Comparison of Coronary Risk Factors and Quality of Life in Coronary Artery Disease Patients With Versus Without Diabetes Mellitus

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It is unclear whether patients with coronary artery disease (CAD) and diabetes mellitus (DM) can make comprehensive lifestyle changes that produce similar changes in coronary risk factors and quality of life compared with patients with CAD and without DM. We examined medical characteristics, lifestyle, and quality of life by diabetic status and gender in the Multicenter Lifestyle Demonstration Project (MLDP), a study of 440 nonsmoking patients with CAD (347 men, 55 with DM; 15.9%; 93 women, 36 with DM; 38.7%). Patients met in groups to improve lifestyle (plant-based, low-fat diet; exercise; stress management) for 1 year. Follow-ups were conducted at 3 and 12 months. At baseline, body mass and systolic blood pressure were significantly higher among patients with DM. Men with DM had a worse medical history (e.g., hypertension, hyperlipidemia, and family history of CAD) than did those without DM. Patients with DM, especially women, reported poorer quality of life than did patients without DM. The 2 groups of patients were able to adhere to the recommended lifestyle, as demonstrated by significant improvements in weight (mean −5 kg), body fat, low-density lipoprotein cholesterol, exercise capacity, and quality of life. No significant changes in triglycerides and high-density lipoprotein cholesterol were noted. By the end of 12 months, improvements in glucose-lowering medications (i.e., discontinuation or a change from insulin to oral hypoglycemic agents) were noted for 19.8% (n = 18) of patients with DM. In conclusion, patients with CAD and DM are able to follow a comprehensive lifestyle change program and show similar improvements in coronary risk factors and quality of life as those without DM. **(Am J Cardiol 2006;97:1267–1273)**

This investigation examined whether patients with coronary artery disease (CAD) and diabetes mellitus (DM) are able to make more intensive changes in diet and lifestyle and show similar improvements in clinical risk factors and quality of life compared with patients with CAD and without DM. To address this question, we compared data from men and women with CAD and DM (predominantly type 2) with those without DM. All patients participated in the Multicenter Lifestyle Demonstration Project (MLDP),[1,2] a multicomponent lifestyle intervention that emphasizes exercise, diet, and stress management (which was found to be especially beneficial for patients with DM[3,4]).

Methods

Design, recruitment, and procedure of the MLDP: The main aim of the MLDP was to examine whether patients can avoid revascularization by making comprehensive lifestyle changes without increasing cardiac events. Patients were classified into group 1 or group 2. Those in group 1 had angiographically documented CAD that was severe enough to warrant revascularization (by insurance coverage policy standards) at study entry but opted for lifestyle changes instead (deemed medically safe). Control group patients, who were matched to group 1 patients by procedure eligibility, age, gender, left ventricular ejection frac-

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tion, and cardiac score,[2] were provided by Mutual of Omaha Insurance Company's database (Omaha, Nebraska). Comparisons between the intervention and control groups indicated that 77% of the intervention group were able to avoid revascularization for ≥3 years by making comprehensive lifestyle changes without increasing cardiac events.[2] Group 2 consisted of patients who had previous coronary artery bypass grafting or percutaneous transluminal coronary angioplasty, were in stable condition, and received the intervention. The focus of this study was on the intervention groups, as only events were monitored in the control group. The size of the intervention group allowed stratification by DM status. For more detail on the MLDP, see Koertge et al[1] and Ornish.[2]

A program staff member contacted potential participants after referral to the program by their physicians or by self-referral as a result of local media publicity. Eligible patients (determined by interview) were sent a description of data collection activities, a release form for medical records, and a medical history questionnaire (including medications). A baseline physical assessment (anthropometrics) was completed during the interview. A second interview was scheduled with the hospital team after the intake interview and records review; this included administration of psychosocial and behavioral questionnaires, instructions for completion of a 3-day diet diary, a blood draw for a baseline lipid profile, and a treadmill exercise stress test. Medical and behavioral variables and quality of life were reassessed at 3 and 12 months.

Subjects: The protocol was approved by the committee on the protection of rights of human subjects and written informed consent was obtained from participants. The sample consisted of 440 subjects with CAD (347 men, 55 with DM; 15.9%; 93 women, 36 with DM; 38.7%) who participated in the intervention arm of the MLDP. The group with DM included 3 men (0.9% of the male sample) and 6 women (6.5% of the female sample) with type 1 DM. Eligibility criteria for study participation have been reported previously.[1,2] Briefly, patients did not smoke, had a diagnosis of CAD, and a history of coronary artery bypass surgery or percutaneous transluminal coronary angioplasty.[1]

Measurements: History of hypertension, hyperlipidemia, myocardial infarction, chest pain, cerebrovascular accident, DM, revascularization procedures, and familial CAD were assessed. Patients were classified as having type 1 or type 2 DM according to guidelines of the American Diabetes Association.[5] Medical variables, including height, weight, percent body fat (skin fold measurement), blood pressure,[6] angina pectoris,[7] plasma lipids and lipoproteins, and exercise capacity (i.e., functional capacity as assessed by symptom-limited maximal graded exercise testing using the Bruce protocol[8]) were assessed at baseline and at 3 and 12 months. METs, a measurement of energy expenditure, were automatically calculated by the testing device during exercise testing (1 MET = ~3.5 mg of oxygen consumed per minute per kilogram of body weight).[8] Diet assessment was based on a 3-day food diary.[9] Currently prescribed medications were documented at baseline and at each follow-up. Types of medication included antihypertensives (e.g., angiotensin-converting enzyme inhibitors), vasodilators (e.g., nitrates), serum glucose-lowering agents (regular insulin or oral hypoglycemic agents, such as glipizide [Glucotrol, Pfizer, Inc., New York, New York], glyburide [Micronase, DiaBeta, Pharmacia Upjohn, Kalamazoo, Michigan], tolbutamide [Orinase, Pharmacia Upjohn], metformin [Glucophage, Bristol-Myers Squibb Company, New York, New York]) antilipemics, and antiarrhythmics. Quality of life was assessed by the Medical Outcomes Study 36-item short-form health survey (MOS SF-36) at baseline and at 3 and 12 months.[10] To summarize the physical and mental components of the MOS SF-36, 2 aggregate scores were computed.[11] Higher scores on the survey reflect better quality of life. Validity and reliability information of the MOS SF-36 and its summary scores have been previously reported.[12,13]

Intervention: the Lifestyle Change Program: The program began with a 12-hour orientation seminar at the hospital that was offered over 2 to 3 days and consisted of scientific lectures and demonstrations (e.g., cooking). Patients then attended sessions in groups 3 times per week for 12 weeks. Two of the 3 weekly sessions focused on the program components in 1-hour blocks. The third weekly session consisted of a 1-hour aerobic exercise session (e.g., on treadmills) and 1-hour lectures that were designed to facilitate long-term adherence to the program. Patients continued to meet in groups weekly for the next 40 weeks. In addition, they were instructed to exercise and practice stress management on their own (also see Koertge et al,[1] Ornish,[14] and Billings[15]).

Adherence to the Lifestyle Change Program: Diet was measured as percent calories from fat (based on 3-day food diary, goal 10%), exercise as hours per week (according to guidelines of the American College of Sports Medicine,[8] goal 3 hours/week), stress management as hours per week (goal 1 hour/day), and attendance of the intervention group as the number of sessions attended divided by the number of sessions offered.

Statistical analysis: Comparisons of group differences (presence/absence of DM, first-year graduate vs drop-out) in baseline demographic, clinical, risk factor, and psychosocial variables were performed with 2-sample *t* tests (for continuous variables) and chi-square tests (for categorical variables) for men and women separately. Analyses of variance for repeated measures with 2 between factors (gender and DM status) and 1 within factor at 3 levels (time: baseline, 3 months, and 1 year) were computed to test for the effects of gender, DM, time, and their interactions on coronary risk factors, lifestyle behaviors, and quality of life. To control for unequal numbers in the analyses, analyses of variance for repeated measures with unweighted sums of squares were computed.[16–18] Bonferroni's adjustments were made for comparisons across baseline, 3

Table 1
Medical risk factors, adherence to lifestyle intervention, and quality of life of patients with complete data at baseline and at three and 12 months by diabetic status and gender*

Measurement	DM Status	Baseline	3 Months	12 Months	p Value		
					Time	DM Status	Gender
Body weight (kg)	Diabetic men	95.3 ± 18.9 (43)[a]	90.9 ± 16.7[b]	89.9 ± 15.6[b]	<0.001	<0.01	<0.001
	Nondiabetic men	85.7 ± 15.8 (220)[a]	81.3 ± 13.3[b]	81.0 ± 13.1[b]			
	Diabetic women	80.3 ± 17.4 (21)[a]	76.4 ± 16.3[b]	75.2 ± 15.5[b]			
	Nondiabetic women	75.5 ± 17.7 (43)[a]	70.6 ± 16.2[b]	69.7 ± 16.3[b]			
Body fat (%)	Diabetic men	24.6 ± 6.8 (40)[a]	21.9 ± 6.4[b]	20.7 ± 6.3[b]	<0.001	0.158	<0.001
	Nondiabetic men	22.3 ± 5.8 (195)[a]	19.4 ± 5.0[b]	18.8 ± 5.2[b]			
	Diabetic women	35.4 ± 6.1 (17)[a]	31.1 ± 7.5[b]	30.4 ± 7.1[b]			
	Nondiabetic women	34.9 ± 5.5 (37)[a]	31.8 ± 5.6[b]	30.5 ± 5.8[b]			
Systolic blood pressure (mm Hg)	Diabetic men	137 ± 19 (40)[a]	132 ± 19[a]	134 ± 21[a]	0.795	0.131	0.735
	Nondiabetic men	131 ± 18 (165)[a]	126 ± 18[a]	128 ± 18[a]			
	Diabetic women	132 ± 15 (18)[a]	129 ± 16[a]	132 ± 20[a]			
	Nondiabetic women	136 ± 20 (33)[a]	129 ± 19[a]	134 ± 16[a]			
Diastolic blood pressure (mm Hg)	Diabetic men	80 ± 10 (40)[a]	74 ± 9[b]	75 ± 11[b]	<0.03[§]	<0.02[§]	0.900
	Nondiabetic men	79 ± 10 (164)[a]	74 ± 11[b]	76 ± 10[b]			
	Diabetic women	77 ± 11 (18)[a]	72 ± 14[b]	72 ± 10[b]			
	Nondiabetic women	81 ± 8 (33)[a]	77 ± 10[b]	78 ± 11[b]			
Heart rate at rest (beats/min)	Diabetic men	73 ± 14 (38)[a]	69 ± 13[b]	72 ± 13[a]	<0.001	<0.05[§]	<0.01
	Nondiabetic men	68 ± 13 (178)[a]	64 ± 11[b]	67 ± 12[a]			
	Diabetic women	77 ± 11 (19)[a]	73 ± 14[b]	77 ± 12[a]			
	Nondiabetic women	76 ± 14 (33)[a]	71 ± 14[b]	73 ± 12[a]			
Total serum cholesterol (mg/dl)	Diabetic men	199 ± 55 (41)[a]	177 ± 69[b]	171 ± 37[b]	0.052	0.704	<0.01
	Nondiabetic men	195 ± 57 (207)[a]	177 ± 55[b]	180 ± 37[b]			
	Diabetic women	210 ± 33 (20)[a]	204 ± 43[b]	192 ± 41[b]			
	Nondiabetic women	222 ± 42 (40)[a]	204 ± 39[b]	204 ± 44[b]			
Low-density lipoprotein cholesterol (mg/dl)	Diabetic men	116 ± 37 (35)[a]	97 ± 32[b]	95 ± 27[b]	<0.01	0.401	<0.05[§]
	Nondiabetic men	121 ± 48 (193)[a]	101 ± 41[b]	105 ± 34[b]			
	Diabetic women	125 ± 31 (19)[a]	115 ± 35[b]	101 ± 23[b]			
	Nondiabetic women	135 ± 40 (39)[a]	115 ± 39[b]	116 ± 36[b]			
High-density lipoprotein cholesterol (mg/dl)	Diabetic men	35 ± 12 (38)[a]	31 ± 9[b]	34 ± 9[a,b]	0.122	0.162	<0.001
	Nondiabetic men	35 ± 10 (198)[a]	31 ± 8[b]	34 ± 9[a,b]			
	Diabetic women	41 ± 10 (20)[a]	38 ± 10[b]	41 ± 12[a,b]			
	Nondiabetic women	47 ± 13 (40)[a]	43 ± 16[b]	47 ± 15[a,b]			
Triglycerides (mg/dl)[†]	Diabetic men	321 ± 488 (41)[a]	277 ± 251[a]	280 ± 359[a]	0.804	0.177	0.409
	Nondiabetic men	213 ± 158 (204)[a]	230 ± 166[a]	222 ± 129[a]			
	Diabetic women	240 ± 155 (20)[a]	262 ± 151[a]	248 ± 176[a]			
	Nondiabetic women	202 ± 83 (40)[a]	244 ± 173[a]	208 ± 97[a]			
Exercise capacity (METs; ml O_2/min/kg)	Diabetic men	8.8 ± 2.8 (37)[a]	10.8 ± 2.7[b]	10.8 ± 2.4[b]	<0.001	<0.01	<0.001
	Nondiabetic men	10.4 ± 2.9 (180)[a]	11.9 ± 2.6[b]	12.5 ± 2.8[b]			
	Diabetic women	6.9 ± 2.1 (20)[a]	8.4 ± 2.6[b]	8.5 ± 2.8[b]			
	Nondiabetic women	8.3 ± 2.8 (33)[a]	9.0 ± 2.9[b]	10.0 ± 3.0[b]			
Diet (% calories from fat)	Diabetic men	14.2 ± 7.8 (38)[a]	6.5 ± 2.1[b]	6.4 ± 2.8[b]	<0.001	<0.04	<0.001
	Nondiabetic men	12.6 ± 7.8 (172)[a]	6.2 ± 2.3[b]	6.2 ± 2.6[b]			
	Diabetic women	19 ± 7.7 (20)[a]	7.1 ± 2.1[b]	8.9 ± 5.3[b]			
	Nondiabetic women	15.9 ± 8.7 (33)[a]	6.8 ± 2.5[b]	7.1 ± 3.3[b]			
Exercise (h/wk)	Diabetic men	1.8 ± 1.7 (44)[a]	4.0 ± 3.3[b]	3.8 ± 2.5[b]	<0.001	0.500	<0.001
	Nondiabetic men	2.4 ± 2.0 (217)[a]	4.1 ± 2.1[b]	3.6 ± 2.1[b]			
	Diabetic women	1.1 ± 1.1 (28)[a]	3.0 ± 1.3[b]	2.8 ± 1.4[b]			
	Nondiabetic women	1.6 ± 1.5 (46)[a]	3.3 ± 1.5[b]	3.0 ± 1.7[b]			
Stress management (h/wk)	Diabetic men	0.5 ± 1.3 (45)[a]	5.5 ± 2.4[b]	4.6 ± 2.6[b]	<0.001	<0.02	0.317
	Nondiabetic men	0.5 ± 1.3 (218)[a]	5.6 ± 2.5[b]	4.8 ± 2.9[b]			
	Diabetic women	0.3 ± 0.7 (28)[a]	4.9 ± 2.7[b]	3.5 ± 2.8[b]			
	Nondiabetic women	0.6 ± 1.1 (46)[a]	5.7 ± 2.2[b]	5.1 ± 2.5[b]			
Intervention group (% attendance)	Diabetic men		0.93 ± 0.08 (51)[a]	080 ± 0.19[b]	<0.001	0.570	<0.03
	Nondiabetic men		0.93 ± 0.10 (272)[a]	0.78 ± 0.20[b]			
	Diabetic women		0.89 ± 0.13 (33)[a]	0.71 ± 0.21[b]			
	Nondiabetic women		0.92 ± 0.10 (54)[a]	0.76 ± 0.23[b]			
MOS SF-36							
Physical health[‡]	Diabetic men	43.6 ± 8.6 (42)[a]	48.2 ± 8.2[b]	48.5 ± 7.7[b]	<0.001	<0.01	<0.02
	Nondiabetic men	48.6 ± 9.1 (211)[a]	51.8 ± 7.5[b]	52.9 ± 7.3[b]			
	Diabetic women	41.7 ± 8.1 (23)[a]	47.5 ± 7.3[b]	46.8 ± 6.3[b]			
	Nondiabetic women	43.3 ± 9.6 (43)[a]	47.7 ± 8.8[b]	50.6 ± 7.9[b]			

Table 1 *Continued on next page.*

Table 1
Continued

Measurement	DM Status	Baseline	3 Months	12 Months	p Value		
					Time	DM Status	Gender
Mental health‡	Diabetic men	46.5 ± 12.1 (42)[a]	50.3 ± 9.2[b]	51.8 ± 10.1[b]	<0.001	<0.01	0.053
	Nondiabetic men	48.4 ± 10.3 (211)[a]	52.9 ± 8.8[b]	52.1 ± 9.7[b]			
	Diabetic women	40.0 ± 10.1 (23)[a]	47.4 ± 10.5[b]	46.2 ± 12.5[b]			
	Nondiabetic women	47.5 ± 9.7 (43)[a]	54.4 ± 8.9[b]	52.0 ± 9.2[b]			

* Analyses of variance for repeated measures with 2 between factors (gender and DM status) and 1 within factor (time: baseline, 3 months, and 1 year). Values are means ± SDs numbers of patients. Means in the same row that do not share superscript letters indicate significant changes over time ($p < 0.05$).

† Winsorizing statistical outliers (i.e., replacing values ± 3 SDs of the mean with "most extreme acceptable values" in the distribution of this variable) did not yield significantly different results.

‡ Scores were standardized to have a mean of 50 and an SD of 10 based on a 1998 representative sample of the general United States population.

§ Adjustments for multiple medical outcomes rendered this finding nonsignificant. After adjusting for multiple medical outcomes, only 1 significant 2-way interaction remained that involved time and DM on heart rate at rest. Two additional significant 2-way interactions could be found: 1 2-way interaction involving gender and DM on mental health and 1 2-way interaction involving the effects of gender and time on dietary fat. These effects indicated lowest heart rates among patients without DM at 1 year and lowest mental health scores among women with DM. The highest fat intake was observed among women at baseline.

Table 2
Demographic and medical characteristics at baseline

Variable	Diabetic Men (n = 55)	Nondiabetic Men (n = 286)	p Value	Diabetic Women (n = 36)	Nondiabetic Women (n = 57)	p Value
Age (yrs)	59 ± 10	58 ± 11	0.54	58 ± 11	60 ± 10	0.19
Education (yrs)	16 ± 3	16 ± 3	0.68	15 ± 3	15 ± 3	0.44
Married or cohabitating	47 (85%)	253 (88%)	0.98	23 (64%)	35 (61%)	0.10
Employed outside the home	33 (60%)	202 (70%)	<0.05	11 (31%)	31 (54%)	0.06
Spousal participation	30 (55%)	138 (48%)	0.07	8 (22%)	15 (26%)	0.87
Family history of CAD*	40 (73%)	156 (54%)	0.08	23 (66%)	35 (61%)	0.38
Previous cigarette smoker	40 (73%)	199 (69%)	0.70	19 (53%)	33 (58%)	0.63
Systemic hypertension	41 (75%)	121 (42%)	<0.01	23 (64%)	29 (51%)	0.38
Hyperlipidemia†	36 (66%)	170 (59%)	<0.01	24 (67%)	42 (74%)	0.70
Previous myocardial infarction	24 (44%)	157 (54%)	0.36	17 (47%)	37 (65%)	0.09
Previous coronary angioplasty	20 (36%)	137 (47%)	0.10	21 (58%)	26 (46%)	0.23
Previous coronary bypass	31 (56%)	139 (48%)	0.52	14 (39%)	17 (30%)	0.37
Angina pectoris (during past 30 d)	34 (63%)	110 (38%)	<0.01	17 (47%)	32 (56%)	0.40
Medication						
Nitrates	22 (40%)	76 (26%)	<0.05	18 (50%)	15 (26%)	<0.05
β Blockers	23 (42%)	145 (50%)	0.19	20 (56%)	25 (44%)	0.27
Angiotensin-converting enzyme inhibitors	21 (38%)	49 (17%)	<0.01	10 (28%)	11 (19%)	0.34
Calcium antagonists	35 (64%)	124 (43%)	<0.05	23 (64%)	37 (65%)	0.92
Diuretics	8 (15%)	22 (8%)	0.22	11 (31%)	12 (21%)	0.30
Antihypertensives	5 (9%)	13 (5%)	0.35	1 (3%)	1 (2%)	0.74
Lipid-lowering therapy	30 (55%)	149 (51%)	0.31	16 (44%)	36 (63%)	0.08

* 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.

† Hyperlipidemia was defined as a low-density lipoprotein cholesterol level >100 mg/dl, a high-density lipoprotein cholesterol level ≤35 mg/dl, or a triglyceride level ≥200 mg/dl (National Cholesterol Education Program guidelines, Adult Treatment Panel II for individuals with established coronary heart disease).

months, and 12 months.[18] However, because the 10 medical outcomes are highly correlated (e.g., cholesterol and low-density lipoprotein, systolic and diastolic blood pressures), adjustments for multiple measurements were applied as follows: we computed a p value midway between the nominal p value of the variable under consideration and the p value that was adjusted for all 10 outcomes (K) ([nominal p +Kp]/2). Resulting nonsignificant findings are listed in Table 1. All analyses were preformed with and without data from the 9 patients with type 1 DM; no significant differences emerged, so results are reported on the entire sample. SPSS 10.1 (SPSS, Inc., Chicago, Illinois) was used to perform statistical analysis.

Results

Baseline characteristics: Baseline characteristics are presented in Tables 2 and 3. Patients with DM did not differ from

Table 3
Medical risk factors, lifestyle behavior, and quality of life at baseline

Variable	Diabetic Men (n = 55)	Nondiabetic Men (n = 286)	p Value	Diabetic Women (n = 36)	Nondiabetic Women (n = 57)	p Value
Systolic blood pressure (mm Hg)	139 ± 21	130 ± 19	<0.01	135 ± 19	135 ± 19	0.98
Diastolic blood pressure (mm Hg)	81 ± 10	79 ± 10	0.33	77 ± 10	79 ± 10	0.34
Heart rate at rest (beats/min)	73 ± 14	68 ± 12	<0.05	78 ± 12	73 ± 14	0.09
Body mass index (kg/m^2)	30.5 ± 5.8	27.3 ± 5.2	<0.01	30.7 ± 5.5	28.8 ± 7.1	0.19
Body weight (kg)	92.8 ± 18.0	86.1 ± 15.6	<0.01	81.6 ± 16.8	73.5 ± 16.8	<0.05
Body fat (%)	24.5 ± 7	22.8 ± 5.9	0.07	34.7 ± 6.3	34.2 ± 5.6	0.72
Total serum cholesterol (mg/dl)	197 ± 52	195 ± 54	0.84	214 ± 41	226 ± 48	0.24
Low-density lipoprotein cholesterol (mg/dl)	114 ± 38	119 ± 46	0.50	133 ± 36	138 ± 44	0.63
High-density lipoprotein cholesterol (mg/dl)	35 ± 11	35 ± 10	0.94	43 ± 12	45 ± 12	0.50
Triglycerides (mg/dl)	244 ± 142	216 ± 156	0.23	228 ± 140	217 ± 93	0.66
Exercise capacity (METs; ml O_2/min/kg)	8.7 ± 2.9	10.2 ± 2.9	<0.01	6.7 ± 1.9	8.1 ± 2.4	<0.01
Diet (% calories from fat)	14.4 ± 8.3	12.9 ± 8.4	0.26	17.8 ± 7.8	16.4 ± 9.4	0.50
Exercise (h/wk)	1.7 ± 1.7	2.4 ± 2.2	<0.05	1 ± 1.1	1.7 ± 1.5	<0.05
Stress management (h/wk)	0.5 ± 1.3	0.5 ± 1.3	0.69	0.37 ± 0.78	0.83 ± 1.5	0.10
MOS SF-36: physical health*	43.1 ± 9.0	48.3 ± 8.9	<0.01	39.4 ± 8.5	44.0 ± 9.5	<0.05
MOS SF-36: mental health*	46.5 ± 11.4	48.1 ± 10.1	0.32	43.0 ± 10.3	47.7 ± 9.7	<0.05

* Scores were standardized to have a mean of 50 and an SD of 10 based on a 1998 representative sample of the general United States population.

Table 4
Changes in glucose-lowering regimen from baseline to one year among patients with diabetes mellitus (n = 91)

Changes*	Baseline*	1 Year
No change: 62 (68.1%)		
16 (17.6%)	No medication, insulin levels controlled by diet	No medication, insulin levels controlled by diet
25 (27.5%)	Insulin	Insulin
21 (23.1%)	Oral antiglycemic	Oral antiglycemic
Improvement: 18 (20%)		
1	Insulin	Discontinued insulin without adopting another medical regimen
6	Insulin	Oral antiglycemic
11	Oral antiglycemic	Discontinued oral antiglycemic without adopting another regimen
Worsening: 6 (6.6%)		
1	Oral antiglycemic	Insulin
1	No medication	Insulin
4	No Medication	Oral antiglycemic

* Five patients with DM (5.4%) dropped out by the 1-year follow-up; 2 were on an insulin regimen, 2 on an oral antiglycemic agent, and 1 was not medicated at baseline.

patients without DM in age, education, marital status, and spousal support. Patients with DM were less likely to be employed outside the home than were patients without DM. Men (but not women) with DM were more likely to have a history of hypertension, hyperlipidemia, and angina pectoris during the previous 30 days than were men without DM. Among men, body mass index, body weight, systolic blood pressure, and heart rate at rest were significantly higher among those with DM than among those without DM. Women with DM weighed more than did women without DM. Men and women with DM had lower METs than did those without DM. Patients with DM did not differ from patients without DM in diastolic blood pressure and plasma lipids. Men and women with DM reported an overall lower quality of life than did those without DM. There were no significant group differences in health behaviors, except that patients with DM exercised significantly less than did their counterparts without DM. Men and women with DM were significantly more often prescribed nitrates than were those without DM. Further, men with DM were more often prescribed angiotensin-converting enzyme inhibitors and calcium channel blockers than were those without DM. The same pattern of prescription was observed for angiotensin-converting enzyme inhibitors among women, but not for calcium channel blockers (for serum glucose-lowering agents at baseline and follow-up in patients with DM, see Table 4).

Participant characteristics at follow-ups: Measurements of anthropometric and medical variables, adherence to the program, and quality of life of patients with complete data at all time points are presented in Table 1. Regardless of gender or DM, all patients lost a significant amount of weight and body fat, significantly lowered their heart rates and levels of low-density lipoprotein cholesterol, and increased their METs. Most of the changes were already evident at 3 months and were maintained over 1 year.

On average, improvement in patients with DM was the same as in patients without DM, although patients with DM weighed more, had a greater percentage of body fat, higher heart rates at rest, and lower METs than did patients without DM across follow-up time points. Women had significantly lower levels of high-density lipoprotein cholesterol than did men regardless of DM. By the end of 1-year follow-up, all patients significantly improved their diet, exercise, and stress management. All patients met program recommendations with regard to diet. All patients, except women with DM (2.8 ± 1.4 hours of exercise per week), exercised the prescribed amount of 3 hours per week. However, patients with DM practiced stress management for only 4 hours/week (patients without DM practiced 5 hours/week). Women with DM reported practicing less stress management compared with women without DM at all 3 time points. Attendance of group support sessions decreased significantly over time. Patients with DM attended an average of 91% and patients without DM attended an average of 92% of the group support meetings offered during the first 3 months of the intervention. At 1 year, an average of 76% of the group meetings were attended by patients with DM and 78% by those without DM. Patients with DM and women as a group reported lower quality of life at all 3 time points. However, all patients, regardless of gender and DM status, improved their quality of life over time (Table 1).

Participants lost to follow-up: For a comparison of those who completed the 12-month follow-up with those who did not (21% of men and 27% of women), see our previous report.[1] Briefly, women who completed follow-up were younger and more likely to be employed at baseline; men who completed the study reported a worse medical history at baseline but indicated more partner support. Within the DM sample (n = 91), a comparison of those who completed the program (n = 69, 76%) with those who did not (n = 22, 24%) showed that those who completed the program were significantly younger ($p < 0.01$) and had more years of education ($p < 0.05$). No other differences emerged. Drop-out rates in the MLDP ranged from 21% to 27% depending on gender and DM status and compared favorably with those in other follow-up studies with cardiac patients.[19,20]

Discussion

The results of the present study indicate that, despite their worse medical and psychosocial risk factor profiles at program entry (also evident in other studies[21–23]), patients with CAD and DM are able to make comprehensive lifestyle changes. At 3 months, improvement in risk factors, lifestyle, and quality of life of patients with CAD and DM paralleled that of patients without DM and was maintained for the entire follow-up. Even women with DM, the most medically and psychosocially disadvantaged group in our sample, were able to follow the intervention and showed significant improvements in CAD risk factors (e.g., weight, body fat, low-density lipoprotein cholesterol, and METs but no change in high-density lipoprotein cholesterol and triglycerides) and quality of life. These findings underscore the need for more aggressive approaches, such as intensive multicomponent interventions, when targeting patients with CAD and DM.[22] Medicare is currently conducting a National Demonstration Project that is testing the feasibility and cost effectiveness of such an intervention for patients with CAD with and without DM.[24]

Quality of life also improved in the 2 groups of patients at 3 months and was maintained at 1 year. Because the MOS SF-36 correlates negatively with measures of depression,[25–27] increased quality of life may also indicate decreased depression, a risk factor for CAD,[27] especially among women with DM.[28]

One limitation of the present study was that the intervention group of the MLDP, but not the matched control group, had systematic assessment of coronary risk factors and quality of life.[2] Thus, inferences about the effectiveness of the intervention cannot be made. Further, as in any multicomponent intervention, we do not know the relative importance of each component. Although the role of exercise and diet in CAD prevention is fairly well established,[20] there is evidence that stress management may decrease clinical events in patients with CAD,[29] decrease hemoglobin A1c in patients with DM,[30] and affect DM control by facilitating adherence to diet or exercise regimens that are often prescribed for DM management.[3]

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