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Original Article

Predictors of lack of improvement in the left ventricular ejection fraction in patients with congestive heart failure 18 months after commencement of a disease management program: A prospective observational study

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ABSTRACT

Objectives: To investigate baseline factors predictive of lack of improvement in the left ventricular ejection fraction (LVEF) 18 months after the beginning of a disease management program in patients with congestive heart failure.

Materials and methods: Patients in whom congestive heart failure is diagnosed in the cardiology outpatient division in a hospital in southern Taiwan were recruited into a disease management program. Echocardiography was performed at baseline and 18 months after commencement of the program to calculate changes in the LVEF.

Results: Eighteen months after the commencement of the program, 29 of the 76 patients (38%) had no improvement in the LVEF over baseline measurements. Multiple logistic regression analysis indicated a younger age (<70 years), no schooling, not being married, and elevated triglyceride levels (≥150 mg/dL) at baseline were significant and independent predictors of no improvement in the LVEF 18 months after commencement of the program.

Conclusion: Younger age, no schooling, not being married, and elevated triglycerides at baseline emerged as significant and independent predictors of a lack of improvement in the LVEF after 18 months of disease management intervention. These findings can serve as a basis for resource allocation when planning future disease management programs.

1. Introduction

Heart failure is a leading cause of hospitalization and readmission in many parts of the world. Despite advances in pharmacotherapeutic strategies, it remains a major clinical and public health concern because of its high morbidity and mortality [1]. Heart failure disease management programs have shown considerable promise in reducing all-cause mortality and readmission [2]. According to the Disease Management Association of America, disease management can be defined as a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant [3]. Typically, a disease management program involves multidisciplinary efforts to improve the quality and cost-effectiveness of care for selected patients with chronic illness. It should include elements such as identification of at-risk populations, a coordinated system of care, support for patient self-care, and a patient and care provider feedback system, with measures of clinical and other outcomes [4]. For example, a randomized controlled trial compared usual care with a disease management program in 71 Taiwanese patients with congestive heart failure. The

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program consisted of evaluations and coordination of plans of care during hospitalization and 90 days after discharge from the hospital. The postdischarge follow-up consisted of three telephone counseling sessions and three outpatient educational sessions during the 90-day period. Patient disease awareness, self-care behavior, and quality of life were significantly improved at the end of the intervention. In addition, the mean length of hospitalization was significantly shorter (2.8 days) and the cost of hospitalization was lower (16,018 New Taiwan Dollars) than in patients with usual care. The 90-day readmission rate was also significantly reduced (20.7%) with the intervention [5].

However, not all patients enrolled in a disease management program have the desired positive outcomes at the end of the program and particularly, for some time after the end of the program [6,7]. It would be useful for a disease management team to know in advance what types of patients are less likely to show long-term success at the start of a program so that efforts can be effectively targeted to these patients. However, little is known about the predictive factors for a lack of successful disease management clinical outcomes. The goal of the current study was to identify factors at baseline that were predictive of a lack of improvement in the left ventricular ejection fraction (LVEF) in patients with congestive heart failure 18 months after commencement of a heart failure disease management program.

2. Materials and methods

2.1. Study design

This study used a prospective design to identify factors at baseline that were predictive of a lack of improvement in the LVEF in patients with congestive heart failure 18 months after commencement of a heart failure disease management program.

2.2. Setting and samples

This study was conducted at a regional teaching hospital in southern Taiwan between June 2011 and March 2012. All patients with a diagnosis of congestive heart failure (International Classification of Diseases, 9th Revision, Clinical Modification, ICD-9-CM code 428.0) were referred by cardiologists in the cardiology outpatient division to a disease management nurse. These patients were invited to enroll in a disease management program. The inclusion criteria were as follows: outpatients with a diagnosis of congestive heart failure, age 18 years or older, able to communicate, and consent to participate in the study. Patients who had previously enrolled in similar programs, either at the study hospital or other hospitals, were excluded from the study (Fig. 1).

2.3. Ethical considerations

All participating patients provided informed consent after they were given a full explanation of the study. The study protocol was approved by the institutional review board of the study hospital (No. B10301002).

2.4. Measurements

Self-care behavior was assessed using the European Heart Failure Self-Care Behavior scale (EHFScBS). The scale was developed based on international guidelines for heart failure management and it defines self-care as the strategies undertaken by an

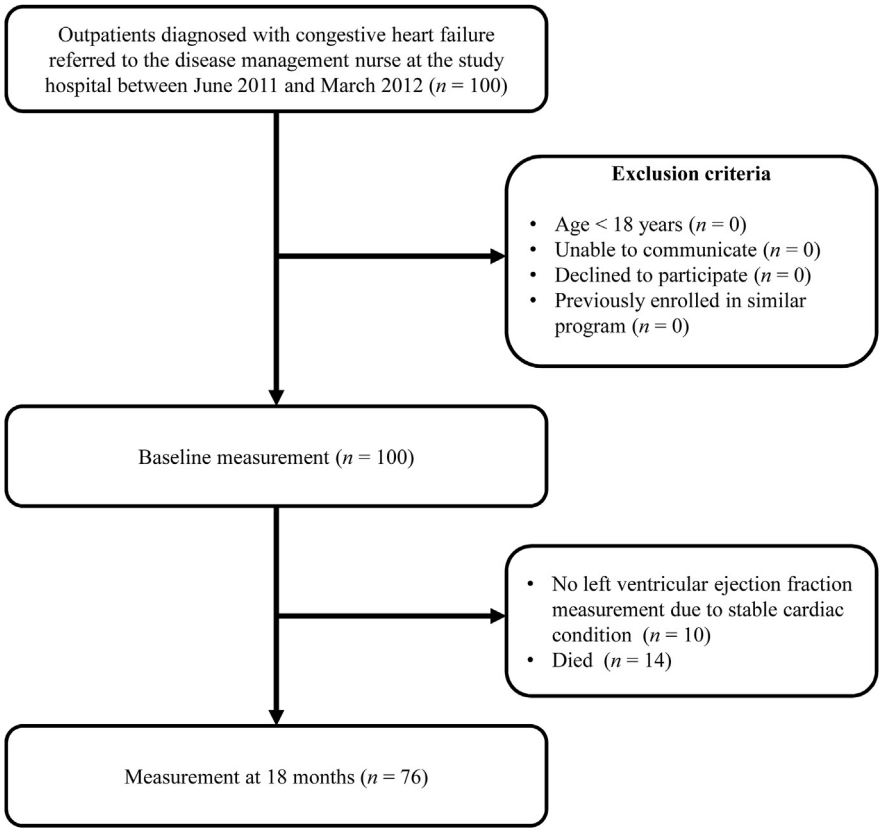

Fig. 1. Flowchart of the study.

individual to maintain and optimize his or her own health and well-being [8]. The scale consists of 12 items divided into three subscales to assess "complying with regimen" (2 items), "seeking help" (4 items), and "adapting activities" (6 items). Each item is rated on a 5-point Likert scale, with a higher score indicating poorer self-care behavior. The translated Chinese version of the EHFScBS showed adequate psychometric properties with an item content validity index of 0.96, a scale content validity index of 0.89, and a Cronbach α of 0.82. In the Chinese version, two items (1 from the complying with regimen subscale and 1 from adapting activities subscale) were removed from the original scale to improve its internal consistency [9]. Therefore, the 10-item scale contains one item in "complying with regimen" (range of scores, 0–5), four items in "seeking help" (range of scores, 0–20), and five items in "adapting activities" (range of scores, 0–25). The full scores of the EHFScBS were further dichotomized based on the median value.

Echocardiography was performed with the patient lying in the left lateral recumbent position. LVEF images were acquired from the parasternal long-axis view. When wall motion abnormalities were present, images were obtained from the apical four-chamber view. When the rhythm was irregular, five consecutive beats were measured. The disc summation method was used to assess the left ventricular end-diastolic volume (EDV) and end-systolic volume (ESV) as recommended by the American Society of Echocardiography [10]. The LVEF was calculated based on volume as follows: (EDV − ESV)/EDV.

An 8-hour fasting blood sample from each participant was analyzed for levels of total cholesterol, high density lipoprotein-cholesterol (HDL-C), low density lipoprotein-cholesterol (LDL-C), triglycerides, and glucose. The clinical severity of heart failure was classified according to the New York Heart Association (NYHA) function classification system.

Risk factors for cardiovascular diseases were categorized according to national guidelines for defining metabolic syndrome [11]. Specifically, waist circumference was dichotomized using cutoff values of 90 cm for men and 80 cm for women. Elevated blood pressure was defined as a systolic blood pressure $\geq$130 mmHg or diastolic blood pressure $\geq$85 mmHg. A high triglyceride level was defined using a cutoff value of $\geq$150 mg/dL. Low HDL-C was defined as levels $\leq$40 mg/dL in men or $\leq$50 mg/dL in women. High fasting blood glucose was defined as levels $\geq$100 mg/dL.

2.5. Data collection

Data on patient characteristics, biochemical parameters, lifestyle factors, and self-care behavior were ascertained from the participants at baseline. The LVEF was determined noninvasively using echocardiography at baseline and 18 months after commencement of the program.

The disease management program in this study consisted of patient educational advice, including disease awareness, medication review, sodium intake restriction, exercise, fluid intake restriction, weight management, and cessation of smoking, alcohol, and betel-nut chewing, where appropriate. Participants were asked to visit the disease management clinic when they visited the hospital for their scheduled medical follow-ups, which occurred at 7-day, 14-day, 1-month, or 3-month intervals depending on their medical conditions. The educational session for each patient lasted ~10 minutes. In addition, patients were encouraged to consult with the disease management nurse over the telephone between scheduled visits as needed. A level III (N3) disease management nurse with >14 years of nursing experience including > 4 years in disease management was responsible for implementing the program. In Taiwan, the clinical nursing ladder system consists of four levels: N1 (advanced beginner), N2 (competent), N3 (proficient), and N4 (expert).

2.6. Data analysis

All data analyses were conducted using IBM SPSS Statistics software package, version 21.0 (IBM Corp., Armonk, NY, USA). Continuous data were expressed as mean ± standard deviation (SD) and categorical variables were represented by frequency and percentage (%). A paired t test was used to assess changes in the LVEF over the two time points. Univariate logistic regression analysis was conducted to assess baseline predictors for no improvement in the LVEF 18 months after commencement of the program. The binary outcome variable was "no improvement in LVEF", which was defined as a lower value for the LVEF 18 months after commencement of the program compared with the baseline value. In addition, multivariate logistic regression analysis was conducted to assess significant and independent predictors of the outcome variable. Because the sample size was small relative to the number of independent variables which were evaluated, we did not rely solely on the automated selection procedures of the statistical program. Instead, we built our final model by first including variables that had $p < 0.10$ obtained from the univariate analysis. Then, other independent variables were evaluated one at a time by manually adding and removing them from the model similar to a stepwise variable selection procedure. The model obtained manually was also compared with that generated by a backward elimination procedure based on the likelihood ratio test from SPSS. Goodness-of-fit assessment using the Hosmer-Lemeshow test and multicollinearity using the variance inflation factor were assessed in the final model. Interactions between age groups and the other significant independent variables were also checked in the final model.

3. Results

Ten of the 100 eligible patients recruited at baseline did not receive an echocardiogram for the LVEF at the end of the program because their cardiac condition was stable. In addition, 14 patients died before the end of the disease management program. The cause of death of five of them was related to heart disease. These 24 patients were excluded from the final analyses.

The mean age of the remaining 76 study participants was 68.3 years ± 12.6 years (range, 41–92 years) and 76% were men. Overall, the mean LVEF at baseline was 34.4% ± 10.7%, which improved to 50.0% ± 15.7% 18 months after commencement of the program. The difference between the two measurements was evaluated with a paired t test and the mean decrease of 15.6% was found to be significant ($p < 0.001$). Nevertheless, at the individual level, not all patients had improvement in the LVEF after the intervention. Twenty-nine of the 76 patients (38%) had no improvement in the LVEF. Table 1 shows the results of univariate analysis of the association between patient and clinical variables at baseline and no improvement in the LVEF 18 months after commencement of the disease management program.

Results from multivariate analysis indicated that four variables were significant and independent predictors of a lack of improvement in the LVEF after 18 months (Table 2). Patients younger than 70 years had a significantly higher risk of no improvement in the LVEF [adjusted odds ratio (OR) = 5.62, $p = 0.011$] than older patients. Patients with no schooling also had a significantly higher risk of no improvement in LVEF (adjusted OR = 7.60, $p = 0.031$) compared with those with at least elementary schooling. Moreover, patients who were not married (single, divorced, or widowed) had an increased risk of no improvement (adjusted OR = 4.61,

Table 1
Univariate logistic regression analyses of the association between demographic and clinical variables at baseline and no improvement in left ventricular ejection fraction 18 months after the commencement of the disease management program ($n = 76$).

Variable	*N* (%)[a]			Odds ratio (95% confidence interval)	*p*
	Total 76 (100)	Improvement in LVEF 47 (62)	No improvement in LVEF 29 (38)		
Sex					
Male	58 (76)	38 (81)	20 (69)	1.00	
Female	18 (24)	9 (19)	9 (31)	1.90 (0.65, 5.54)	0.240
Age (y)					
≥70	37 (49)	27 (57)	10 (35)	1.00	
<70	39 (51)	20 (43)	19 (66)	2.57 (0.98, 6.70)	0.054
Body mass index[b]					
Normal & underweight	29 (38)	18 (38)	11 (38)	1.00	
Overweight	19 (25)	13 (28)	6 (21)	0.76 (0.22, 2.57)	0.653
Obese	28 (37)	16 (34)	12 (41)	1.23 (0.43, 3.54)	0.705
Waist circumference[c]					
Normal	33 (43)	21 (45)	12 (41)	1.00	
Abnormal	43 (57)	26 (55)	17 (59)	1.14 (0.45, 2.92)	0.778
Educational level					
Elementary school or above	64 (84)	41 (87)	23 (79)	1.00	
No schooling	12 (16)	6 (12)	6 (21)	1.78 (0.52, 6.17)	0.361
Living arrangement					
Living alone	16 (21)	10 (21)	6 (21)	1.00	
Living with someone	60 (79)	37 (79)	23 (79)	1.04 (0.33, 3.23)	0.951
Marital status					
Married	55 (72)	39 (83)	16 (55)	1.00	
Single, divorced, or widowed	21 (28)	8 (17)	13 (45)	3.96 (1.38, 11.38)	0.011
Smoking					
No	25 (33)	15 (32)	10 (35)	1.00	
Yes	51 (67)	32 (68)	19 (66)	0.89 (0.34, 2.38)	0.817
Alcohol use					
No	41 (54)	25 (53)	16 (55)	1.00	
Yes	35 (46)	22 (47)	13 (45)	0.92 (0.36, 2.34)	0.866
Exercise regularly					
No	37 (49)	26 (55)	11 (38)	1.00	
Yes	39 (51)	21 (45)	18 (62)	2.03 (0.79, 5.21)	0.143
Type 2 diabetes					
No	46 (61)	30 (64)	16 (55)	1.00	
Yes	30 (39)	17 (36)	13 (45)	1.44 (0.46, 1.44)	0.454
Blood pressure (mmHg)[d]					
Normal	43 (57)	28 (60)	15 (52)	1.00	
Abnormal	33 (43)	19 (40)	14 (48)	1.38 (0.54, 3.50)	0.503
Self-care behavior (EHFScBS)					
Better (score ≤ 45)	29 (38)	19 (40)	10 (35)	1.00	
Worse (score ≥ 46)	47 (62)	28 (60)	19 (66)	1.29 (0.49, 3.38)	0.605
EHFScBS full scale	45.5 ± 2.9	45.4 ± 2.9	45.6 ± 2.8	not applicable	0.707
EHFScBS adapting activities subscale	22.1 ± 2.0	22.0 ± 2.1	22.4 ± 1.9	not applicable	0.417
EHFScBS seeking for help subscale[e]	20.0 ± 0	20.0 ± 0	20.0 ± 0	not applicable	no applicable
EHFScBS complying with regimen subscale	3.4 ± 1.8	3.4 ± 1.8	3.3 ± 1.8	not applicable	0.764
Blood glucose					
Normal (<100)	15 (20)	10 (21)	5 (17)	1.00	
Abnormal (≥100)	61 (80)	37 (79)	24 (83)	1.30 (0.40, 4.27)	0.668
HDL-C[f]					
Normal	27 (36)	14 (30)	13 (45)	1.00	
Abnormal	49 (64)	33 (70)	16 (55)	0.52 (0.20, 1.37)	0.186
Triglycerides (mg/dL)					
Normal (<150)	41 (54)	33 (70)	8 (28)	1.00	
Abnormal (≥150)	35 (46)	14 (30)	21(72)	6.19 (2.22, 17.27)	0.001
Years diagnosed with heart failure					
0–2	43 (57)	27 (57)	16 (55)	1.00	
3–12	33 (43)	20 (43)	13 (45)	0.91 (0.36, 2.32)	0.846
Pacemaker use					
No	70 (92)	43 (92)	27 (93)	1.00	
Yes	6 (8)	4 (9)	2 (7)	0.80 (0.14, 4.65)	0.800
β-blocker use					
No	37 (49)	25(53)	12 (41)	1.00	
Yes	39 (51)	22 (47)	17 (59)	1.64 (0.64, 4.22)	0.308
ACE inhibitors use					
No	45 (59)	29 (62)	16 (55)	1.00	
Yes	31 (41)	18 (38)	13 (45)	1.37 (0.52, 3.56)	0.524
ARB use					
No	49 (64)	28 (60)	21 (72)	1.00	
Yes	27 (36)	19 (40)	8 (28)	0.54 (0.20, 1.50)	0.237

(*continued on next page*)

Table 1 (*continued*)

Variable	*N* (%)[a]			Odds ratio (95% confidence interval)	*p*
	Total 76 (100)	Improvement in LVEF 47 (62)	No improvement in LVEF 29 (38)		
NYHA functional classification					
Class I	17 (22)	11 (23)	6 (21)	1.00	
Class II	51 (67)	31(66)	20 (69)	1.18 (0.38, 3.71)	0.773
Class III & IV	8 (11)	5 (11)	3 (10)	1.10 (0.19, 6.29)	0.915

Data are presented as *n* (%) or mean ± SD.
ARB = angiotensin-receptor blocker; ACE = angiotensin-converting enzyme; EHFScBS = European Heart Failure Self-Care Behavior Scale; HDL-C = high density lipoprotein-cholesterol; LDL-C = low Density lipoprotein-cholesterol; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; SD = standard deviation.
[a] % are column percentages except in the header row where they are row percentages.
[b] Body mass index categories was defined as the following: underweight (<18.5 kg/m^2), normal (18.5 kg/m^2 ≤ BMI ≤ 23.9 kg/m^2), overweight (24.0 kg/m^2 ≤ BMI ≤ 26.9 kg/m^2), and obese (≥27.0 kg/m^2).
[c] Normal waist circumference was defined as <90 cm for men and <80 cm for women.
[d] Normal blood pressure was defined as systolic blood pressure <130 mmHg and diastolic blood pressure <85 mmHg.
[e] All 76 patients responded to all four items of the EHFScBS "seeking for help" subscale with the answer "I completely disagree" and therefore, the mean score for this subscale is 20 (5 marks × 4 items) with no standard deviation.
[f] Normal high density lipoprotein-cholesterol was defined as > 40 mg/dL in men and >50 mg/dL in women.

$p = 0.018$) compared with those who were married. Finally, patients with an elevated triglyceride level at baseline had a significantly increased risk of no improvement in the LVEF (adjusted OR = 9.27, $p = 0.001$) compared with those with normal levels of triglycerides.

4. Discussion

Although disease management programs have been shown to lead to favorable clinical outcomes in patients with heart failure, there are always individuals who fail to show improvement with these interventions. If these patients could be identified at the start of the program, it might be possible to increase the success of the intervention by reallocating available resources to meet their needs. This study followed patients with heart failure for 18 months and used an objective clinical indicator, the LVEF, to assess the success of the program. Results showed that younger age, no schooling, not being married, and elevated triglycerides at baseline were significant and independent predictors of a lack of improvement in the LVEF 18 months after commencement of the program. It is not surprising to find that patients with no schooling have a higher risk of no improvement because they might be less likely to read and comprehend even the most basic health-related materials [12]. A prospective cohort of 3,260 Medicare managed care enrollees reported that literacy levels could affect the risk of hospital admission in individuals with congestive heart failure [13].

Although older age has been associated with a worse functional health literacy even after adjusting for performance on the Mini Mental State Examination [14], younger age (<70 years) was observed to be independently associated with no improvement in the LVEF in our study. The reasons for this association were not clear but could be due to higher intervention compliance in elderly patients. A study of 140 patients with heart failure reported that elderly patients were significantly more compliant with diet and exercise than their younger counterparts [15].

The presence of supportive relationships has been reported to positively influence self-care behaviors in patients with heart failure [16]. Married patients with heart failure, through better decision making and emotional support, might have higher self-care confidence, which thereby indirectly leads to improved outcomes [17].

Our study showed a strong association between elevated baseline triglyceride levels and no improvement in the LVEF after 18 months. The plasma triglyceride level is a significant correlate of visceral adiposity [18], and increased visceral adiposity has been associated with left ventricular diastolic dysfunction even after adjusting for patient characteristics, cardiovascular risk factors, antihypertensive medication, physical activity, and left ventricular mass [19]. Therefore, it is plausible that elevated visceral adiposity at baseline might be a barrier to improvement in the LVEF in these patients.

In contrast to predictive models for hospital readmission, a lower functional status and female sex [20,21] were not significant factors predicting no improvement in the LVEF in our model. In addition, neither the total score on the EHFScBS nor scores on its subscales at baseline were significant factors. It should be noted that only the baseline values on the EHFScBS were used in this study. Because self-care behavior should improve with patient education, EHFScBS scores are likely to change over time. Furthermore, studies have shown both direct and inverse associations between self-care and cardiac functions. A study on self-care of 94 heart failure patients at a multidisciplinary heart function clinic in Canada found worsening heart function as measured by the LVEF was associated with better self-care. The authors postulated that patients with worse conditions perceived a greater need to take care of themselves [22]. Nevertheless, another study on therapy with warfarin in 80 patients with chronic health failure found that nonadherence was associated with improvement in the LVEF over time. It was hypothesized that with improvement in cardiac function, patients may feel better, which leads them to neglect proper self-care practices [23].

Although predictive models for identifying patients with heart failure at risk for hospital readmission are available [24,25], to our knowledge, no studies have attempted to develop predictive

Table 2
Multivariate logistic regression analysis of the association between factors at baseline and no improvement in left ventricular ejection fraction 18 months after the commencement of the disease management program ($n = 76$).[a]

Variable	Adjusted odds ratio (95% CI)	*p*
Age (y)		
≥70	1.00	
<70	5.62 (1.49, 21.20)	0.011
Educational level		
Elementary school or above	1.00	
No schooling	7.60 (1.20, 48.05)	0.031
Marital status		
Married	1.00	
Single, divorced, or widowed	4.61 (1.29, 16.45)	0.018
Triglycerides (mg/dL)		
Normal (<150)	1.00	
Abnormal (≥150)	9.27 (2.55, 33.62)	0.001

CI = confidence interval.
[a] Nagelkerke $R^2 = 0.43$, Hosmer and Lemeshow goodness-of-fit test, $p = 0.336$.

models to identify factors associated with negative outcomes of disease management programs for these patients. Nevertheless, our results should be interpreted with caution given the limitations of our study, namely, the small number of participants and the fact that they were recruited from a single hospital. In addition, it is possible that there were other unmeasured factors that contributed to the lack of improvement in the LVEF. However, the factors in our study were those that could typically be collected at the commencement of a disease management program.

In conclusion, in this prospective observational study of patients with congestive heart failure, we found four factors, namely, age younger than 70 years, no schooling, not being married, and an elevated triglyceride level, at baseline of a disease management program were significant and independent predictors of a lack of improvement in the LVEF 18 months after commencement of the program. Our findings can provide insight for heart failure disease management teams when developing interventions and allocating available resources to those who are less likely to gain positive outcomes in disease management programs. For example, the role of families and caregivers should be examined to assess whether they can affect the outcome of a disease management program [26].

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