RESEARCH ARTICLE

Heart failure treatment patterns: A pharmacoepidemiological descriptive study in Colombia (The HEATCO study)

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Citation: Machado-Duque ME, Gaviria-Mendoza A, Valladales-Restrepo LF, Sebastián Franco J, Forero MdR, Vizcaya D, et al. (2025) Heart failure treatment patterns: A pharmacoepidemiological descriptive study in Colombia (The HEATCO study). PLoS One 20(6): e0325515. https://doi.org/10.1371/journal.pone.0325515

Editor: Francesco Curcio, University of Naples Federico II, ITALY

Received: January 27, 2025

Accepted: May 14, 2025

Published: June 24, 2025

Peer Review History: PLOS recognizes the benefits of transparency in the peer review process; therefore, we enable the publication of all of the content of peer review and author responses alongside final, published articles. The editorial history of this article is available here: https://doi.org/10.1371/journal.pone.0325515

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Abstract

Introduction

Heart failure is a common condition associated with significant mortality. *Objective*: to determine the prescription patterns of medications for the treatment of heart failure in a cohort of patients from Colombia.

Methods

This was a retrospective study based on the clinical records of patients diagnosed with heart failure between 2019 and 2020. Sociodemographic, clinical, paraclinical, and pharmacological variables and the specialty of the treating physician were identified. Patients were classified according to functional class, stage, and left ventricular ejection fraction (LVEF).

Results

A total of 4742 patients were evaluated, with a mean age of 68.2 ± 13.8 years and a male predominance (61.3%). A total of 92.0% were classified as stage C and 54.8% as functional class I, the mean LVEF was 42.9 ± 14.8%, and 32.53% had reduced LVEF. 30.7% did not have LVEF data. The most common causes were ischemic heart disease (44.0%) and arterial hypertension (29.7%). A total of 5.2% had hospitalizations for heart failure in the last year, and 75.6% were attended by a general practitioner. These patients were treated with β-blockers (88.3%), renin-angiotensin-aldosterone system inhibitors (RAASis) (83.1%), loop diuretics (46.8%), and mineralocorticoid receptor antagonists (MRAs) (46.5%). Triple therapy with RAASis + β-blockers+MRAs was received by 56.4% of patients with reduced LVEF, 32.8%

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Data availability statement: data available at https://www.protocols.io/private/520BB3503DB111F0803E0A58A9FEAC02.

Funding: This work was supported by Bayer AG, (Bogotá, Colombia).

Competing interests: Manuel Machado-Duque have a contractual relationship with Audifarma SA and Institución Universitaria Visión de las Américas. Andres Gaviria-Mendoza have a contractual relationship with Audifarma SA and Institución Universitaria Visión de las Américas. Luis Valladales-Restrepo have a contractual relationship with Audifarma SA and Institución Universitaria Visión de las Américas. Juan-Sebastian Franco are full-time employee of Bayer Colombia. Maria del Rosario Forero are full-time employee of Bayer Colombia. David Vizcaya are full-time employee of Bayer Hispania (Spain). Jorge E. Machado-Alba have a contractual relationship with Universidad Tecnológica de Pereira and Audifarma SA. This does not alter our adherence to PLOS ONE policies on sharing data and materials.

with mildly reduced LVEF and19.5% with preserved LVEF, while quadruple therapy adding a sodium-glucose cotransporter-2 inhibitor (SGLT2i) was given just to 4.6% with reduced LVEF.

Conclusion

The treatment that patients with heart failure with preserved LVEF is relatively simpler and is closer to the recommendations, while the proportion of indicated therapies according to guidelines is lower among those with reduced LVEF.

Introduction

Heart failure (HF) is a common condition that is increasingly prevalent worldwide, with an estimated 64 million people suffering from this disease according to reports in 2023 [1]; HF is currently estimated to affect approximately 2% of the world's population, reaching up to 10% among those over 75 years of age [2]. In Colombia, an overall prevalence of 2.3% was estimated for 2018, which would indicate that more than a million Colombian patients had HF [3].

The classification of HF has been given from different points of view, and each of these can be complementary to the others for diagnostic, therapeutic, and follow-up purposes. HF can be classified based on manifestation into New York Heart Association (NYHA) functional classes I to IV, by disease progression into American College of Cardiology (ACC) and American Heart Association (AHA) stages A to D (ACC/AHA), and according to left ventricular ejection fraction (LVEF) (reduced ≤40% and preserved ≥ 50%) (Yancy et al., 2017). Particularly, these classifications are important to establish the treatment for HF because there are drugs, including renin-angiotensin-aldosterone system inhibitors (RAASis), such as angiotensin II receptor blockers (ARBs) and angiotensin-converting enzyme inhibitors (ACEIs), as well as β-blockers, that are indicated in practically all stages of HF [4,5], unlike drugs such as loop diuretics, which are indicated in stage C patients with congestive symptoms, or mineralocorticoid receptor antagonists (MRAs) in the same patient population with the addition of reduced LVEF (HFrEF); similarly, the use of ARBs plus neprilysin inhibitors (ARNIs) is recommended for patients with persistent symptoms [6], which together with other drugs with neurohormonal effects (ARBs, ACEIs, MRAs) can improve survival, especially in cases of HFrEF [7]. The use of other therapies such as ivabradine, digoxin, and oral vasodilators and the use of devices such as cardiac resynchronization in different particular indications must also be recognized [8]. In general, the treatment of HF should be multidisciplinary to achieve the appropriate and indicated use of drugs and proper treatment compliance, Due to current evidence of new therapies with endocrine, renal and cardiac effects [6]. In the Colombian context, a study by Rojas-Sanchez et al. in 2014 reported in a sample of 161 patients that 38.5% used ACEIs, 49.7% used ARBs, 95.0% used β-blockers, 68.9% used spironolactone, 68.9% used furosemide, and 41.6% used digoxin; a drug therapy noncompliance rate of 16.1% was reported [9].

The Colombian health system offers universal coverage to the entire population through two insurance schemes, one contributory or paid by the employer and the worker, and another subsidized by the state for people without the ability to pay, both of which have a benefit plan that includes most drugs required for the treatment of HF. It is important to know the treatment patterns among patients with HF in a larger sample representing different regions of the country, as well as to be able to evaluate the indications for the use of each drug according to the stage and LVEF and the introduction of new therapies, information that is not available and may be of interest to multiple parties in the health system. Therefore, the objective of this study was to determine the prescription patterns of drugs for the treatment of HF in a group of patients affiliated with one healthcare insurer of Colombia between 2019 and 2020.

Materials and methods

A descriptive, retrospective study was carried out on the prescription patterns of drugs used in the treatment of HF from a population-based drug dispensing database and clinical records. The prescriptions of adult patients diagnosed with HF from June 01, 2019, to May 31, 2020, were analyzed.

The initial information was obtained from the drug dispensing database of Audifarma S.A., the main pharmaceutical manager in Colombia for the delivery of institutional drugs to outpatients and hospital patients, including patients diagnosed with HF, according to the International Classification of Diseases, Tenth Revision (ICD-10), with the dispensing of some medications during the observation period in outpatient context. Subsequently, individuals who were affiliated with one insurer of the contributory scheme were selected (The insurer provided authorization for access to the clinical record), and their clinical records were reviewed for clinical variables of HF and comorbidities. No exclusion criteria were considered for this study.

From the information on the dispensing of drugs to the included population, the data from the electronic clinical records of the patients were obtained by a group of trained physicians. In addition, two researchers consolidated and validated the information for inconsistent data and errors. The following groups of variables were recorded:

- Sociodemographic: Sex, age, city where health care was sought, and department or region of the country (Bogotá-Cundinamarca, Caribbean region, Central region, Eastern region, Pacific region and Amazon-Orinoquía region)
- Diagnosis and comorbidities: Primary and secondary diagnoses of heart failure according to ICD-10 codes (I50.0; I50.1; I50.9; I11.0; I11.9; I13.0; I13.1; I13.2; I13.9; I42.0; I42.1; I42.2; I51.0; I51.1-I51.9). Each patient was identified according to the classification of a) the NYHA, b) the ACC/AHA, and c) reduced or preserved LVEF. Information on comorbidities was obtained during the entire observation period, including the etiology of heart failure.
- Hospitalizations: The number of hospitalizations and visits to the emergency department during the study period was recorded from the outpatient primary care clinical record.
- Prescribing physician: The specialty of the prescribing physician was identified: general practitioner, internist, cardiologist, pulmonologist, or other.
- Symptoms and signs/paraclinical parameters: a) Symptoms and signs included dyspnea, fatigue, lower limb edema, etc. b) Paraclinical parameters included LVEF (reduced (HFrEF) ≤40%, Mildly reduced (HFmrEF) 41–49% and preserved (HFpEF) ≥50%, no data recorded) – (Left ventricular ejection fraction value was obtained from the report in the medical record of the first echocardiogram recorded during the observation period), creatinine and glomerular filtration rate (GFR), which was calculated by CKD-EPI equation.
- Drugs used for HF: The information of drugs used in the treatment of HF was collected, including active substance, mean dose, dosage form and frequency of use by LVEF classification. The defined daily dose (DDD) was used as the unit of measurement for drug use, according to the recommendations of the World Health Organization (WHO).

a. Comedications: The following were identified: a) antidiabetics, b) antihypertensives and diuretics, c) lipid-lowering agents, d) antiulcer agents, e) antidepressants, f) anxiolytics and hypnotics, g) thyroid hormone, h) antipsychotics, i) antiepileptics, j) analgesics and anti-inflammatories, k) bronchodilators and/or inhaled corticosteroids, l) antiplatelet agents, and m) anticoagulants, among others.

Statistical analysis

The data were analyzed with the statistical package SPSS Statistics, version 28.0 for Windows (IBM, USA). A descriptive analysis was performed with frequencies and proportions expressing qualitative variables and central trend and dispersion measures for quantitative variables. For quantitative variables, normality was initially tested using the Kolmogorov–Smirnov test; for those variables with a normal distribution, means and standard deviations are reported, and for those with asymmetrical distribution, medians and interquartile ranges are reported. A division of the sociodemographic, clinical, and comorbidity characteristics was made according to LVEF. Regarding the use of medications, the average dose, relationship with the daily dose defined by the WHO, and frequency of use by LVEF classification were identified for those prescribed for HF. UpSet library version 0.6.1 in Python was used to generate the combined drug consumption figure [10].

Bioethical considerations

The protocol was classified according to Resolution 8430/1993 of the Ministry of Health as research without risk. The ethical principles of justice, nonmaleficence, beneficence, and confidentiality established by the Declaration of Helsinki were respected. The protocol was approved by the Bioethics Committee of the Universidad Tecnológica de Pereira (approval number: 12–150221. Date February 16 of 2021). According to Resolution 8430 of the Colombian Ministry of Health, observational research carried out on clinical records does not require informed consent. Date of access to clinical records: December 9 of 2021 to June 30 of 2022. No personal data of any of the research subjects were included. Patient information was completely anonymized.

Results

Sociodemographic and clinical characteristics of patients with HF

A total of 4742 patients diagnosed with HF were evaluated, with a mean age of 68.2 ± 13.8 years and a male predominance (61.3%). The median disease progression time at the start of follow-up was 800 days (interquartile range: 208–1792 days). The main regions represented were the Central, Bogotá-Cundinamarca and Caribbean regions. Most of the patients had a reduced LVEF (n = 1533; 32.3%), followed by those with preserved LVEF (n = 1244; 26.3%), and mildly reduced LVEF (n = 506; 10.7%), missing LVEF record data (n = 1459; 30.7%). Table 1 shows the general characteristics of the included patients.

The vast majority of patients in all categories were classified as stage C (AHA/ACC), with a higher percentage of stage B among patients with preserved LVEF than among those with reduced LVEF (8.5% vs. 1.4%). On average, for the entire group analyzed, the LVEF was above 40%. The main etiologies of HF identified were coronary artery disease (44.9%) and arterial hypertension (29.7%). The most frequently identified comorbidity in all subgroups was arterial hypertension, followed by coronary artery disease, obesity, diabetes mellitus, and atrial fibrillation, among others. In addition, approximately one-third of the patients had a GFR of less than 60 mL/min, placing them in groups of stage 3A or more severe chronic kidney disease (see Table 1).

Some symptoms were identified in patients at the start of follow-up, with reports of dyspnea upon slight exertion or worse (n = 1150; 24.3%), angina (n = 682; 14.4%), lower limb edema (n = 583; 12.3%), fatigue (n = 189; 4.0%), and paroxysmal nocturnal dyspnea (n = 103; 2.2%) among the most frequent, but clinical signs such as jugular venous distention (n = 9; 0.2%) and hepatomegaly (n = 7; 0.1%) were also reported.

Table 1. Sociodemographic, clinical, pharmacological and health care characteristics of 4742 patients diagnosed with HF, from Colombia.

Characteristic	Total (n = 4742)		Preserved [a]LVEF (HFpEF) (n = 1244; 26,3%)		Mildly reduced LVEF (HFmrEF) (n = 506; 10,7)		Reduced LVEF (HFrEF) (n = 1533; 32,3%)		LVEF No data (n = 1459; 30,7%)	
	n	%	n	%	n	%	n	%	n	%
Age										
Mean (SD)[b]	68.2 (13.8)		69.6 (13.7)		68.6 (13.3)		66.6 (12.9)		68.7 (14.7)	
Median (IQR)[c]	69.0 (59.0 - 79.0)		71.0 (60.0 - 80.0)		69.0 (59.0 - 79.0)		67.0 (58.0 - 76.0)		69.0 (59.0 - 80.0)	
Gender										
Male	2907	61.3	718	57.7	315	62.3	999	65.2	875	60.0
Female	1835	38.7	526	42.3	191	37.7	534	34.8	584	40.0
Geographic regions										
Central	1438	30.3	357	28.7	154	30.4	473	30.9	454	31.1
Bogota-Cundinamarca	1271	26.8	350	28.1	137	27.1	444	29.0	340	23.3
Caribbean	1197	25.2	322	25.9	114	22.5	312	20.4	449	30.8
Oriental	579	12.2	152	12.2	71	14.0	200	13.0	156	10.7
Pacific	257	5.4	63	5.1	30	5.9	104	6.8	60	4.1
Body-mass index										
Mean (SD)	27.2 (5.2)		27.7 (5.3)		27.0 (5.0)		26.4 (4.8)		27.7 (5.4)	
Median (IQR)	26.7 (23.7 - 30.0)		27.3 (24.2 - 30.4)		26.4 (23.7 - 29.7)		26.0 (23.3 - 29.1)		27.0 (24.0 - 30.8)	
AHA classification[d] (A.B.C.D)										
A	0	0	0	0.0	0	0.0	0	0.0	0	0.0
B	318	6.7	106	8.5	41	8.1	21	1.4	150	10.3
C	4361	92.0	1133	91.1	460	90.9	1470	95.9	1298	89.0
D	63	1.3	5	0.4	5	1.0	42	2.7	11	0.8
Functional class NYHA[e]										
I	2598	54.8	691	55.5	290	57.3	782	51.0	835	57.2
II	1376	29	391	31.4	149	29.4	422	27.5	414	28.4
III	680	14.3	144	11.6	63	12.5	295	19.2	178	12.2
IV	88	1.9	18	1.4	4	0.8	34	2.2	32	2.2
First LVEF value %										
Mean (SD)	42.9 (14.8)		58.6 (5.6)		45.2 (2.3)		29.4 (7.7)		NA	
Median (IQR)	43.0 (30.0 - 55.0)		59.0 (55.0 - 61.0)		45.0 (43.0 - 47.0)		30.0 (25.0 - 35.0)		NA	
Comorbidities										
Arterial hypertension	4200	88.6	1121	90.1	458	90.5	1305	85.1	1316	90.2
Coronary artery disease	2260	47.7	505	40.6	297	58.7	865	56.4	593	40.6
Obesity	1272	26.8	365	29.3	122	24.1	328	21.4	457	31.3
Diabetes mellitus	1200	25.3	297	23.9	108	21.3	416	27.1	379	26
Atrial fibrillation	998	21.0	276	22.2	105	20.8	347	22.6	270	18.5
Chronic Obstructive Pulmonary Disease	876	18.5	280	22.5	76	15.0	244	15.9	276	18.9
Sleep apnea	238	5.0	83	6.7	29	5.7	62	4.0	64	4.4
Kidney failure GFR < 90 (n = 4080)[f]	3216	78.8	868	77.7	347	77.1	1053	80.3	948	78.9
GFR – mean (SD)	70.1 (22.7)		71.2 (22.4)		70.5 (22.4)		68.9 (22.7)		70.2 (23.2)	
Stage 1 (normal)	864	21.2	249	22.3	103	22.9	259	19.7	253	21.1
Stage 2	1924	47.2	543	48.6	209	46.4	604	46.0	568	47.3
Stage 3a	701	17.2	164	14.7	78	17.3	251	19.1	208	17.3
Stage 3b	392	9.6	116	10.4	37	8.2	129	9.8	110	9.2

(Continued)

Table 1. (Continued)

Characteristic	Total (n = 4742)		Preserved [a]LVEF (HFpEF) (n = 1244; 26,3%)		Mildly reduced LVEF (HFmrEF) (n = 506; 10,7)		Reduced LVEF (HFrEF) (n = 1533; 32,3%)		LVEF No data (n = 1459; 30,7%)	
	n	%	n	%	n	%	n	%	n	%
Stage 4	145	3.6	34	3.0	18	4.0	48	3.7	45	3.7
Stage 5	54	1.3	11	1.0	5	1.1	21	1.6	17	1.4
No data	662	NA	127	NA	56	NA	221	NA	258	NA
Possible causes/ mechanisms heart failure										
Coronary artery disease	2130	44.9	470	37.8	279	55.1	814	53.1	567	38.9
Arterial hypertension	1410	29.7	373	30.0	121	23.9	390	25.4	526	36.1
Cardiomyopathies	766	16.2	172	13.8	86	17.0	285	18.6	223	15.3
Arrythmias	541	11.4	157	12.6	53	10.5	163	10.6	168	11.5
Valvulopathies	547	11.5	199	16.0	58	11.5	138	9.0	152	10.4
Infections	171	3.6	34	2.7	16	3.2	87	5.7	34	2.3
Congenital	53	1.1	13	1.0	3	0.6	11	0.7	26	1.8
Metabolic and autoimmune	23	0.5	8	0.6	2	0.4	8	0.5	5	0.3
Adverse drug reaction	22	0.5	6	0.5	0	0.0	12	0.8	4	0.3
Neuromuscular	5	0.1	0	0.0	0	0.0	1	0.1	4	0.3
Pericardial disease	3	0.1	1	0.1	0	0.0	2	0.1	0	0.0
Infiltrative	1	0.0	0	0.0	0	0.0	1	0.1	0	0.0
Endomyocardial	1	0.0	0	0.0	0	0.0	1	0.1	0	0.0
Other	2	0.0	0	0.0	0	0.0	0	0.0	2	0.1
Hospital care										
Hospitalizations for any cause										
0	4332	91.4	1155	92.8	468	92.5	1386	90.4	1323	90.7
1	345	7.3	75	6.0	34	6.7	129	8.4	107	7.3
2 or more	65	1.4	14	1.1	4	0.8	18	1.2	29	2.0
Average hospitalizations (at least one) (SD)	1.2 (0.6)		1.2 (0.4)		1.2 (0.6)		1.1 (0.4)		1.4 (0.9)	
Heart failure hospitalizations										
0	4467	94.2	1183	95.1	491	97.0	1424	92.9	1369	93.8
1	247	5.2	51	4.1	13	2.6	99	6.5	84	5.8
2 or more	28	0.6	10	0.8	2	0.4	10	0.7	6	0.4
Average hospitalizations (at least one) (SD)	1.1 (0.4)		1.2 (0.4)		1.2 (0.6)		1.1 (0.4)		1.1 (0.5)	
Emergency consultation for any reason										
0	4113	86.7	1083	87.1	448	88.5	1319	86.0	1263	86.6
1	399	8.4	96	7.7	41	8.1	134	8.7	128	8.8
2 or more	230	4.9	65	5.2	17	3.4	80	5.2	68	4.7
Average emergencies (at least one) (SD)	1.7 (1.5)		1.8 (1.5)		1.6 (1.0)		1.8 (1.7)		1.7 (1.4)	
Emergency visit for heart failure										
0	4548	95.9	1208	97.1	491	97.0	1454	94.8	1395	95.6
1	168	3.5	28	2.3	13	2.6	71	4.6	56	3.8
2 or more	26	0.5	8	0.6	2	0.4	8	0.5	8	0.5
Average emergencies (at least one) (SD)	1.2 (0.7)		1.3 (0.6)		1.1 (0.4)		1.2 (1.0)		1.2 (0.5)	
Medical specialty										
General medicine	3585	75.6	929	74.7	356	70.4	1081	70.5	1219	83.6

(Continued)

Table 1. (Continued)

Characteristic	Total (n = 4742)		Preserved [a]LVEF (HFpEF) (n = 1244; 26,3%)		Mildly reduced LVEF (HFmrEF) (n = 506; 10,7)		Reduced LVEF (HFrEF) (n = 1533; 32,3%)		LVEF No data (n = 1459; 30,7%)	
	n	%	n	%	n	%	n	%	n	%
Internal medicine	727	15.3	217	17.4	88	17.4	260	17.0	162	11.1
Cardiology	304	6.4	69	5.5	44	8.7	152	9.9	39	2.7
Other	126	2.7	29	2.3	18	3.6	40	2.6	39	2.7
Medications										
Number of medications – mean (SD)	2.9 (1.1)		2.6 (1.0)		2.9 (1.0)		3.4 (1.1)		2.8 (1.1)	
RAASi [g]	3940	83.1	1030	82.8	437	86.4	1312	85.6	1161	79.6
ARB[h]	2295	48.4	724	58.2	268	53.0	532	34.7	771	52.8
ACEi[i]	1148	24.2	274	22.0	121	23.9	450	29.4	303	20.8
ARNI[j]	612	12.9	45	3.6	61	12.1	405	26.4	101	6.9
β-blocker	4187	88.3	1064	85.5	468	92.5	1443	94.1	1212	83.1
Loop diuretic	2218	46.8	488	39.2	202	39.9	827	53.9	701	48.0
Thiazide diuretic	541	11.4	212	17.0	62	12.3	79	5.2	188	12.9
Mineralocorticoid receptor antagonist (MRA)	2205	46.5	341	27.4	204	40.3	1097	71.6	563	38.6
Ivabradine	124	2.6	16	1.3	13	2.6	77	5.0	18	1.2
Digoxin	331	7.0	39	3.1	22	4.3	156	10.2	114	7.8
SGLT2i (Flozins) [k]	256	5.4	53	4.3	22	4.3	108	7.0	73	5.0
Uses RAASi + β-bloquer+MRA	1654	34.9	242	19.5	166	32.8	865	56.4	381	26.1
Uses RAASi + β-bloquer+MRA+ SGLT2i	117	2.5	15	1.2	8	1.6	70	4.6	24	1.6

[a]LVEF: Left ventricular ejection fraction.

[b]SD: standard deviation.

[c]IQR: interquartile range.

[d]AHA: American Heart Association.

[e]NYHA: New York Heart Association.

[f]% of patients with glomerular filtration rate-GFR data n = 4080 and according to LVEF categories (preserved n = 1727. reduced n = 1152 and without data n = 1201).

[g]RAASi: Renin angiotensin aldosterone system inhibitors.

[h]ARB: Angiotensin II receptor blocker.

[i]ACEi: Angiotensin converting enzyme inhibitor.

[j]ARNI: Angiotensin Receptor-Neprilysin Inhibitor.

[k]SGLT2i: Sodium Glucose Cotransporter 2 inhibitor.

https://doi.org/10.1371/journal.pone.0325515.t001

Regarding hospitalizations and emergency department visits due to HF during the observation period, there were similar results in the preserved mildly reduced and reduced LVEF groups (Table 1). However, proportionally, 5.2% (n = 51) of those with preserved LVEF had one or more hospitalizations for HF, compared to 6.5% (n = 99) of people with reduced LVEF. Similarly, 2.3% (n = 28), 2.6% (n = 13) and 5.2% (n = 71) patients visited the emergency department for HF in each group, respectively. Finally, most of the patients were managed by general medicine practitioners, followed by internists and cardiologists.

Pharmacological management of HF

Regarding pharmacological management, most of the patients were on β-blockers (88.3%), particularly carvedilol (61.4%), and 83.1% were on RAASis. In this last group, the most commonly used were ARBs (48.4%), with a lower proportion of ACEIs and ARNIs (sacubitril-valsartan) used. Triple therapy with β-blockers, RAASis, and MRAs was observed in 34.9%, whereas quadruple therapy adding a sodium-glucose cotransporter-2 inhibitor (SGLT2i) was identified in only 2.5% of patients. Table 2 shows the drugs used for HF by group, mean dose, range, and category of recorded LVEF. Homogeneity was found in the selection of specific drugs within each class, with the predominant use of enalapril among ACEIs, losartan among ARBs, spironolactone among MRAs, etc. In addition, Fig 1 shows the main drug combinations according to frequency of use, the most common being the combination of β-blockers + ARBs + loop diuretics. A total of 24 patients (0.5%) who did not receive any specific therapy for the management of their cardiac condition were identified.

When reviewing pharmacological management according to LVEF, in patients with reduced LVEF, a high use of β-blockers (94.1%) and RAASis (85.6%) was maintained, with greater use of ARNIs (26.4%). Similarly, in this group of patients, a greater use of MRA was identified (71.6%), particularly spironolactone, as well as loop diuretics (53.9%). Triple and quadruple therapy was also used more frequently in this group, at proportions of 56.4% and 4.6%, respectively. In patients with preserved LVEF, the use of β-blockers (88.3%) and RAASis (83.1%) was maintained, with a higher proportion of thiazide diuretics (17.0%) and less use of MRAs (27.4%) compared with patients with reduced LVEF. And in patients with mildly reduced LVEF a higher proportion of use of RAASi (86.4%) than in the other groups, and more frequent use of β-blockers (92.5%) compared to those with preserved LVEF and less frequent than those with reduced LVEF. In general, SGLT2is were used infrequently, with empagliflozin being the most common. The most frequently used concomitant medication was part of the statin group, followed by acetylsalicylic acid, proton pump inhibitors, anticoagulants, and vasoselective calcium channel blockers, but there was a great diversity of drugs that accompanied the management of this group of patients and their comorbidities (see Table 3).

Discussion

Patients with heart failure with preserved ejection fraction (HFpEF) and mildly reduced ejection fraction (HFmrEF), but mainly those with reduced ejection fraction (HFrEF) have high mortality, suffer frequent hospitalizations and, in addition, their quality of life is seriously affected; therefore, the use of drugs with a positive impact on these outcomes constitutes a critical point in long-term therapy [7,11]. Thus, the identification and clinical classification of this group of patients with HF in Colombia, which established treatment patterns categorized by different variables such as clinical and functional classification, mean LVEF value, comorbidities, and even region of the country, provides relevant information for the identification of patients who are receiving management that is not optimal, insufficient or inappropriate and creates the opportunity to improve the prescription of medications.

The study published in 2021 by the RECOLFACA group in Colombia evaluated 2528 patients with HF and found that there was a male predominance and a median age similar to that of this analysis [12]; however, unlike this previous study, it was possible to identify the use of new drugs such as ARNIs and SGLT2is that have recently been incorporated into clinical practice guidelines [13–15]. The results related to age and sex were also consistent with the findings of the study by Störk et al. in Germany, who reported a male predominance (65.9%) and a mean age of 68 years from a database with a record of more than 120,000 patients with HF [16], And this is consistent with the report from the INTER-CHF study with 5,823 patients worldwide, of whom 9% were from Latin America, with an average age of 67%, but different from Africa with 53%, and maintaining a male predominance [17].In Italy, Rea et al. found a median age of 76 years, with those with HFpEF [18] being approximately three years older, which is higher than that identified in the Colombian patient groups, which can be explained by differences in population, health systems, access to more timely treatment for coronary syndromes and interventions for different risk factors; this study reported that the Hispanic population has a higher frequency

Table 2. Pharmacological treatment received by 4742 patients in ambulatory setting diagnosed with HF. From Colombia.

Characteristic	Total (n = 4742)		Average dose (SD)[a] – mg/day	Average daily dose ratio/DDD[b]	Min	Max	Median	Preserved LVEF[c] (HFpEF) (n = 1244)			Mildly reduced LVEF (HFmrEF) (n = 506)			Reduced LVEF (HFrEF) (n = 1533)			No data LVEF (n = 1459)		
	n	%						n	%	Average dose – mg/day	n	%	Average dose – mg/day	n	%	Average dose – mg/day	n	%	Average dose – mg/day
Medications																			
ACEi[d]	1148	24.2						274	22.0		121	23.9		450	29.4		303	20.8	
Enalapril	1125	23.7	17.1 (13.9)	1.7	2.5	40	10	264	21.2	18.9	120	23.7	16.9	445	29.0	15.6	296	20.3	17.9
Captopril	10	0.2	82.5 (44.2)	1.7	25	150	75	2	0.2	100.0	1	0.2	50.0	3	0.2	116.7	4	0.3	56.2
Perindopril	10	0.2	6.8 (2.8)	1.7	4	10	5	7	0.6	7.7	0	0.0	0.0	2	0.1	4.5	1	0.1	5.0
Ramipril	2	0.0	7.5 (3.5)	3.0	5	10	7.5	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	2	0.1	7.5
Lisinopril	1	0.0	5.0	0.5				1	0.1	5.0	0	0.0	0.0	0	0.0	0.0	0	0	0.0
ARB[e]	2295	48.4						724	58.2		268	53.0		532	34.7		771	52.8	
Losartan	1978	41.7	90.4 (31.2)	1.8	25	200	100	628	50.5	94.0	221	43.7	93.9	460	30.0	83.9	669	45.9	90.5
Valsartan	128	2.7	211.9 (93.7)	2.6	40	320	160	38	3.1	240.0	16	3.2	210.0	30	2.0	173.3	44	3	214.5
Candesartan	78	1.6	16.6 (10.8)	2.1	4	64	16	13	1.0	19.7	20	4.0	15.4	27	1.8	15.0	18	1.2	18.0
Irbesartan	65	1.4	251.5 (70.7)	1.7	150	0	0	30	2.4	265.0	3	0.6	250.0	9	0.6	233.3	23	1.6	241.3
Telmisartan	33	0.7	77.6 (26.3)	1.9	40	160	80	12	1.0	90.0	7	1.4	68.6	5	0.3	72.0	9	0.6	71.1
Olmesartan	12	0.3	38.3 (15.9)	1.9	20	80	40	3	0.2	26.7	1	0.2	40.0	0	0.0	0.0	8	0.5	42.5
Eprosartan	1	0.0	600.0	1.0				0	0.0	0.0	0	0.0	0.0	1	0.1	600.0	0	0	0.0
ARNI (sacubitril-valsartan)[f]	612	12.9	144.2 (94.4)	0.4	50	400	100	45	3.6	151.1	61	12.1	142.5	405	26.4	141.3	101	6.9	153.5
β-blocker	4187	88.3						1064	85.5		468	92.5		1443	94.1		1212	83.1	
Carvedilol	2913	61.4	22.2 (15.1)	0.6	3.1	75	12.5	639	51.4	21.8	322	63.6	23.5	1107	72.2	23.4	845	57.9	20.2
Metoprolol	991	20.9	92.4 (46.9)	0.6	25	300	100	330	26.5	88.4	101	20.0	103.5	249	16.2	94.4	311	21.3	91.5
Bisoprolol	229	4.8	6.1 (3.1)	0.6	1.3	10	5	77	6.2	6.3	34	6.7	6.4	75	4.9	5.9	43	2.9	6.0
Nebivolol	48	1.0	6.3 (3.8)	1.3	2.5	25	5	13	1.0	6.0	11	2.2	6.4	12	0.8	4.6	12	0.8	8.5
Propranolol	6	0.1	63.3 (36.7)	0.4	20	120	60	5	0.4	60.0	0	0.0	0.0	0	0.0	0.0	1	0.1	80.0
Loop diuretic	2218	46.8	41.7 (11.2)	1.0	10	200	40	488	39.2	40.8	202	39.9	41.1	827	53.9	42.5	701	48	41.7
Thiazide diuretic	541	11.4						212	17.0		62	12.3		79	5.2		188	12.9	

(Continued)

Table 2. (Continued)

Characteristic	Total (n = 4742)		Average dose (SD)[a] – mg/day	Average daily dose ratio/ DDD[b]	Min	Max	Median	Preserved LVEF[c] (HFpEF) (n = 1244)			Mildly reduced LVEF (HFmrEF) (n = 506)			Reduced LVEF (HFrEF) (n = 1533)			No data LVEF (n = 1459)		
	n	%					n	%	Average dose – mg/day	n	%	Average dose – mg/day	n	%	Average dose – mg/day	n	%	Average dose – mg/day	
Hydrochlorthiazide	505	10.6	23.4 (4.2)	0.9	12.5	25	25	198	15.9	23.8	55	10.9	22.7	73	4.8	22.9	179	12.3	23.2
Indapamide	33	0.7	1.97 (0.7)	0.8	1.5	5	1.5	14	1.1	2.1	4	0.8	2.6	6	0.4	1.5	9	0.6	1.8
Chlorthalidone	3	0.1	16.7 (7.2)	0.7	12.5	25	12.5	0	0.0	0.0	3	0.6	16.7	0	0.0	0.0	0	0	
Mineralocorticoid Receptor Antagonist (MRA)	2205	46.5						341	27.4		204	40.3		1097	71.6		563	38.6	
Spironolactone	2090	44.1	26.0 (9.2)	0.3	12.5	150	25	328	26.4	25.6	191	37.7	25.4	1032	67.3	25.8	539	36.9	26.6
Eplerenone	115	2.4	26.8 (7.6)	0.5	12.5	50	25	13	1.0	29.8	13	2.6	25.0	65	4.2	26.8	24	1.6	26.0
Ivabradine	124	2.6	9.9 (3.4)	1.0	2.5	17.5	10	16	1.3	10.0	13	2.6	10.6	77	5.0	9.6	18	1.2	10.9
Digoxin	331	7.0	0.23 (0.22)	0.9	0.1	1	0.1	39	3.1	0.2	22	4.3	0.2	156	10.2	0.3	114	7.8	0.2
SGLT2i (Flozins)[g]	256	5.4						53	4.3		22	4.3		108	7.0		73	5	
Empagliflozin	213	4.5	19.8 (7.4)	1.1	10	50	25	45	3.6	20.0	17	3.4	24.7	88	5.7	19.3	63	4.3	19.0
Dapagliflozin	42	0.9	9.8 (1.1)	1.0	5	10	10	8	0.6	10.0	5	1.0	10.0	19	1.2	10.0	10	0.7	9.0
Canagliflozin	1	0.0	100.0	0.5				0	0.0	0.0	0	0.0	0.0	1	0.1	100.0	0	0	0.0

[a]SD: standard deviation.

[b]DDD: defined daily dose.

[c]LVEF: left ventricular ejection fraction.

[d]ACEI: angiotensin converting enzyme inhibitors.

[e]ARB: angiotensin II receptor antagonists.

[f]ARNI: Angiotensin Receptor-Neprilysin Inhibitor.

[g]SGLT2i: Sodium Glucose Cotransporter 2 inhibitor. Note: Of the SGLT2i. 28 were used specifically for heart failure. the rest for diabetes.

https://doi.org/10.1371/journal.pone.0325515.t002

of obesity and adverse cardiovascular outcomes, representing a greater risk of developing HF earlier [19,20], which can be added to the recently published analysis based on information from 40 countries in which the differences in the causes of HF were identified between high-income and lower-income regions, showing a higher proportion of coronary disease in high-income and medium-to-high-income countries. Likewise, a better opportunity for care and lower mortality due to complications of HF in the first 30 days after hospitalization were identified, highlighting the importance of timely management and access to recommended therapies [21]. An additional point to keep in mind is that these older adult patients, with multiple comorbidities, are at high risk of presenting frailty from a multidimensional perspective, as they are affected by reduced physical activity, asthenia, decreased gait and speed, and muscle weakness, all directly or indirectly associated

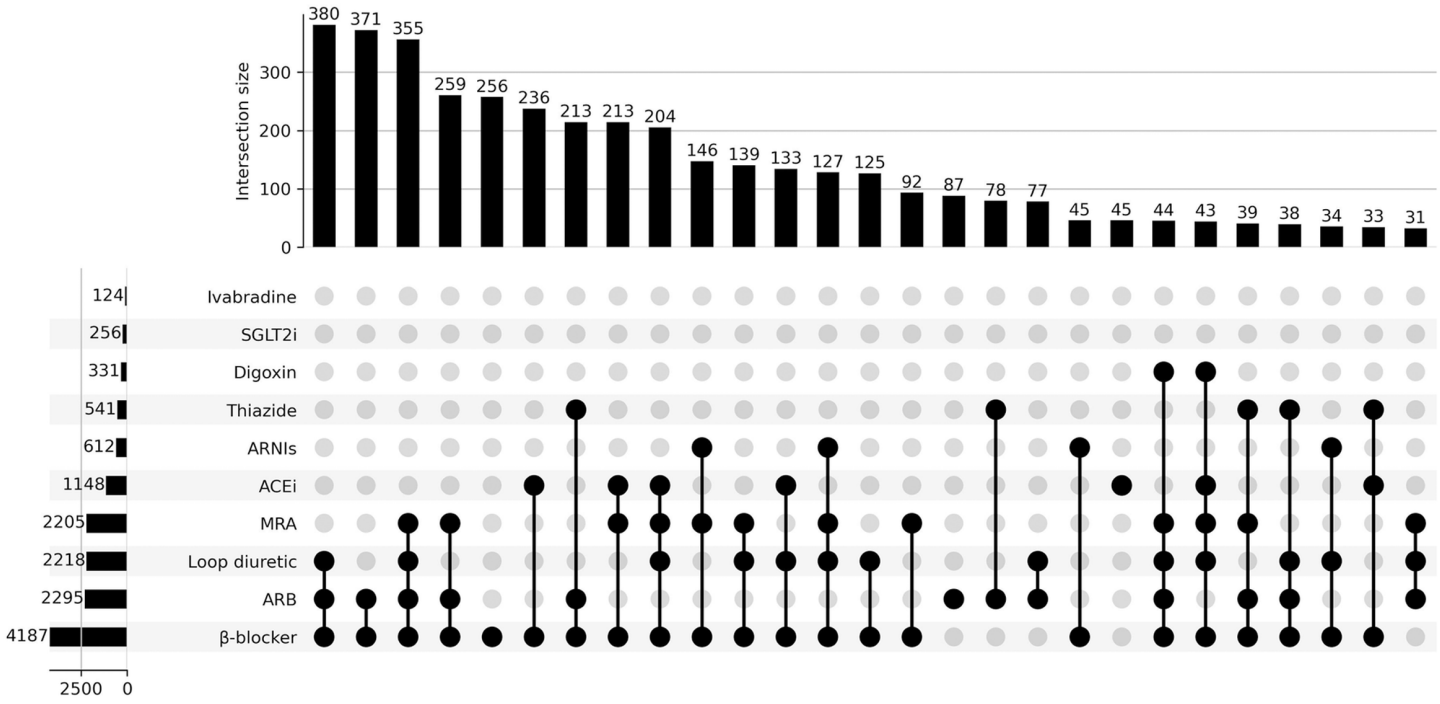


Fig 1. Main drug therapies used to manage heart failure in the study population (including those combinations or drugs with at least 30 observations).

https://doi.org/10.1371/journal.pone.0325515.g001

with heart failure, creating the need to timely identify and improve the prevention of complications and adverse outcomes [22,23].

When comparing the results with the AMERICANS ASS Registry study, which included 1,000 patients, mainly from Colombia (19.2%), the patients were of similar age and predominantly male. However, they had a lower frequency of hypertension and coronary artery disease, but similar rates of AF and diabetes. Interestingly, they found that the most frequent group, with more than half of the patients (59.5%), were those with reduced failure, similar to this study. Regarding the use of medications, 70.7% were using a β-blocker, 56.8% an ARB, and 30.7% an SGLT2i; however, they were all grouped together without separating by ejection fraction classification. And interestingly, 21.7% received optimal therapy with a β-blocker, ARB, SGLT2i, and an ACEI, ARB, or ARNI [24].

In the management of patients with HFpEF, or HFmrEF some points of interest were identified, such as the use of ARNIs in up to 3.6% and 12.1 respectively of cases and a clear recommendation for this therapy by clinical practice guidelines for patients with HFrEF due to its impact on morbidity and associated mortality [25,26]. The evidence is not conclusive in those whose LVEF is above 40%, but the costs of therapy, as well as the risk of adverse reactions, especially severe hypotension, and their low impact on mortality may make them a therapy that is not so necessary [27,28]. Similarly, in the group of patients with HFpEF, 27.4% used an MRA, which did not have an impact on mortality either but has been associated with endocrine-type adverse reactions and hyperkalemia, although MRAs may reduce the risk of HF hospitalization [29]. Additionally, 4.3% of the patients with HFpEF and with HFmrEF were treated with an SGLT2i during the observation period, which, at the time, did not have any evidence or recommendation for its use; however, in studies published in 2021 and 2022, empagliflozin and dapagliflozin, respectively, showed a significant benefit in the primary composite outcome of hospitalization for heart failure or cardiovascular death, and the results were mainly explained by a

Table 3. Main concomitant medications received by a group of 4742 patients diagnosed with HF. from Colombia.

Comedications	Total (n = 4742)		Preserved LVEF[a] (HFpEF) (n = 1244)		Mildly reduced LVEF (HFmrEF) (n = 506)		Reduced LVEF (HFrEF) (n = 1533)		No data LVEF (n = 1459)	
	n	%	n	%	n	%	n	%	n	%
Statins	3398	71.7	907	72.9	392	77.5	1151	75.1	948	65.0
Aspirin	2455	51.8	658	52.9	267	52.8	822	53.6	708	48.5
Proton pump inhibitor	1454	30.7	363	29.2	143	28.3	516	33.7	432	29.6
Anticoagulants[b]	1223	25.8	308	24.8	144	28.5	437	28.5	334	22.9
Calcium channel blockers (vasoselective)	1031	21.7	375	30.1	100	19.8	181	11.8	375	25.7
Levothyroxine	997	21.0	278	22.3	111	21.9	333	21.7	275	18.8
Acetaminophen	971	20.5	274	22.0	104	20.6	286	18.7	307	21.0
Metformin	908	19.1	222	17.8	97	19.2	316	20.6	273	18.7
Basal insulin	532	11.2	116	9.3	43	8.5	196	12.8	177	12.1
Other antiplatelet agents[c]	451	9.5	81	6.5	67	13.2	176	11.5	127	8.7
Selective Serotonin Reuptake Inhibitors	344	7.3	108	8.7	33	6.5	97	6.3	106	7.3
Partial agonist opioids	309	6.5	94	7.6	37	7.3	81	5.3	97	6.6
DPP-4i[d]	303	6.4	70	5.6	26	5.1	115	7.5	92	6.3
Fast acting insulin	287	6.1	64	5.1	23	4.5	101	6.6	99	6.8
Anti-arrhythmics	265	5.6	50	4.0	24	4.7	129	8.4	62	4.2
Aluminium hydroxide	243	5.1	75	6.0	19	3.8	75	4.9	74	5.1
Ranitidine	234	4.9	55	4.4	26	5.1	88	5.7	65	4.5
Alpha blockers	218	4.6	61	4.9	26	5.1	60	3.9	71	4.9
1st-generation antihistamines	150	3.2	47	3.8	12	2.4	41	2.7	50	3.4
Clonidine	126	2.7	44	3.5	13	2.6	26	1.7	43	2.9
Antiepileptics	124	2.6	34	2.7	17	3.4	39	2.5	34	2.3
Tricyclic Antidepressants	122	2.6	26	2.1	12	2.4	46	3.0	38	2.6
Total agonist opioids	101	2.1	28	2.3	13	2.6	29	1.9	31	2.1
Fibrates	99	2.1	25	2.0	16	3.2	26	1.7	32	2.2
GLP-1 analogs[e]	80	1.7	18	1.4	7	1.4	27	1.8	28	1.9
Ezetimibe	79	1.7	18	1.4	14	2.8	34	2.2	13	0.9
Glucocorticoids	78	1.6	18	1.4	12	2.4	24	1.6	24	1.6
Benzodiazepines	76	1.6	20	1.6	9	1.8	23	1.5	24	1.6
Sucralfate	63	1.3	11	0.9	10	2.0	21	1.4	21	1.4
Non-steroidal anti-inflammatory drugs	63	1.3	12	1.0	5	1.0	22	1.4	24	1.6
Atypical antipsychotic	60	1.3	13	1.0	7	1.4	18	1.2	22	1.5
Hyoscine butylbromide	50	1.1	10	0.8	4	0.8	21	1.4	15	1.0
Calcium channel blockers (cardiodepressants)	45	0.9	20	1.6	3	0.6	5	0.3	17	1.2
Typical antipsychotic	38	0.8	12	1.0	3	0.6	12	0.8	11	0.8
2nd generation antihistamine	30	0.6	8	0.6	2	0.4	10	0.7	10	0.7
Antiparkinsonians	26	0.5	7	0.6	2	0.4	5	0.3	12	0.8
Memantine	18	0.4	6	0.5	2	0.4	3	0.2	7	0.5
Sulfonylureas	15	0.3	4	0.3	1	0.2	4	0.3	6	0.4
Serotonin and norepinephrine reuptake inhibitors	14	0.3	4	0.3	2	0.4	6	0.4	2	0.1
Z Drugs	7	0.1	2	0.2	1	0.2	1	0.1	3	0.2
Antidementia	7	0.1	1	0.1	2	0.4	1	0.1	3	0.2
Omega-3 acids	2	0.0	1	0.1	0	0.0	0	0.0	1	0.1

(Continued)

Table 3. (Continued)

Comedications	Total (n = 4742)		Preserved LVEF[a] (HFpEF) (n = 1244)		Mildly reduced LVEF (HFmrEF) (n = 506)		Reduced LVEF (HFrEF) (n = 1533)		No data LVEF (n = 1459)	
	n	%	n	%	n	%	n	%	n	%
Dipyrone	1	0.0	1	0.1	0	0.0	0	0.0	0	0.0

[a]LVEF: left ventricular ejection fraction.

[b]Includes orals and heparins.

[c]Clopidogrel. prasugrel. and ticagrelor.

[d]DPP-4: dipeptidyl peptidase 4 inhibitors.

[e]GLP-1: glucagon-like peptide 1.

https://doi.org/10.1371/journal.pone.0325515.t003

significant reduction in hospitalizations but without a clear benefit in mortality [30,31]. Additionally, as found in this analysis by studying not only the use of medications but also the reasons for hospitalization in depth, hospitalization was not only due to HF, but a significant proportion (approximately 40%) of individuals were hospitalized for any other cause, indicating the importance of providing multidisciplinary management and a comprehensive approach, including an optimal approach to secondary cardiovascular prevention, arrhythmias, diabetes mellitus, or chronic obstructive pulmonary disease, which could be a therapeutic strategy better than the use of therapies with a benefit/risk balance that is not currently clear in HFpEF [32,33]. It is important to identify new therapeutic options with an impact on morbidity and with a good safety profile and that may even have some impact on cardiovascular mortality [34,35].

The assessment of the treatment prescribed to patients with HFrEF identified that 85% received RAASis, and only 26.4% received ARNIs, which are currently the recommended first-line therapy due to their impact on survival, hospitalization, and quality of life compared to other available treatments [7,13,25,36]. During the observation period of this study, ARNIs were an alternative to ACEIs, although they are already used in similar proportions as the other two therapies, which translates into a progressive adoption of the recommendation based on published evidence at the time. A total of 7.0% of patients with reduced LVEF used SGLT2is, despite the recommendations made in the clinical practice guidelines from studies with empagliflozin and dapagliflozin in the management of HF starting in 2021 [14,15], optimizing the pharmacological treatment of these patients.

The study by Störk et al. found that patients with better functional classes (I and II) according to the NYHA had 93% and 55% compliance, respectively, with the optimal therapy according to the recommendations of the clinical practice guidelines, while this was reduced to 21% when they had functional classes III and IV, although the patients were not classified by LVEF [16]. A study conducted by Rastogi et al. in France between 2015 and 2019 found suboptimal management in approximately 70% of patients [37], especially a lack of prescriptions of MRAs and ARNIs for patients with HFrEF, similar to what was found in Colombia, where among patients with reduced LVEF, only 58.1% used the recommended triple therapy (RAASis + β-blockers+MRAs) and only 4.9% also used an SGLT2i, showing a potential possibility of optimizing drug treatment according to current recommendations [11]. According to the meta-analysis by Vaduganathan et al. in 2020, the combination of an ARNI, an SGLT2i, an MRA and a β-blocker can achieve up to 8.3 years of cardiovascular survival time and up to 6.3 years of additional survival time compared to conventional ACEI treatment plus a β-blocker [38], constituting a therapy based on pathophysiology and the best evidence with a significant impact on survival, hospitalization rates, symptoms and quality of life. In addition, different authors have recently identified that the unique clinical profiles of patients with heart failure may partly explain their failure to comply with the recommendations of the clinical practice guidelines, mainly explained by low drug tolerability caused by severe hypotension, bradycardia, altered renal function or hyperkalemia [39–42]. According to these situations, in 2021, the European Society of Cardiology defined,

through expert consensus, nine patient profiles that may be relevant for the therapeutic management of HFrEF, including heart rate ranges, presence of atrial fibrillation, symptomatic hypotension, impaired renal function, and presence of hyperkalemia in the differentiating profile, thus showing the importance of offering personalized management of heart failure and adjusting the optimal therapy recommended according to clinical practice guidelines to the profile of the patient to achieve a more comprehensive management of the disease [43].

Different studies carried out among patients with heart failure, such as EMPEROR that evaluated empagliflozin in the management of subjects with preserved LVEF [35] or the report by Rastogi et al. [37], showed that patients received β-blockers in cases of reduced LVEF in proportions greater than 80% and 90%, respectively, which is comparable with the findings of this analysis. However, the usefulness of this therapy is currently being discussed in cases with preserved LVEF due to insufficient evidence to support its impact on clinical outcomes, added to the possibility of altering central arterial pressure, increasing wall stress, and exacerbating chronotropic incompetence; therefore, symptoms may worsen without the benefit shown in patients with reduced LVEF [44]. Enriching the discussion regarding the responsible use of β-blockers for the appropriate indications can enhance rationality in the prescription and optimization of resources.

This study has some limitations that must be taken into account. First, due to its observational nature and the secondary source of information from electronic clinical records, including the lack of data such as LVEF or GFR in a portion of patients, it was difficult to perform certain evaluations in this study, but this study did show the reality of medical care in a real-life context and the follow-up that is provided to patients with heart failure in Colombia. There have been no reports of other paraclinical tests of interest, and the information on hospital care was insufficient. It can be assumed that some patients may be misclassified and a significant proportion were low risk, being classified as stage B or stage C functional class I, still showing the reality of patients under treatment. The strengths include the large sample size for an observational study with a systematic review of medical records; this was one of the largest studies conducted in Colombia with coverage of the main regions of the country and the complete identification of treatment patterns according to the clinical categories of heart failure.

Conclusions

In this study, the cohort of patients with heart failure in Colombia mainly comprised men, had a mean age of 68 years, mostly had preserved LVEF and stage C, had HF caused by ischemic heart disease or arterial hypertension and were also affected by obesity, diabetes mellitus, or atrial fibrillation; many participants experienced dyspnea on exertion, anginal pain, and lower limb edema, leading tso hospitalization in the last year, and were primarily treated with β-blockers, RAASis, especially ARBs, and a low proportion of ARNIs. However, the treatment that patients with HFpEF and HFmrEF receive is simpler, as fewer medications are used and the control of comorbidities is prioritized. Thus, it was found that the current therapy for these groups in this study more similar to the recommendations made by clinical practice guidelines and current evidence, while for those with HFrEF, the proportion of therapies according to these recommendations is lower, which provides an important opportunity to optimize and personalize management and therefore surely improve clinical outcomes.

Acknowledgments

We thank Ana Maria Baena, Vanessa Parra, Julio Cesar Arce and Harrison Ospina for their work in obtaining the database. Marcela Rivera for your support in discussion or results.

Consent to participate. No applicable, is a retrospective observational study

Consent to publish: all authors consent to participate

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