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Lifestyle changes and clinical profile in coronary heart disease patients with an ejection fraction of ≤40% or >40% in the Multicenter Lifestyle Demonstration Project☆

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Abstract

Background: Lifestyle changes are recommended for coronary heart disease (CHD) patients at risk for heart failure (HF) [ACC/AHA stage B; left ventricular ejection fraction (LVEF)≤40%]. However, it is not clear whether changes in lifestyle are feasible and beneficial in these patients.
Aim: To investigate the feasibility of intensive lifestyle changes for CHD patients at risk for HF.
Methods: We compared 50 patients (18% female) with angiographically documented LVEF ≤ 40% (mean = 33.4 ± 7.3; range: 15–40%) to 186 patients (18% female) with LVEF > 40% (mean = 58.2 ± 9.6; range: 42–87%), who were participants in the Multicenter Lifestyle Demonstration Project (MLDP). All were non-smoking CHD patients. The MLDP was a community-based, insurance-sponsored intervention (low-fat, plant-based diet; exercise; stress management) implemented at 8 sites in the US. Coronary risk factors, lifestyle and quality of life (SF-36) were assessed at baseline, 3 and 12 months.
Results: Regardless of LVEF, patients showed significant improvements (all $p < .05$) in lifestyle behaviours, body weight, body fat, blood pressure, resting heart rate, total and LDL-cholesterol, exercise capacity, and quality of life by 3 months; most improvements were maintained over 12 months.
Conclusion: CHD patients at risk for heart failure with an LVEF ≤ 40%, can make changes in lifestyle to achieve similar medical and psychosocial benefit to patients with an LVEF > 40%.

Keywords: Heart failure (ACC/AHA stage B); Left ventricular ejection fraction; Diet; Lifestyle; Coronary risk factors; Quality of life

1. Introduction

Prevalence of heart failure (HF) remains high and its prognosis poor [1]. The importance of early intervention in patients at risk for HF has been emphasized [2]. One group of patients at high risk for HF and associated mortality are those classified as stage B according to the guidelines of the American College of Cardiology/American Heart Association (ACC/AHA) [i.e., patients with structural heart disease and left ventricular ejection fraction (LVEF) ≤ 40% but without current signs or symptoms of HF] [3–5]. While medical treatments vary according to each stage of the disease (Stage A: high risk for HF but no structural heart disease or symptoms of HF; Stage C: structural heart disease with prior or current symptoms of HF; Stage D: refractory HF requiring specialized interventions) [2,3,6], lifestyle changes (e.g., smoking cessation, regular exercise, reduced alcohol intake) are recommended regardless of stage [2,6].

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In two randomised controlled trials, intensive lifestyle changes (low-fat diet, exercise, stress management) have been shown to reduce cardiac risk factors in patients with coronary heart disease (CHD) and slow the progression of the disease [7,8], which is the major underlying cause of HF [9]. However, it is not clear whether patients at risk for HF (i.e., stage B patients with LVEF ≤ 40%) can adhere to an intensive lifestyle change program and benefit from making such changes.

There is some indication from small studies that single-component interventions targeting exercise are related to improvements in symptoms, LVEF, exercise capacity, and quality of life in patients with chronic HF [10–13]. Promoting multiple lifestyle behaviours in stage B patients may be of even greater importance for stabilizing clinical status and reducing the rate of disease progression [6,9,14]. However, it is not clear whether these CHD patients can follow comprehensive lifestyle changes, particularly patients with reduced LVEF, given their disease severity.

The aim of this study was to investigate whether CHD patients at risk for HF (ACC/AHA stage B) can make comprehensive changes in diet, exercise, and stress management to achieve a similar improvement in medical risk factors and quality of life as those with LVEF > 40%. Data from a subsample (n = 236) of the Multicenter Lifestyle Demonstration Project [MLDP] comparing outcomes of patients with an LVEF ≤ 40% to those with an LVEF > 40%, were analysed. Findings based on the entire sample of the MLDP have been reported elsewhere [15–17].

2. Methods

2.1. Recruitment and procedure

Recruitment and methodology have been described previously [15–17]. Briefly, MLDP was a multi-site, insurance-sponsored, secondary prevention study of patients with angiographically documented CAD severe enough to warrant revascularization (according to the coverage policy standards of the Mutual of Omaha Insurance Company) but who opted for lifestyle changes instead. (This was deemed medically safe.) The study also included patients who had previous coronary artery bypass graft (CABG) or percutaneous transluminal bypass graft (PTCA) and were in a stable condition. Medical history was assessed at baseline; all other variables were assessed at baseline, 3 months and 1 year.

2.2. Participants

Participants in the present study were a subgroup (N = 236) of patients from the intervention arm of the MLDP [N = 440; 347 men; 93 women; sex differences have been reported elsewhere [16]]; who had angiographically determined LVEF at study entry and were in a medically stable condition. The MLDP was an ambulatory, community-based, Phase IV clinical trial evaluation, conducted between 1993 and 1997. Eligibility criteria for study participation have been reported previously [15,16]. Briefly, patients were excluded from the study if they had one or more of the following conditions: (1) left main CAD with > 50% occlusion or left main equivalent CAD; (2) CABG within the past 6 weeks; (3) angioplasty within the previous 6 months; (4) myocardial infarction within the last month; (5) chronic congestive heart failure with New York Heart Association class symptoms III or greater and unresponsive to medications; (6) malignant uncontrolled ventricular arrhythmias; (7) hypotensive blood pressure response to exercise testing; and (8) diagnosed homozygous hypercholesterolaemia. This investigation conforms with the principles outlined in the Declaration of Helsinki (Br Med J 1964;ii:177). The research protocol was approved by the Committee on the Protection of Rights of Human Subjects and written informed consent was obtained from all participants. Patients were placed into one of two groups: those with an LVEF ≤ 40% [3] who were at risk for HF [ACC/AHA, 2005 [2], Stages B (N = 49) or C (N = 1)[1]] or those with an LVEF > 40%. All patients were non-smokers.

2.3. Measures

2.3.1. Determination of LVEF

In the group with an LVEF ≤ 40%, ejection fraction had been determined by left ventricular contrast angiography with direct left ventriculography in 46 patients (92%) and by quantitative two-dimensional echocardiography in 4 patients (8%). In the group with LVEF > 40%, 178 patients (96%) had undergone left ventricular contrast angiography with direct left ventriculography and 8 patients (4%) had undergone quantitative two-dimensional echocardiography.

2.3.2. Medical variables

Recorded medical variables included; history of hypertension, hyperlipidaemia, myocardial infarction, chest pain, cerebrovascular accident, diabetes, revascularization procedures, familial CHD, height, weight, % body fat (skin fold measurement), blood pressure, angina, plasma lipids and lipoproteins, and exercise capacity. Exercise capacity was assessed by a symptom-limited treadmill test according to the Bruce protocol [18], and the guidelines of the American College of Sports Medicine [19]. In brief, patients following the conventional Bruce treadmill protocol started the test at 1.7 mph, 10% grade (for 3 min) and continued in 3-minute intervals (i.e., at 2.5 mph, 12% grade; at 3.4 mph, 14% grade; at 4.2 mph, 16% grade; 5.0 mph, 18% grade; and 5.5 mph, 20% grade, respectively). The test was discontinued in the event of limiting symptoms (angina, dyspnoea, or fatigue), abnormalities of rhythm or blood pressure, or marked and progressive ST-segment deviation. Target heart rates were not used as a predetermined end point. Metabolic equivalents (METs), a

[1] Stage C patient (1) was not excluded from the sample secondary to a history of HF, controlled with medication, and physician approval to participate in the program.

measure of energy expenditure, were automatically calculated by the testing device during the exercise testing (1 MET equals approximately 3.5 mL of oxygen consumed per minute per kilogram of body weight). Diet assessment was based on a 3-day food diary. Types of medication documented included anti-hypertensives (e.g. ACE-inhibitors, beta-blockers), calcium channel blockers, nitrates and cardiac glycosides (e.g. digoxin). For details on the administration of the measures, see (16).

2.3.3. Quality of life

Quality of life was measured by the Medical Outcomes Study 36-item Short Form Health Survey (MOS SF-36) and summarized as physical and mental health aggregate scores [20]. Validity and reliability information for the MOS SF-36 have been reported previously [21].

2.4. Intervention: the Lifestyle Change Program

The program began with a twelve-hour weekend orientation. Patients then attended program sessions in groups three times per week for 12 weeks. Two of these weekly sessions focused on the four program components (diet, exercise, stress management, group support) in 1-hour blocks. The third weekly session consisted of a 1-hour aerobic exercise session (for example on a treadmill) and a 1-h lecture. Overall, 36 sessions were offered during the first 3 months of the program. Over the following 40 weeks, patients continued to meet in intervention groups once a week for a 4-hour session, focusing on the program components. In addition, they were instructed to follow the diet and exercise program and practice stress management on their own [15].

2.4.1. Adherence to the Lifestyle Change Program

Diet: percent of calories from fat (based on 3-day food diary; goal: 10%). *Exercise*: hours per week [according to the guidelines of the American College of Sports Medicine, [19]; goal: 3 h/week]. *Stress management*: hours per week of yoga/meditation (goal: 1 h/day). *Attendance at intervention groups*: number of sessions attended divided by the number of sessions offered.

2.5. Statistical analysis

Comparisons of group differences at baseline (LVEF ≤ 40% or > 40%; first year graduate vs. drop-out) were performed with two-sample *t*-tests for continuous variables and with Chi-square tests for categorical variables. ANOVAs for repeated measures with one within factor at three levels (time: baseline, 3 months, 1 year) and one between-subjects factor (LVEF: ≤ 40%, > 40%) were computed to test for the effects of time and LVEF and their interaction on coronary risk factors, lifestyle behaviours, and quality of life. All analyses were re-run with sex as a between-subjects factor. Significant sex differences are indicated in the results. Bonferroni adjustments were made for multiple comparisons. SPSS 12.0 was used to perform the statistical analysis.

Table 1
Baseline characteristics of patients according to left ventricular ejection fraction (LVEF)

Measure	LVEF ≤ 40%	LVEF > 40%	*p*-value
	N = 50	*N* = 186	
Age (years; Mean, SD)	56.9 ± 10.1	59.0 ± 9.8	.187
Sex (% male)	82%	82%	.966
Education (years; Mean, SD)	14.5 ± 2.8	16.0 ± 3.1	< .01
Married or cohabiting (%)	88%	82%	.425
Employed outside the home (%)	59%	66%	.258
Spousal participation (%)	51%	47%	.494
Left ventricular ejection fraction (Mean, SD)	33.4 ± 7.2	58.2 ± 9.6	< .001
Family history of CAD [a] (%)	64%	56%	.475
History of diabetes (%)	20%	22%	.847
Previous cigarette smoker (%)	72%	60%	.110
Systemic hypertension (%)	56%	47%	.247
Hyperlipidaemia [b] (%)	58%	60%	.951
Previous myocardial infarction (%)	80%	50%	< .001
Previous coronary angioplasty (%)	60%	37%	< .01
Previous coronary bypass (%)	50%	30%	< .01
Angina pectoris (during past 30 d) (%)	42%	59%	< .05
Beta-blockers (%)	66%	55%	.157
Angiotensin-converting enzyme inhibitors (%)	58%	14%	< .001
Anti-platelet or anti-coagulants (%)	84%	82%	.773
Nitrates (%)	28%	44%	< .05
Diuretics (%)	28%	5%	< .001
Calcium antagonists (%)	38%	61%	< .01
Digoxin (%)	22%	6%	< .01
Antiarrhythmics (%)	2%	4%	.541
Lipid lowering therapy (%)	58%	53%	.504
BMI (kg/m^2; Mean, SD)	29.2 ± 5.0	28.1 ± 5.8	.240
Body weight (kg; Mean, SD)	89.0 ± 17.6	84.6 ± 17.9	.124
Body fat (%; Mean, SD)	15.6 ± 8.3	13.7 ± 8.9	.286
Systolic blood pressure (mm Hg; Mean, SD)	126.0 ± 16.5	133.5 ± 19.3	< .05
Diastolic blood pressure (mm Hg; Mean, SD)	78.5 ± 9.8	79.1 ± 9.7	.675
Heart rate at rest (beats/min; Mean, SD)	74.0 ± 13.6	68.4 ± 12.9	< .01
Total serum cholesterol (mg/dL; Mean, SD)	204.4 ± 37.5	202.2 ± 60.2	.812
LDL cholesterol (mg/dL; Mean, SD)	125.0 ± 34.3	123.6 ± 49.1	.862
HDL cholesterol (mg/dL; Mean, SD)	35.3 ± 10.4	36.7 ± 11.5	.472
Triglycerides (mg/dL; Mean, SD)	248.6 ± 185.6	221.4 ± 154.3	.305
Exercise capacity (METs; 3.5 $mL \cdot kg^{-1} \cdot min^{-1}$; Mean SD)	9.1 ± 3.2	9.1 ± 2.9	.968
Diet (% of calories from fat; Mean, SD)	15.6 ± 8.3	13.7 ± 8.9	.189
Exercise (h/week; Mean, SD)	1.9 ± 1.9	2.1 ± 2.1	.488
Stress management (h/week; Mean, SD)	.23 ± .67	.62 ± 1.5	.089
Physical health [c] (Mean, SD)	44.8 ± 10.0	45.7 ± 9.6	.556
Mental health [c] (Mean, SD)	47.6 ± 11.3	47.8 ± 10.6	.903

[a] Family history of CAD was considered positive if a male (< 60 years of age) or female (< 70 years of age) first-degree relative had CAD, myocardial infarction, or a cerebrovascular accident.

[b] Hyperlipidaemia was defined as LDL cholesterol > 100 mg/dL, or HDL cholesterol ≤ 35 mg/dL, or triglycerides ≥ 200 mg/dL (National Cholesterol Education Program guidelines Adult Treatment Panel II for individuals with established CHD).

[c] Scores were standardized to have a mean of 50 and a SD of 10 based on a 1998 representative sample of the general US population; higher scores indicate better quality of life.

3. Results

3.1. Baseline characteristics

Baseline characteristics of all patients are presented by LVEF in Table 1. Patients with an LVEF ≤ 40% had fewer years of education than those with an LVEF > 40%. In the US 14 or more years of education are equivalent to a college degree indicating rather similar educational levels in both samples. As expected, patients with LVEF ≤ 40% were more likely to have a worse medical history (i.e., previous myocardial infarction, cardiac procedures; $p < .01$) than those with an LVEF > 40% but showed similar clinical profiles as those with an LVEF > 40%. However, patients with an LVEF ≤ 40% had higher heart rates but had lower systolic blood pressure and were less likely to report symptoms of angina than those with an LVEF > 40% (all $p < .05$). As expected, patients with an LVEF ≤ 40% were more aggressively medicated at baseline to improve ventricular function which may have been beneficial in reducing symptoms of angina. Patients with an LVEF ≤ 40% were more likely to use angiotensin-converting enzyme inhibitors, diuretics, and digoxin than those with an LVEF > 40% (all $p < .05$). However, they were less likely to be on nitrates and calcium antagonists than patients with an LVEF > 40% (all $p < .05$).

3.2. Participant characteristics at follow-up

Table 2 shows all outcomes by LVEF and time points. Regardless of LVEF, patients showed reductions in weight, body fat, systolic and diastolic blood pressure, resting heart rate, total cholesterol, LDL-C, and improved their METs at 3 months (all $p < .05$). Improvements in body weight, diastolic blood pressure, total cholesterol, LDL-C, and METs

Table 2
Medical risk factors, lifestyle behaviours, and quality of life of patients with complete data and left ventricular ejection fraction ≤ or > 40% at baseline, 3 months, and 1 year (LVEF ≤ 40%: $N = 39$; LVEF > 40%: $N = 142$)

Measure	Left ventricular ejection fraction (LVEF)	Mean ± SD			*p*-value		
		Baseline	3 months	12 months	Time	Group	Time × Group
Diet (% of calories from fat)	LVEF ≤ 40%	15.1 ± 7.5[a]	6.4 ± 2.2[b]	6.3 ± 2.5[b]	<.001	.389	.449
	LVEF > 40%	13.5 ± 8.2[a]	6.3 ± 2.5[b]	6.5 ± 2.7[b]			
Exercise (h/week)	LVEF ≤ 40%	1.9 ± 1.9[a]	4.4 ± 3.0[b]	4.4 ± 3.4[b]	<.001	.113	<.05
	LVEF > 40%	2.0 ± 1.8[a]	3.7 ± 1.8[b]	3.5 ± 2.0[b]			
Stress management (h/week)	LVEF ≤ 40%	.24 ± .68[a]	5.9 ± 2.3[b]	5.3 ± 2.8[c]	<.001	.430	.145
	LVEF > 40%	.55 ± 1.4[a]	5.6 ± 2.5[b]	4.6 ± 3.1[c]			
Group support (% attendance)	LVEF ≤ 40%		.92 ± 1.3[a]	.77 ± .21[b]	<.001	.907	.910
	LVEF > 40%		.92 ± 1.1[a]	.77 ± 2.1[b]			
Body weight (kg)	LVEF ≤ 40%	90.5 ± 17.1[a]	84.9 ± 16.0[b]	84.1 ± 15.8[b]	<.001	.065	.149
	LVEF > 40%	84.2 ± 17.5[a]	80.1 ± 15.1[b]	79.4 ± 14.8[b]			
Body fat (%)	LVEF ≤ 40%	27.1 ± 6.4[a]	23.3 ± 6.1[b]	22.6 ± 6.5[c]	<.001	.109	.212
	LVEF > 40%	24.3 ± 8.1[a]	21.6 ± 7.6[b]	20.6 ± 7.3[c]			
Systolic blood pressure (mm Hg)	LVEF ≤ 40%	125.5 ± 15.3[a]	121.9 ± 17.1[b]	122.8 ± 20.3[a]	<.05	<.01	.572
	LVEF > 40%	134.3 ± 18.4[a]	127.4 ± 18.5[b]	131.8 ± 18.5[a]			
Diastolic blood pressure (mm Hg)	LVEF ≤ 40%	78.5 ± 9.3[a]	72.1 ± 9.1[b]	74.5 ± 10.9[b]	<.001	.360	.880
	LVEF > 40%	79.2 ± 9.9[a]	73.8 ± 10.7[b]	76.0 ± 10.0[b]			
Heart rate at rest (beats/min)	LVEF ≤ 40%	75.9 ± 12.9[a]	68.0 ± 13.6[b]	73.9 ± 16.3[a]	<.001	<.01	.404
	LVEF > 40%	68.7 ± 12.9[a]	64.0 ± 12.9[b]	67.6 ± 11.7[a]			
Total serum cholesterol (mg/dL)	LVEF ≤ 40%	204.6 ± 37.4[a]	176.4 ± 35.8[b]	189.5 ± 45.7[a]	<.001	.804	<.05
	LVEF > 40%	201.9 ± 65.4[a]	191.2 ± 72.1[b]	184.9 ± 42.3[b]			
Low-density lipoprotein cholesterol (mg/dL)	LVEF ≤ 40%	126.7 ± 32.6[a]	98.2 ± 27.6[b]	109.1 ± 38.4[b]	<.001	.851	.190
	LVEF > 40%	124.8 ± 52.6[a]	106.5 ± 47.5[b]	107.0 ± 36.2[b]			
High-density lipoprotein cholesterol (mg/dL)	LVEF ≤ 40%	34.9 ± 10.4[a]	31.5 ± 12.5[b]	36.2 ± 14.1[a]	<.001	.864	.089
	LVEF > 40%	36.9 ± 11.8[a]	31.9 ± 8.8[b]	34.8 ± 10.5[a]			
Triglycerides (mg/dL)	LVEF ≤ 40%	258.8 ± 208.7[a]	253.2 ± 137.5[a]	246.3 ± 155.8[a]	.268	.592	.187
	LVEF > 40%	215.3 ± 151.1[a]	266.8 ± 210.9[a]	232.5 ± 144.1[a]			
Exercise capacity (METs; 3.5 $mL \cdot kg^{-1} \cdot min^{-1}$)	LVEF ≤ 40%	8.9 ± 3.4[a]	10.5 ± 3.0[b]	10.6 ± 2.7[b]	<.001	.413	.359
	LVEF > 40%	9.2 ± 2.8[a]	10.7 ± 2.8[b]	11.4 ± 3.2[b]			
Physical health * (MOS SF-36)	LVEF ≤ 40%	44.8 ± 10.3[a]	48.0 ± 9.3[b]	49.4 ± 8.9[b]	<.001	.272	.985
	LVEF > 40%	46.2 ± 9.7[a]	49.7 ± 8.5[b]	51.0 ± 7.8[b]			
Mental health* (MOS SF-36)	LVEF ≤ 40%	48.2 ± 10.9[a]	51.3 ± 10.6[b]	52.9 ± 11.4[b]	<.001	.873	.481
	LVEF > 40%	47.6 ± 10.5[a]	52.2 ± 9.2[b]	51.7 ± 10.1[b]			

Mean scores sharing a common superscript in a row of this table were not significantly different at the .05 level.
* Scores were standardized to have a mean of 50 and a SD of 10 based on a 1998 representative sample of the general US population; higher scores indicate better quality of life.

were maintained over 1 year. Body fat was reduced at 3 months and further reduced at 1 year in all patients. Systolic blood pressure and resting heart rate improved at 3 months but reverted to baseline levels at 1 year. Triglyceride levels remained constant and HDL-C reverted to baseline levels at 1 year. Overall, patients with an LVEF ≤ 40% improved similarly compared to those with an LVEF > 40%, although patients with an LVEF ≤ 40% had higher heart rates and lower levels of systolic blood pressure at all time points. Patients with an LVEF ≤ 40% lowered their total cholesterol similarly compared to their counterparts over 3 months but reverted to baseline levels at 1 year, whereas patients with an LVEF > 40% maintained the reductions ($p < .05$). The expected main effects for sex were noted, indicating that women had lower body weight and METs and higher percentages of body fat, higher heart rate and HDL-cholesterol than men at all 3 time points (all $p < .01$). No significant main effects or interactions were observed for the other outcomes. Medications remained relatively stable during the study period. Use of ACE-inhibitors in patients with LVEF ≤ 40% vs. > 40% remained the same in 68% vs. 81% of patients, 14% vs. 4% stopped medication from baseline to 1 year, 8% vs. 2% were not medicated at baseline but at 1 year and 10% vs. 13% did not have complete data at 1 year. Use of beta-blockers in patients with LVEF ≤ 40% vs. > 40% remained constant in 72% vs. 72% of patients over time, 16% vs. 9% stopped medication, 2% vs. 6% were not medicated at baseline, but at 1 year, and 10% vs. 13% did not have complete data at 1 year.

Regarding angina (data not shown), 131 patients reported angina at baseline (42% of patients with LVEF < 40; 59% of patients with LVEF > 40). Of those 131 patients, 53% were angina-free at 1 year (57% of patients with LVEF < 40; 53% of patients with LVEF > 40), 35% still reported angina (33% of patients with LVEF < 40; 34% of patients with LVEF > 40), and 12% had missing data at follow-up (10% of patients with LVEF < 40; 13% of patients with LVEF > 40). Of the 105 patients that did not report angina at baseline (29 patients with LVEF < 40; 76 patients with LVEF > 40), 76% were still angina-free (76% of patients with LVEF < 40; 76% of patients with LVEF > 40), 11% reported angina at 1 year (14% of patients with LVEF < 40; 11% of patients with LVEF > 40), and 13% had missing data at follow-up (10% of patients with LVEF < 40; 13% of patients with LVEF > 40).

By the end of 1 year, and already evident at 3 months, both groups significantly improved diet, exercise, and stress management. All patients met program requirements regarding diet and exercised the prescribed amount of 3 h/week at 3 months and 1 year regardless of LVEF, although patients with an LVEF ≤ 40% improved exercise more from baseline to 1 year than patients with an LVEF > 40% ($p < .01$). Patients with LVEF ≤ 40% and those with LVEF > 40% fell short of the recommended stress management by only 1.1 and 1.4 h, respectively, per week at 3 months and by 1.6 and 2.4 h, respectively, at 1 year. Patients in both groups attended an average of 92% of the group support meetings offered during the first 3 months of the intervention and 77% during the remaining follow-up.

All patients showed improvements in both the physical and mental health summary scores at 3 months which were maintained at 1 year ($p < .001$).

3.3. Participants lost to follow-up

A comparison of baseline characteristics in patients with complete data and those without complete data at 1 year (20%), found that patients with an LVEF ≤ 40% and complete data were more likely to be married or to be cohabiting ($p < .01$), their spouses were more likely to participate in the program ($p < .01$), and they were more likely to be medicated with nitrates at baseline ($p < .05$), than those without complete data. No other differences emerged. Comparing baseline characteristics of those patients with complete data to those without complete data at 1 year (24%) in patients with an LVEF > 40%, found that patients with complete data were more likely to have their spouses participate in the program ($p < .01$), reported higher scores on the physical health summary score of the MOS SF-36 ($p < .05$), and had higher METs ($p < .01$) than those without complete data.

4. Discussion

Our results indicate that comprehensive lifestyle changes are feasible for CHD patients with an LVEF ≤ 40%, despite their worse medical history at baseline. These patients were able to make similar changes in lifestyle as those with an LVEF > 40% over the course of 3 months, and were able to maintain most of these changes over 1 year. The patients also showed similar improvements in body weight and body fat, blood pressure, heart rate, lipid profile, exercise capacity, and quality of life.

The magnitude of lifestyle changes in this subsample of CHD patients with an LVEF ≤ 40% (stage B), was similar to (and sometimes exceeded) that observed in patients with an LVEF > 40% and also to that reported in the experimental group of an earlier randomised controlled clinical trial [Lifestyle Heart Trial (LHT); [7]]. For example, by the end of 1 year, stage B patients reported similar levels of dietary fat intake (6.4% of total calories from fat) when compared to patients with LVEF > 40 (6.3%), and the LHT experimental group (6.8%). Exercise levels among stage B patients (4.4 h/week) were similar to those observed in patients with LVEF > 40% (3.5 h/week) and equalled those observed in the LHT experimental group (4.4 h/week). Stage B patients practiced stress management for a similar amount of time (5.3 h/week) as patients with LVEF > 40% (4.6 h/week), but for fewer hours than the LHT experimental group patients (9.6 h/week).

Stage B patients also showed significant risk factor reduction, which was comparable to that observed in patients with an LVEF > 40% and the LHT experimental group over the same time period [7]. For example, LDL-C levels, blood

pressure, body weight, and body fat were significantly lowered, and triglyceride levels and HDL-C remained constant over 1 year in all three groups. METs improved similarly in stage B patients when compared to patients with an LVEF > 40% over the course of 1 year (data not available for LHT). For total cholesterol levels, similar reductions were noted after 3 months in both groups. However, patients with an LVEF < 40% reverted to baseline levels after 1 year whereas patients with an LVEF > 40% maintained their improvements. Similar improvements in CHD risk factors were noted in another more recent (ongoing) phase IV trial [22].

Our subsample of stage B patients not only improved lifestyle behaviours and clinical profile, but also showed similar improvements in quality of life (MOS SF-36 summary scores), as patients with LVEF > 40% from baseline to 1 year, reaching the *minimally clinically important difference* of 3–5 points [23]. Considering that the MOS SF-36 correlates negatively with measures of depression [24], increased quality of life may also indicate improvements in depression, a major risk factor for HF, especially in elderly women [25], and highly prevalent in post-MI patients with a reduced LVEF [26].

Comparing patients who completed the 1-year follow-up, to those who did not, few significant differences emerged. One major difference was that patients with an LVEF ≤ 40% who completed the 1-year follow-up, were more likely to be married or to be cohabiting and have their spouses participate in the program. A similar pattern was observed in patients with LVEF > 40%. This finding underscores the importance of partner support for comprehensive lifestyle interventions. Patients with LVEF > 40% with complete data, also reported greater physical health (SF-36) and higher exercise capacity than those without complete data, indicating that greater psychological well-being and physical fitness at baseline may have affected program participation.

Our findings contribute to the current knowledge of stage B patients with LVEF ≤ 40%. To date, there is limited evidence that these patients benefit from traditional (i.e., exercise-focused) cardiac rehabilitation, with regard to clinical risk factors and general well-being [27–29]. Some reports have suggested that patients participating in these exercise-based interventions are able to remain clinically stable and pursue a more physically active lifestyle [30]. Our results indicate that targeting multiple lifestyle behaviours to modify major risk factors appears to be of use in this population.

There are several limitations to our study. The MLDP was a Phase IV clinical trial evaluation based on insurance data from Mutual of Omaha, providing coverage for the same lifestyle intervention at 8 different hospital sites in the U.S. Phase IV research typically consists of long-term surveillance of an intervention shown to be effective in previous Phase III trials. According to Friedman et al. [31], no control groups are necessary for Phase IV trials. Glasgow et al. [32] also acknowledge decreased experimental rigor during this phase of research. Thus, our Phase IV research presents a unique opportunity to examine whether comprehensive lifestyle intervention works under real-world conditions [32], providing us with important information about its feasibility for patients at risk for HF. A second limitation is the fact that our sample consisted of predominantly white participants. This is a major shortcoming, considering that the prevalence of HF is higher and survival is worse in African-Americans than in the general population [2,33]. Furthermore, there were very few women with LVEF ≤ 40%, which precluded meaningful analysis by sex. Thirdly, LVEF was not assessed at follow-up. However, data from an earlier clinical trial in patients with LVEF ≥ 40% indicated that the same lifestyle changes significantly improved LVEF compared to a control group receiving usual care [8].

In summary, patients with reduced LVEF were able to adhere to comprehensive lifestyle changes, showing similar improvements in clinical profile and quality of life compared to those with an LVEF > 40%. Considering that the prevalence of HF is increasing and its prognosis is poor, comprehensive lifestyle interventions aimed at the modification of major risk factors in CHD should target patients at risk for HF to improve clinical outcomes and prevent further progression and clinical deterioration into the more severe and costly stages of the disease.

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