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CLÍNICA

Adherence to phararmacological and non-pharmacological treatment in patients with heart failure

Adherencia al tratamiento farmacológico y no farmacológico en pacientes con falla cardiaca

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Palabras clave: Adherencia al tratamiento; adhesión; cumplimiento de la medicación; falla cardiaca; prevalencia

Keywords: Adherence to treatment; adhesion; medication compliance; heart failure; prevalence.

RESUMEN

Las consecuencias de la no adherencia al tratamiento se expresan en diversas esferas de la vida de la persona, en diversos componentes del sistema de salud y en el cuadro de morbilidad y mortalidad de la población, lo cual genera grandes repercusiones desde el punto de vista médico, económico y en la calidad de vida de la persona.

Objetivo: Determinar la prevalencia de adherencia al tratamiento farmacológico y no farmacológico en pacientes con falla cardiaca.

Métodos: Se realizó un estudio de corte transversal en pacientes con falla cardiaca en el 2012 en la Clínica de Falla Cardiaca y Trasplante Cardiaco de la Fundación Cardiovascular de Colombia. Se incluyeron 161 pacientes adultos con diagnóstico médico de falla cardiaca. Se evaluó la adherencia al tratamiento farmacológico y no farmacológico y el cumplimiento en los pacientes con falla cardiaca.

Resultados: El 80.12% (n=129; IC 95% 73.11 - 85.98%) de los pacientes se encuentra frecuentemente adheridos al tratamiento farmacológico y no farmacológico, el cumplimiento al tratamiento farmacológico con el test de Morisky-Green fue de 53.42% (n=86; IC 95% 45.39 - 61.3%).

Conclusiones: Los resultados del presente estudio son un acercamiento a la problemática de la adherencia al tratamiento farmacológico y no farmacológico de los pacientes con falla cardiaca. Se

recomienda para futuras investigaciones, la realización de estudios multicéntricos con muestreos probabilísticos.

ABSTRACT

Consequences of non-adherence to treatment are expressed in various spheres of the individual's life, in various components of the health system and in the population's morbidity and mortality, which generates repercussions in the medical and economical aspects and in the individual's life quality.

Objective: To determine the prevalence of adherence to pharmacological and non-pharmacological treatment in patients with heart failure.

Methods: A cross sectional study was conducted in patients with heart failure during 2012 in the Heart Failure and Heart Transplant Clinic of the Fundación Cardiovascular de Colombia. 161 adult patients were included with the diagnosis of heart failure. Adherence to pharmacological and non-pharmacological treatment was evaluated as well as compliance of the patients with heart failure.

Results: 80.12% (n=129; 95% CI 73.11 – 85.98%) of the patients are often adhered to pharmacological and non-pharmacological treatment, compliance to pharmacological treatment with the Morisky-Green test was of 53.42% (n=86; 95% CI 45.39 - 61.3%).

Conclusions: The results of this study are an approach to the problem of adherence to pharmacological and non-pharmacological treatment of patients with heart failure. It is recommended for future researches, the realization of multicenter studies with probabilistic samplings.

INTRODUCTION

Heart Failure (HF) is a relevant public health problem; it still remains one of the most common, expensive, disabling and deadly medical condition worldwide[1]. The global prevalence of HF is 20.3 per 1000 population and it overpasses the 100 per 1000 population in people older than 65 years. The annual incidence of HF is 1 to 5 per each 1000 population and the relative incidence doubles for each decade of life after age 45[2]. The increased prevalence of HR reflects a raise in the incidence, aging of the population and advances in the treatment of cardiac diseases[3].

Despite the advances in the treatment of HF, the lack of adherence to therapeutic prescriptions remains a problem within patients with HR[4]. Adherence to treatment recommendations is the main preventable cause of re-hospitalization and premature mortality in patients with HF[5]. World Health Organization defines therapeutic adherence as "the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider"[6].

Wu et al in a review about adherence to medication in patients with HF, estimated the prevalence of non-adherence to medication in patients with HF between 10%-93%, most researchers cite prevalence around 40% and 60%, this due to the way adherence is measured and defined[7]. Consequences of non-adherence are expressed in various spheres of the individual's life, in various components of the health system and in the population's morbidity and mortality, which generates repercussions in the medical and economical aspects and in the individual's life quality[8].

In our country, adherence to treatment in patients with HF has been little studied [9]. Therefore, the purpose of this study was to determine the prevalence of adherence to pharmacological and non-pharmacological treatment in patients attending the Heart

Failure and Heart Transplant Clinic of the Fundación Cardiovascular de Colombia (HFHTC).

METHODS

An analytical cross sectional study was conducted in patients with HF between July and October 2012 in the HFHTC. This is a private fourth level healthcare institution located in Floridablanca-Santander-Colombia, attending patients from any health regimen, mainly from Bucaramanga and its metropolitan area but also from other regions. This institution had at that time 406 active patients with HF; active patients had at least one control during the last year.

The study population recruited was people older than 18 years with the diagnosis of HF and active in the HFHTC. People with impaired mental sphere, chronic or serious alterations and/or with communication limitations that do not allow them to answer the structured interview were excluded. Research protocol was approved by the Technical-Scientific Committee and Ethics Committee in Researches of the Fundación Cardiovascular de Colombia and the informed consent was done verbally.

Sample size was calculated in StatCalc of Epi Info 6.04d[10], considering: a 95% confidence level, an available population for the study of 406 active patients of the HFHTC, hoping for an adherence treatment frequency of 50% and confidence intervals between 45 and 55%, resulting in a size of 198 patients. This last prevalence of expected adherence to treatment was selected according to the Wu et al study, who reported a prevalence of non-adherence between 40 and 60%[7]. Sampling was done by convenience. All participants who met the inclusion criteria were invited to the study, at the time they entered to the Heart Failure Clinic and a survey-interview was applied.

The dependent variable was the adherence to pharmacological and non-pharmacological treatment defined by the "Instrument for the evaluation of pharmacological and non-pharmacological adherence in patients with HF"[11]. This instrument has 10 indicators and 30 items that evaluate the following aspects; confidence in the healthcare professional, access to health services, knowledge in the management of the pharmacological treatment, acceptance of the disease, recognition of the signs and warning symptoms, social support, weight maintenance, knowledge of proper diet, performance of physical activity, and emotional status, it has an internal consistency of 0.72.

The instrument has a likert scale of four response alternatives where one (never or nothing) means the lowest value of adherence and four (much or always) means the highest. The minimum value a patient could obtain was 30 and the maximum was 120 points. A patient was considered non-adherent with a punctuation between 30 and 55, low adherent between 56 and 80, often adherent between 81 and 105 and adhered between 106 and 120 points. Written authorization was given by the instrument's author to be used in this research. Also, compliance to treatment was measured by the Morisky-Green Test, which assesses patients' attitudes towards the pharmacological treatment [12].

The person responsible for data collection was a professional nurse, who was instructed in regards to the obtention of informed consent, application of the instrument and filling of the collection format. Before beginning data collection, a pilot test with 10

people was done and adjustments were made. Supervision of the fieldwork and weekly verification of the information was done before being entered into the database, in order to detect inconsistencies in the information.

Simultaneously to data collection, two databases were built separately in EpiData 3.1[13]. A validation of these databases was done in the same program to correct errors. Besides, in the construction of the database, the subprogram CHECK of EpiData 3.1 was used to restrict data entry and reduce keying or coding errors. After database correction, it was exported for the information analysis in the statistical program Stata v12[14].

A descriptive analysis of study population's characteristics was done. The qualitative variables were described as absolute and relative frequencies; continuous variables were described using measures of central tendency and of dispersion according to their characteristics. Adherence prevalence and its 95% confidence intervals (CI) were calculated.

RESULTS

General aspects of the study population

Sociodemographic characteristics

161 patients were studied, median age was 66 years with first and third quartile of (Q1=56;Q3=73), a minimum age of 20 and a maximum age of 93 years; the median of distance in time from the place of residence to the Heart Failure Clinic was 60 minutes (Q1=15,Q3=180), with a minimum distance of 5 minutes and a maximum of 960 minutes; the median of school years taken and passed was 6 years (Q1=3;Q3=11), with a minimum of 0 years and a maximum of 16 years (Table 1).

Table 1. Sociodemographic characteristics of patients with Heart Failure (n=161)

Variable	n (%)
Sex	
Female	64 (39.75)
Male	97 (60.25)
Marital status	
Single	8 (4.97)
Married	93 (57.76)
Common-law marriage	28 (17.39)
Divorced/Separated	10 (6.21)
Widower	22 (13.66)
Caregiver support	
Yes	144 (89.44)
No	17 (10.56)
Socioeconomic strata	
Low	71 (44.10)
Medium	73 (45.34)
High	17 (10.56)
Area of residence	
Urban	140 (86.96)
Rural	21 (13.04)

Social security	
Contributory	83 (51.55)
Subsidized	30 (18.63)
Prepaid	17 (10.56)
Special regimen	29 (18.01)
Private	2 (1.24)
Occupation	
Employee	5 (3.11)
Independent	21 (13.04)
Unemployed	87 (54.04)
Pensioner/Retired	48 (29.81)
Familiars' Monthly Incomes	
0 - 1 L.M.M.W	60 (37.27)
1 - 2 L.M.M.W	38 (23.60)
2 - 4 L.M.M.W	33 (20.50)
4 - 8 L.M.M.W	17 (10.56)
> 8 L.M.M.W	11 (6.83)
Do not know or refuses	2 (1.24)

L.M.M.W= *Legal minimum monthly wage.*

Clinical characteristics

The median time of HF diagnosis was 39 months (Q1=18; Q3=72), with a minimum of 1 and a maximum of 300 months; the median of left ventricular ejection fraction was 25% (Q1=15;Q3=38) with a minimum of 8% and a maximum of 70%; the median of the number of hospitalizations in the last year was 0 times Q1=0;Q3=1); the mean of the abdominal perimeter in men was 89.4 with a standard deviation (SD) of ±13.5 and in women was 91.6 cm (SD±10.8) (Table 2).

Table 2. Clinical characteristics of patients with Heart Failure (n=161)

Variable	n (%)
Comorbidities	
Cerebrovascular disease	17 (10.56)
Diabetes	33 (20.50)
COPD	16 (9.94)
Peripheral arterial disease	9 (5.59)
Renal failure on dialysis	2 (1.24)
Hypothyroidism	28 (17.39)
Chagas disease	32 (19.88)
Hypertension	91 (56.52)
Dyslipidemia	76 (47.20)
Charlson Index	
Absence of comorbidity (0-1 comorbidity)	97 (60.25)
Low comorbidity (2 Comorbidities)	47 (29.19)
High comorbidity (≥ 3 comorbidities)	17 (10.56)
Etiology of Heart Failure	
Ischemic	55 (34.16)
Chagasic	30 (18.63)
Unknown origin	29 (18.01)
Valvular	15 (9.32)
Hypertension	13 (8.07)

Multifactorial	9 (5.59)
Another	7 (4.35)
Congenital	1 (0.62)
Pulmonary Hypertension	2 (1.24)
NYHA Functional Classification	
I	13 (8.07)
II	89 (55.28)
III	54 (33.54)
IV	5 (3.11)
Any Cardiac Surgery	
Yes	58 (36.02)
No	103 (63.98)
Pacemaker	
Yes	54 (33.54)
No	107 (66.46)
Type of Pacemaker	
Pacemaker	18 (11.18)
Cardioverter	17 (10.56)
Cardiac resynchronization therapy pacemaker	23 (14.29)
Alcohol	
Yes	7 (4.35)
No	154 (95.65)
Smoking	
Yes	1 (0.62)
No	160 (99.38)

NYHA (New York Heart Association).

Current treatment for Heart Failure

Median of pills taken by a patient per day was 8 pills (Q1=7;Q3=10), with a minimum of 2 and a maximum of 17 pills per day, in table 3 we can see the medications the patient is receiving for HF treatment.

Table 3. Current treatment of patients with heart failure (n=161)

Variable	n (%)
ACEI	62 (38.51)
Enalapril	61 (98.39)
Quinapril	1 (1.61)
Beta-blockers	153 (95.03)
Carvedilol	76 (49.67)
Bisoprolol	53 (34.64)
Metoprolol	23 (15.04)
Nebivolol	1 (0.65)
ARBs	80 (49.69)
Losartan	37 (46.25)
Cardesartan	35 (43.75)
Valsartan	4 (5.0)
Irbesartan	3 (3.75)
Telmisartan	1 (1.25)
Spironolactone	111 (68.94)
Furosemide	111 (68.94)

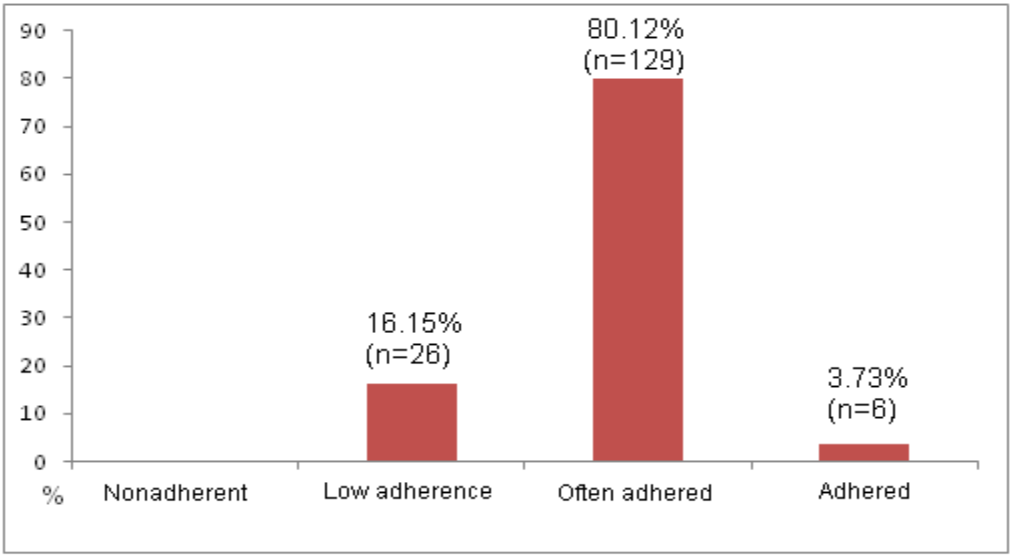
Hydrochlorothiazide	6 (3.73)
Digoxin	67 (41.61)
Antiplatelet	92 (57.14)
Anticoagulants	53 (32.92)
Other drugs	147 (91.3)

ACEI=Angiotensin-converting-enzyme inhibitor**; ARBs=** angiotensin receptor blockers.

Adherence to pharmacological and non- pharmacological treatment

The mean adherence to pharmacological and non- pharmacological treatment obtained by the instrument was 89.3 points (SD±9.04), with a minimum score of 61 and a maximum of 113 points. No patient was found in the category of non-adherence, 16.15% (n= 26; 95% CI 10.82 - 22.75%) has low adherence, 80.12% of the patients are often adhered to treatment and 3.73% (n=6; 95% CI 1.38 - 7.93%) is adhered to treatment (Figure 1).

Figure 1. Adherence to pharmacological and non-pharmacological treatment of patients with Heart Failure (n=161)



In table 4, we can see the adherence level for each instrument indicator.

Table 4. Description of the adherence to pharmacological and non-pharmacological treatment in patients with Heart failure (n=161)

Indicators	Total of Subindicators	Range Likert Scale	Classification scale	Interpretation	Average of adherence
1. Trust in the healthcare professional.	1	2.0 - 3.5	Never	Nonadherent	7.59 (SD±0.7)
	2	3.6 - 5.5	Very little	Low adherence	
		5.6 - 7.0	Often	Often adhered	
		7.1 - 8.0	Always	Adherent	
2. Knowledge of the pharmacological treatment.	3	4.0 - 7.0	Never	Nonadherent	9.27 (SD±1.9)
	4	7.1 - 11.0	Very little	Low adherence	
	5	11.1 - 15.0	Often	Often adhered	
	6	15.1 - 16.0	Always	Adherent	
3. Information about the possibility of access to services.	7	3.0 - 5.5	Never	Nonadherent	9.44 (SD±2.1)
	8	5.6 - 8.0	Very little	Low adherence	
	9	8.1 - 11.0	Often	Often adhered	

		11.1 - 12.0	Always	Adherent	
4. Acceptance of the diagnosis given by the healthcare professional	10	4.0 - 7.0	Never	Nonadherent	13.34 (SD±1.8)
	11	7.1 - 11.0	Very little	Low adherence	
	12	11.1 - 15.0	Often	Often adhered	
	13	15.1 - 16.0	Always	Adherent	
5. Recognition of signs and symptoms.	14	3.0 - 5.5	Never	Nonadherent	6.85 (SD±2.7)
	15	5.6 - 8.0	Very little	Low adherence	
	16	8.1 - 11.0	Often	Often adhered	
		11.1 - 12.0	Always	Adherent	
6. Seeks external support to comply with the health behaviours.	17	2.0 - 3.5	Never	Nonadherent	5.46 (SD±1.3)
	18	3.6 - 5.5	Very little	Low adherence	
		5.6 - 7.0	Often	Often adhered	
		7.1 - 8.0	Always	Adherent	
7. Keeps his/her weight within the recommended range.	19	4.0 - 7.0	Never	Nonadherent	10.88 (SD±2.5)
	20	7.1 - 11.0	Very little	Low adherence	
	21	11.1 - 15.0	Often	Often adhered	
8. Knows the recommended diet.	22	15.1 - 16.0	Always	Adherent	
	23	2.0 - 3.5	Never	Nonadherent	6.24 (SD±1.1)
	24	3.6 - 5.5	Very little	Low adherence	
		5.6 - 7.0	Often	Often adhered	
9. Performs daily activity, according to the recommendations of the healthcare professional.		7.1 - 8.0	Always	Adherent	
	25	3.0 - 5.5	Never	Nonadherent	9.88 (SD±1.6)
	26	5.6 - 8.0	Very little	Low adherence	
10. Proper mood for his/her health condition.	27	8.1 - 11.0	Often	Often adhered	
		11.1 - 12.0	Always	Adherent	
	28	3.0 - 5.5	Never	Nonadherent	10.30 (SD±1.5)
	29	5.6 - 8.0	Very little	Low adherence	
	30	8.1 - 11.0	Often	Often adhered	
		11.1 - 12.0	Always	Adherent	

SD±=Standard Deviation.

Compliance to pharmacological treatment was also measured with the Morisky-Green test, 53.42% (n=86; 95% CI 45.39 – 61.30%) are compliant of the pharmacological treatment; 34.78% (n=56) forgets to take the medication at least once, 59.63% (n=96) takes the medication on time, 3.11% (n=5) when feels good stops taking the medication sometime, and 3.73% (n=6) if feels bad, stops taking the medication.

DISCUSSION

A mean adherence of 89.3 points was determined in patients of the HFHTC, which indicates patients are often adhered. These results are similar to the ones described in the Achury study[9] in Bogota, with a mean adherence of 89.4 points, after the implementation of an educational plan to encourage self-care. The similarities of the mean prevalence of adherence could be explained by the characteristics of the study population; mean age was 68 years, 54% were men, 76% had primary education only, New York Heart Association functional class was I in 6% of the participants, 66% were class II and 28% were class III. In our population, mean age was 64 years, 60.25% were men, 50.93% had at least 6 years of school taken or approved and the proportion of NYHA functional class was similar.

With respect to the confidence in the healthcare professional, the mean of adherence indicates that they are adhered. Heszen and Lapinska[15], determined that a positive attitude between the physician-patient interactions promotes compliance of the physicians' orders for the patient. A qualitative research, found that a relation

characterized by confidence between the patient and the healthcare provider was a motivating factor for keeping a high adherence level[16].

Regarding the knowledge of pharmacological treatment, the mean showed a low adherence level. Knowledge is closely related to educational level; several studies have consistently related a higher adherence with a higher educational level[17,18]. In our study, the median of years taken and approved was 6 years, which may be explaining the low adherence in this indicator.

In the indicator information about the possibility of accessing to health services, patients are often adhered. Basterra[19] states that easy access to health services, minimization of waiting times, previous coordination and planification of appointments or even home assistance to patients, have demonstrated a positive influence in the degree of compliance.

Acceptance of the diagnosis made by the healthcare professional, patients are often adhered. Salinas and Nava[20] concluded that some causes of therapeutic breach are due to the no acceptance of the diagnosis, denial of the illness, and stigmatization among others.

The mean of the indicator recognition of signs and symptoms is in a level of low adherence, while Achury[9] found that patients in relation with this indicator are often adhered. This could be explained because of the studied population (hospitalized patients versus outpatients); inpatients remember more the signs and symptoms of HF, while individuals of the HF clinic are stable patients with none or few hospitalizations in the last year.

Although 89.44% of the patients has a caregiver and carries out their controls in a HF clinic, the indicator seeks external support in order to meet the health behaviors, is low adherent. The HF clinic has an interdisciplinary team that offers regularly training to their patients, however there are several reasons for patients non assistance to such trainings: they do not have a person to go with; they live in other cities and all things that this involves such as displacement, time, and economic resources among others.

The indicator keeps his/her weight between the recommended range, patients show low adherence. This indicator evaluates the daily weight control, the absence of edema, the knowledge of the amount of water allowed and the daily realization of a balance between consumption and liquid elimination.

In relation to the indicator 8 and 9, which refer to diet and physical activity, patients are often adhered. This means patients know and take a diet rich in fruits, vegetables, low in salt and fat, and that they perform the physical activity recommended by the professional and identify the signs for cessation of physical activity.

Regarding to the proper mood for their health condition, patients are often adhered. In a qualitative research, patients that believe they could improve or have a good life quality as a result of taking their medications were more willing to comply with the prescribed regimen[21].

One of the possible limitations of this study is the ability to generalize the results, because the type of sampling was non-probabilistic, however the methodology conducted, favors the internal validit Adherence was measured by self-report, which

may be overestimating the results of treatment adherence, as it has been suggested by other authors[22]. However the instrument for the evaluation of adherence to pharmacological and non- pharmacological treatment in patients with HF, has been previously validated, showing a good performance as an adherence diagnostic tool. Actions were also taken to avoid information bias.

CONCLUSIONS

The results of this study are an approach to the problem of adherence to pharmacological and non- pharmacological treatment of patients with HF. In this study with regard to the global adherence to pharmacological and non- pharmacological treatment, most patients of the HFHTC are often adhered to the therapeutic regimen. Half of the patients are compliant with the pharmacological treatment according to the Morisky-Green test.

Patients demonstrated often adherence to 6 indicators: trust the healthcare professional; information about the possibility of access to services; acceptance of the diagnosis given by the professional; know the recommended diet; perform daily physical activity according to the recommendations of the healthcare professional and proper mood for their health condition.

Low adherence was identified in four indicators: knowledge of the pharmacological treatment; recognition of signs and symptoms; seeks external support in order to comply with the health behaviors and keeps their weight within the recommended range.

It is recommended for future researches, the realization of multicenter trials with probabilistic sampling, in order to obtain generalizable results to all patients with HF of our country attending a HF program or clinic. These results may allow the implementation of actions directed to improve or maintain adherence levels as well as improve life quality of patients living with this disease.

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