599 patients with HF, the number of comorbidities and medications was associated with worse adherence.³⁰ The number of medications and daily doses, which have been identified as a barrier in several studies,^{23,29} can be reduced by means of interventions that simplify therapeutic regimens, which have shown to be effective in improving appropriate medication use.^{3,5,7,24,29,31}

Specific comorbidities, such as diabetes and atrial fibrillation, were more prevalent in the low adherence group, although multivariate analysis did not demonstrate a significant independent association. The literature on this relationship is conflicting. In 2018, Peres et al. reported worse adherence among patients with diabetes and HF, whereas Bagchi et al. associated diabetes and coronary artery disease with better adherence in 2007.^{32,33} Patients with HF and atrial fibrillation have worse prognosis,³⁴ and the need for anticoagulation to prevent thromboembolic events adds complexity to treatment, impacting adherence due to concerns regarding side effects and drug interactions.³⁵

Moreover, polypharmacy is common in patients with both conditions.³⁵ Conversely, a history of ACS was a predictor of good adherence, possibly due to greater disease severity, which may raise patient awareness regarding the importance of treatment.¹⁷

Elderly patients generally face more comorbidities, polypharmacy, and a greater tendency toward forgetfulness, all of which are factors that hinder treatment adherence.^{24,25} In our study, we observed no differences in adherence between sexes, which is consistent with the literature.^{14,36} Mixed race and Black patients showed a higher prevalence of low adherence. The literature reiterates racial disparities in medication adherence among patients with HF,³⁷ which may be attributed to unfavorable socioeconomic conditions, lower health literacy, and greater difficulty accessing healthcare. Additionally, social support plays a crucial role in this association,^{4,23,36} with studies indicating that the lack of a consistent support network is associated with worse adherence.¹⁷

Patients with HFimpEF often experience significant symptomatic improvement, which may contribute to a mistaken perception of cure and a reduced appreciation for ongoing treatment. Observational evidence has indicated that the discontinuation of disease-modifying therapies is common in this group and is associated with worse outcomes, including the recurrence of ventricular dysfunction.³⁸ Although specific data on adherence in HFimpEF remain limited, these findings support a plausible hypothesis for lower therapeutic engagement, reinforcing the need for targeted education regarding the chronic nature of the disease.

This study has some limitations. First, it has been recognized that self-report questionnaires tend to overestimate good adherence.^{3,39} Consequently, the proportion of patients with good adherence found in this study may be even lower than reported. The cross-sectional study design precludes the establishment of risk or causal relationships between the variables of interest. Furthermore, a cross-sectional study does not allow for the observation of changes in adherence behavior over time or in response to potential interventions. Another point to consider is that this is a single-center study using convenience sampling, which may limit the generalizability of data to other populations and introduce selection bias due to the specific profile of patients treated at the facility. However, the sociodemographic characteristics of our sample are comparable to national Brazilian statistics, suggesting that the findings may, to a certain extent, reflect the broader reality of the HF patient population nationwide.^{6,40}

One of the key strengths of this study is the relevance of assessing treatment adherence in patients with HF, an essential aspect for understanding the effectiveness of the care provided at our outpatient clinic. Despite the limitations, the data obtained are highly valuable for planning comprehensive care, enabling more efficient interventions tailored to patients' actual needs. This study's results provide an important foundation for structuring and continuously improving the outpatient service, enabling the development of strategies to enhance the quality of care and patient monitoring, with the aim of positively impacting clinical outcomes.

Conclusion

The prevalence of low adherence to drug therapy among patients with HF was a significant issue in our sample. This behavior is influenced by socioeconomic determinants, social support, polypharmacy, and factors related to patients' clinical conditions. These findings underscore the need to promote health education and to implement strategies that simplify therapeutic regimens whenever possible. Furthermore, they provide valuable insights for optimizing the quality of care provided in outpatient settings, with the aim of improving adherence and clinical outcomes.

Author Contributions

Conception and design of the research: Jesus BGAS, Latado AL; acquisition of data: Jesus BGAS, Oliveira FB; analysis and interpretation of the data and statistical analysis: Jesus BGAS, Oliveira LB, Latado AL; writing of the manuscript: Jesus BGAS, Oliveira FB, Meira FCA, Latado AL; critical revision of the manuscript for intellectual content: Costa FF, Latado AL.

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.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of HUPES-UFBA/EBSERH under the protocol number Parecer 2.626.243 / CAE 73034723.0.0000.0049. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

Use of Artificial Intelligence

The authors did not use any artificial intelligence tools in the development of this work.

Availability of Research Data

All datasets supporting the results of this study are available upon request from the corresponding author.

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