

ORIGINAL STUDIES

Analysis of Heart Failure Management at the Heart Failure and Transplantation Clinics of the Cardiovascular Center of Puerto Rico and the Caribbean

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Background: Disease management programs (DMP) have been shown to be effective in management of patients with heart failure (HF).

Objective: To describe the experience at the Heart Failure and Transplantation Clinic of the Cardiovascular Center of Puerto Rico and the Caribbean (HFTC-CCPRC) implementing a model of DMP to a Hispanic population afflicted by HF.

Methods: A retrospective study was performed. Medical records from patients referred to the HFTC-CCPRC from 1999 to 2005 were selected for review. Information regarding drug regimen, New York Heart Association (NYHA) functional class, left ventricular ejection fraction (LVEF) determinations by echocardiography or scintigraphic ventriculography, left ventricular dimensions measurements, maximal oxygen consumption (MVO₂ max) determination, hospitalizations, and death cases were obtained from the initial evaluation and at 3, 6, and 12 months post-intervention at the HFTC-CCPRC.

Results: A total of 633 records were screened, from which 244 had complete information for analysis. After 12 months of treatment at the HFTC-CCPRC, NYHA functional class had decreased from 2.70 + 0.59 to 2.13 ± 0.53 (p < 0.01). LVEF had also increased from 21.0 ± 8.2% to 39.9 ± 14.6% (p < 0.01). Hospitalization rate was reduced from 62.7% within the year prior to initial evaluation to 7.2% at the end of the 12-month period (p < 0.01).

Conclusions: In our patient population, we found significant improvement in several parameters, including NYHA functional class, LVEF, and hospitalization rate after intervention at the HFTC-CCPRC. These findings are most likely related to improved guideline adherence, and are consistent with published data regarding the value of DMP's.

Key words: Heart failure, Disease management programs, Heart failure clinics

Despite advances in prevention, screening measures, diagnosis, and therapeutics, heart disease continues to be the leading cause of death in the United States (1). Heart failure (HF) afflicts over 5 million Americans, and has had a steadily rising prevalence and incidence over the past few decades (1-9). HF is responsible for over one million hospitalizations every year (1), with approximately 30% of patients being recurrently readmitted owing to HF exacerbation (2-3).

Current recommended medical therapies for HF have been proven to be effective in reducing re-hospitalization rates, improving survival, and overall quality of life. Advances in treatment of HF and early intervention to prevent decompensation are keys to delaying disease progression and improving survival (6). Despite the availability of effective treatments, multiple studies have documented substantial underuse of evidence-based, guideline-recommended therapies (4, 10-11). Furthermore, not only are treatments underused but also inappropriately used regarding dosing (12-13), which translates into adverse events and impaired prognosis (13-15). Clinical practice guidelines are designed to improve patient care, but physicians are often slow to incorporate these recommendations into their daily practice (16-19). Studies have demonstrated that patients treated by cardiologists are more likely to receive recommended diagnostic tests and treatment strategies (20), resulting

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in improved guideline adherence and quality of life, and a reduced death and cardiovascular hospitalization rates (21). Probable barriers to appropriate implementation of guideline-driven therapies include lack of awareness of existing recommended therapies, the physician's inertia and, lack of time, and supporting staff (16-19, 22).

Implementation of guideline-based medical practices is more likely to be successful in the presence of organized systems in a specialized clinic (16, 23-24). The aims of HF-DMPs include optimization of drug therapy, intensive patient education, vigilant follow-up, identification and management of patients' comorbidities (4, 25-30); being its main goal the improvement in quality of care and patient outcomes (31).

The Cardiovascular Center of Puerto Rico and the Caribbean (CCPRC) is a tertiary specialty hospital serving a large Hispanic population. At the Heart Failure & Transplantation Clinic of the CCPRC (HFTC-CCPRC), patients receive direct care from two cardiologists with specialized training in management of heart failure. Three nurses assist cardiologists in coordinating care, including titration of medications, providing patient education and follow up phone calls to ensure therapeutic compliance. When patients are hospitalized, they are cared for by the HFTC-CCPRC team for the length of their stay.

In this study, we describe the experience at the HFTC-CCPRC implementing this model of DMP to a Hispanic population afflicted by HF.

Methods

A retrospective study was performed to evaluate the experience implementing a specialty clinic DMP for Hispanic HF patients at the HFTC-CCPRC. A total of 633 medical records from patients referred to the HFTC-CCPRC from 1999 to 2005 were sequentially analyzed in this review. This study considered only patients with a properly documented diagnosis of heart failure at the time of initial evaluation, including a baseline left ventricular ejection fraction (LVEF) determination. Information regarding drug regimen, New York Heart Association (NYHA) functional class, subsequent LVEF determinations, left ventricular dimensions measurements, maximal oxygen consumption (MVO₂ max) determination, hospitalizations, and death cases were obtained from the initial evaluation and at 3, 6, and 12 months post-intervention at the HFTC-CCPRC. Records with insufficient information, those from patients lost to follow-up prior to completion of the 12-month period, records lacking a LVEF determination at the end of the 12 months, and patients submitted to transplantation were excluded from analysis.

For statistical analysis, categorical variables were reported as percentage and continuous variables were reported as mean \pm SD. All calculations were conducted using the Statistical Package for the Social Sciences (SPSS) software. Baseline characteristics for public vs. private health insurance were compared with the use of chi-square tests and Fisher's exact tests, as appropriate. Pre- and post-intervention drug regimen, NYHA functional class, LVEF, hospitalization rate, and death rate were compared using the Pair T-test and T test. In the interpretation of results, p values $<$ 0.05 were considered statistically significant.

Results

A total of 633 records were sequentially screened, from which a sample of 244 complied with established inclusion criteria for analysis. Out of the 244 patients included in the study, 72.9% (178) were men whereas 27.1% (66) were women, with an average age of 48.9 \pm 16.7 years. A total of 54.5% (133) patients had public health insurance and 45.5% (111) had private insurance. There were no differences in baseline characteristics of the population between public and private insurance patients (Table 1), except for NYHA functional class at the time of initial evaluation. Patients with public health insurance had symptoms corresponding to a NYHA class 2.78 \pm 0.57 vs. 2.60 \pm 0.59 in patients with private insurance (p 0.017). Non-ischemic cardiomyopathy was the etiology of HF in 61.5% (150) and in 28.5% (66) of cases was due to ischemic cardiomyopathy.

Use of typical therapeutic drugs for HF prior to intervention at the HFTC-CCPRC was similar among both groups, with marked underuse of aspirin (21.7%), aldosterone antagonists (27.9%), beta-adrenergic blockers (59.0%), and angiotensin converting enzyme (ACE) inhibitors (73.0%). From those receiving ACE inhibitors and beta-adrenergic blockers, there were many patients receiving suboptimal doses or agents other than those recommended for management of HF. At the end of the 12-month period, the use of beta-adrenergic blockers had increased from 59.0% to 85.3% of patients, the use of aldosterone antagonists nearly doubled from 27.9% to 54.5%, and the use of ACE inhibitors increased to 75.4% (Figure 1). Use of digitalis decreased from 87.3% to 84.4%, as well as use of diuretics declined from 84.8% to 81.2%. Over the year, use of rhythm devices, including intracardiac defibrillators (ICD) and cardiac resynchronization therapy (CRT), increased from 9.8% to 31.2%.

After 12 months of treatment, NYHA functional class had decreased from 2.70 \pm 0.59 to 2.13 \pm 0.53 (p $<$ 0.01), with a significant increase in patients with NYHA class I and II

Table 1. Baseline Characteristics of the Population. Baseline characteristics of patients with private vs. public (Reforma) health insurance were compared, the only difference being NYHA functional class at the time of referral to the Clinic.

Characteristic	Public (n = 133)	Private (n = 111)	Total (n = 244)	P-value
Age (years)	49.8 ± 20.4	47.8 ± 10.6	48.9 ± 16.7	0.360
Sex				
Men	93 (69.9%)	85 (76.6%)	178 (72.9%)	
Women	40 (30.1%)	26 (23.4%)	66 (27.1%)	
Body mass index (Kg/m ²)	29.8 ± 6.12	30.3 ± 6.14	30.0 ± 6.11	0.671
Arterial hypertension	71 (53.4%)	63 (56.8%)	134 (54.9%)	0.608
Diabetes mellitus	36 (27.1%)	31 (27.9%)	67 (27.5%)	0.887
Cigarette smoking	49 (36.8%)	52 (46.8%)	101 (41.4%)	0.120
Bronchial asthma	31 (23.3%)	20 (18.0%)	51 (20.9%)	0.345
Dyslipidemia	11 (8.3%)	8 (7.2%)	19 (7.9%)	0.814
Intracardiac defibrillator (ICD)	9 (6.7%)	6 (5.4%)	15 (6.1%)	0.791
NYHA [†] functional class (I-IV)	2.78 + 0.57	2.60 + 0.59	2.70 + 0.59	0.017*
Ejection fraction (%)	20.97 + 8.37	20.96 + 8.00	20.97 + 8.19	0.813
Left ventricular end-diastolic dimension (LVEDD, cm)	6.76 ± 0.90	6.70 ± 0.87	6.73 ± 0.88	0.713
Left ventricular end-systolic dimension (LVESD, cm)	5.73 ± 1.05	5.74 ± 0.83	5.73 ± 0.96	0.717
Use of digitalis	117 (88.9%)	96 (86.5%)	213 (87.3%)	0.697
Use of diuretics	114 (85.7%)	93 (83.4%)	207 (84.8%)	0.722
Use of aldosterone antagonists	38 (28.6%)	30 (27.0%)	68 (27.9%)	0.886
Use of beta-adrenergic blockers	81 (60.9%)	63 (56.8%)	144 (59.0%)	0.517
Use of aspirin	31 (23.3%)	22 (19.8%)	53 (21.7%)	0.537
Use of ACE [‡] inhibitors	100 (75.2%)	78 (70.3%)	178 (73.0%)	0.470
Use of angiotensin receptor blockers (ARBs)	23 (17.3%)	22 (19.8%)	45 (18.4%)	0.623

†New York Heart Association ‡Angiotensin converting enzyme *Values followed by asterisk are statistically significant at $p < 0.05$

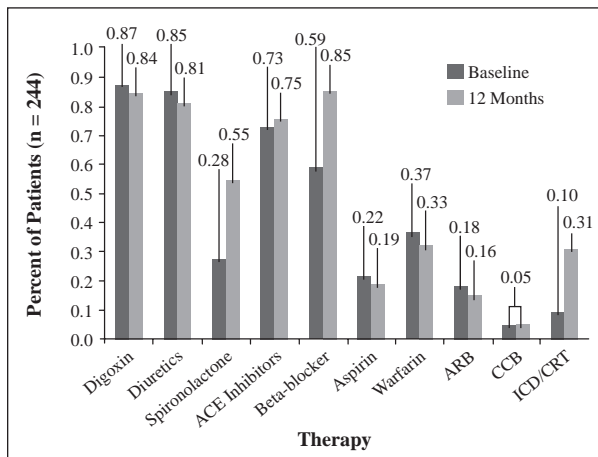


Figure 1. Medical Therapy Pre- and Post-Intervention at the HFTC-CCPRC. This graphic compares medical therapy pre- and post-intervention at the HFTC-CCPRC. ARB, angiotensin receptor blocker; CCB, calcium channel blocker; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator.

symptoms with decrease in NYHA class III and IV symptoms following intervention (Figure 2). This is compatible with a rise in LVEF (Figure 3) from $21.0 \pm 8.2\%$ at baseline to $39.9 \pm 14.6\%$ after 12 months ($p < 0.01$), including 44 (18.0%) of patients achieving a LVEF above 50%. Left ventricular end-diastolic dimension (LVEDD) decreased from 6.76 ± 0.90 cm to 6.31 ± 0.87 cm and left ventricular end-systolic

dimension (LVESD) declined from 5.73 ± 1.05 cm to 5.06 ± 0.61 cm. This finding is suggestive of reverse remodeling of the myocardium, but it did not reach statistical significance. A non-statistically significant increase in maximal oxygen consumption determination, from 16.50 ± 5.14 mL/kg/min at baseline to 17.55 ± 4.70 mL/kg/min at the end of the year was observed.

Hospitalizations rate decreased from 62.7% within the year prior to initial evaluation to 7.2% at the end of the 12-month period ($p < 0.01$). Out of the 244 patients, 6 (2.5%) were submitted to heart transplantation and 13 (5.3%) died (7 from sudden cardiac death, 5 from deteriorating HF, and 1 from myocardial infarction).

Discussion

The aim of this study was to describe the experience at the HFTC-CCPRC implementing a model of DMP to a Hispanic population afflicted by HF. We found significant improvement in several parameters, including NYHA functional class, LVEF, and hospitalization rate after intervention at the HFTC-CCPRC.

At the time of referral for heart transplantation, only 36% of patients had a NYHA functional classification I or II. In contrast, 82% of the patients had reached this classification by the end of the year. Similarly, average LVEF increased twofold from 21% to 40%, including 18% of our patients achieving a normal ejection fraction.

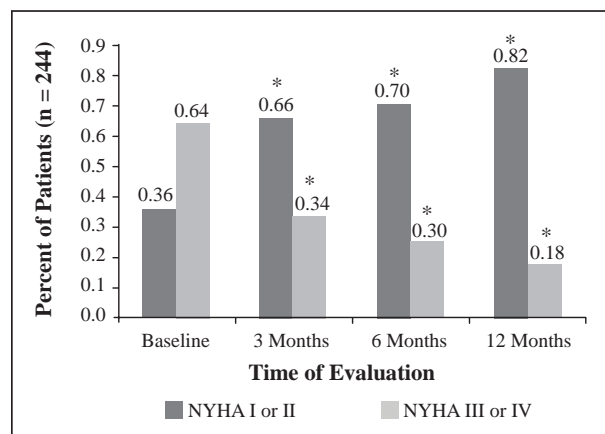


Figure 2. New York Heart Association Functional Class Symptoms at Baseline, 3-, 6-, and 12-Month Post-Intervention. Functional class according to the NYHA classification is shown at baseline and at 3-month intervals after initial evaluation at the HFTC-CCPRC. *Values followed by asterisk are statistically significant at $p < 0.05$ compared with baseline.

Hospitalization rate decreased from 62.7% to 7.2%, reflecting the improvement in both functional capacity and LVEF. These findings are most likely related to improved adherence to recommended scientifically derived, peer-reviewed HF management guidelines, demonstrated by the improvement in the use of appropriate drug regimens, dosing, and electrical devices observed in many patients from initial evaluation to one year follow up post intervention. Besides the improvement in patients' quality of life and decreased in health care costs, an important benefit from improving LVEF and functional class is a decrease in the number of patients requiring heart transplantation.

The fact that patients with public health insurance had a poorer NYHA functional class at the time of referral is probably related to delays and difficulties in obtaining proper treatment; though there were no other significant differences between public and private health insurance patients.

The results obtained in this study are consistent with published studies which have shown that DMPs represent an effective way of improving adherence to medical therapy, quality of life and overall functional status, consequently reducing rehospitalization rates and healthcare-related costs (5-6, 9, 24-30). Furthermore, they validate the need for HF patients to be cared for by a multidisciplinary team including specialists in this condition. Early referral of HF patients to this sort of specialized clinics ought to result in improved quality of life, decreased cost of care, and improved outcomes including important secondary benefits such as the

reduction in the number of patients who need a heart transplant.

In the future, a long-term prospective study, specifically designed to assess costs of care, may be performed. Inclusion of other clinical indicators, such as the six-minute walk test and validated questionnaires for assessing patients' perception regarding quality of life, may also provide for further determination of patients' well-being.

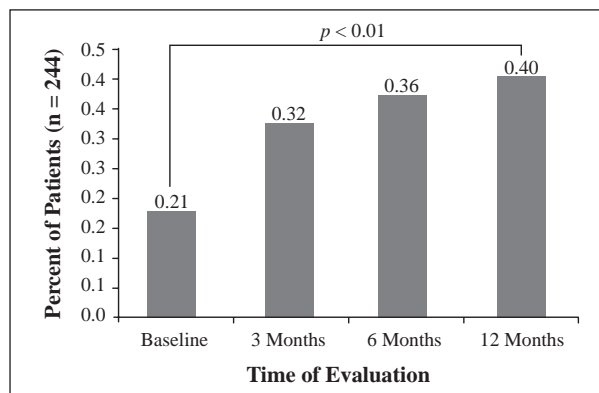


Figure 3. Left Ventricular Ejection Fraction at Baseline, 3-, 6-, and 12-Month Post-Intervention. Average left ventricular ejection fraction is shown at baseline and at 3-month intervals after initial evaluation at the HFTC-CCPRC. There is a significant increase in LVEF from baseline to end of the year.

Resumen

Se analizó la experiencia en el manejo de los pacientes atendidos entre 1999 y 2005 en la Clínica de Fallo Cardíaco y Transplante del Centro Cardiovascular de Puerto Rico y el Caribe con una muestra de 244 pacientes. La Clínica está organizada bajo el concepto de Programas de Manejo de Enfermedades (DMP, por sus siglas en inglés). Los pacientes son manejados por dos cardiólogos y tres enfermeras. Se evaluó la experiencia a los 12 meses de la intervención. La fracción de eyección aumentó de 21% a 40%. Concomitantemente, la capacidad funcional de acuerdo a la Asociación del Corazón de Nueva York (NYHA por sus siglas en inglés) mejoró en la mayoría de los pacientes, con un 74% de estos con síntomas clase III o IV al comienzo de estudio contra 82% alcanzando una clasificación I o II al final del mismo. Estos cambios ocurrieron a la par con una optimización de terapia médica para fallo cardíaco, incluyendo un mayor uso de beta-bloqueadores y antagonistas de aldactona, así como aparatos de resincronización cardíaca y defibriladores. Nuestra experiencia en el Centro Cardiovascular de Puerto Rico y el Caribe es cónsona con estudios publicados con respecto a programas de manejo de enfermedad en pacientes de fallo cardíaco y transplante.

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