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Long-Term Disease Management of Patients With Coronary Disease by Cardiac Rehabilitation Program Staff

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- **PURPOSE:** Randomized-clinical trials have demonstrated the benefits of disease management for patients with coronary disease. It is not known if long-term disease management in routine clinical practice provided by cardiac rehabilitation (CR) program staff is possible. The goal of this study was to evaluate the feasibility and clinical benefits of a 3-year disease-management program in the setting of an outpatient CR facility.
- **METHODS:** Consecutive patients (n = 503) referred to CR and who were available for long-term follow-up served as subjects. After a phase II CR program, disease managers assessed secondary-prevention goals every 3 to 6 months via face-to-face meetings with each patient. Outcome measures included use of cardioprotective medications, coronary risk factors, amount of habitual exercise training, and all-cause mortality.
- **RESULTS:** At 3 years, aspirin usage was 91%, statin usage 91%, β-blocker usage 78%, and angiotensin-converting enzyme inhibitor usage 76%. Low-density lipoprotein cholesterol was 90 ± 23 mg/dL, systolic blood pressure was 126 ± 19 mm Hg, and body mass index was 29.0 ± 5.1 kg/m^2. Exercise training averaged 139 ± 123 minutes per week. Annual mortality was 1.9%. There were no differences ($P > .05$) in medication usage or low-density lipoprotein cholesterol for men versus women, or for age below 65 years versus age 65 years or greater.
- **CONCLUSIONS:** Long-term disease management of patients with coronary disease in routine clinical practice by CR program staff is feasible and effective in achieving and maintaining secondary-prevention goals. Overweight remains a prevalent and persistent risk factor. We advocate expansion of CR programs into long-term coronary disease-management programs.

K E Y W O R D S

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Traditional cardiac rehabilitation (CR) programs in the United States include up to 36 sessions of supervised exercise, risk factor education, and counseling over a 3-month period of time. However, long-term adherence to blood lipid–improving medications remains problematic even for patients who participate in traditional CR.[1] In routine clinical practice, there is a continually diminishing level of adherence to treatment recommendations including medications (eg, aspirin and antihypertensives) and lifestyle factors such as regular exercise.[2,3] For the state of Minnesota in the year 2004, only 38% of patients with coronary heart disease received optimal care for secondary prevention defined as a low-density lipoprotein (LDL) cholesterol < 100 mg/dL, blood pressure less than 140/90 mm Hg, daily aspirin, and no smoking.[4]

In 1987, we described a long-term program to control risk factors in patients who had completed a phase II outpatient CR program.[5] With this approach, patients periodically returned to the CR program to

have face-to-face meetings with nonphysicians (case managers) in order to review all aspects of secondary prevention. Subsequently, investigators from Stanford University demonstrated in 2 separate studies that it was possible to achieve improved risk-factor control, reduced angiographic progression of disease, and decreased clinical events for patients who were randomized to nurse case management for 1 to 4 years versus usual care provided by physicians.[6,7] Recently, systems for longitudinal care for patients with chronic diseases (case management) have been renamed as "disease-management" programs.[8]

A concern regarding randomized trials of lifestyle factors and compliance with medical treatment is the potential problem of subject recruitment bias. Patients who meet inclusion criteria for trials and who agree to be randomized may be inherently different from the typical patient in routine clinical practice. The results from randomized trials may not be absolutely applicable to the general population of patients with coronary disease. Another concern is the feasibility of applying, in routine clinical practice, the well-developed disease-management systems employed in the randomized trials. Therefore, the purpose of this project was to determine the feasibility and clinical benefits of long-term (3 years) disease management of patients with coronary disease in routine clinical practice utilizing CR program staff.

METHODS

The study design was a retrospective analysis of 503 consecutive patients who were referred to and who agreed to participate in outpatient CR in 1999 and 2000. All had suffered an acute-cardiac event including acute myocardial infarction, coronary bypass surgery, and/or percutaneous coronary revascularization. The only exclusion criterion was unavailability for long-term disease management. Of the 605 patients who started outpatient CR in 1999 and 2000, 83% (503 of 605 patients) were available for long-term follow-up. Advanced age was not an exclusion criterion and 54% of the patients were at least 65 years of age. Patient characteristics are provided in Table 1. Women were slightly older than men (69 ± 12 years vs 65 ± 11 years, $P < .01$).

Outpatient CR (phase II) began within 1 to 2 weeks after hospital discharge. Program components included 1 to 3 supervised exercise sessions per week (aerobic, strengthening, and flexibility exercises) plus unsupervised "home" exercise as well as group educational meetings. The length of the phase II program ranged from 2 to 8 weeks. Patients participated in 13 ± 7 supervised exercise sessions during the phase II cardiac-rehabilitation program. At the beginning and at the end of phase II, patients met face-to-face with disease managers (PhD-level exercise physiologists or registered nurses). Subsequently, patients met with their disease manager every 3 to 6 months for 3 years. A small minority of patients (6%) continued to exercise in a supervised phase III-IV type program for more than 6 months.

Table 1 • BASELINE CHARACTERISTICS OF THE ENTIRE COHORT (*N* = 503)

Age, y	66 ± 12
Men/women, *n*	375/128
BMI, kg/m^2	28.5 ± 4.9
Index cardiac event, *n*	
CABG	149 (30%)
MI + PCI	132 (26%)
PCI	102 (20%)
MI	53 (11%)
MI + CABG	42 (8%)
MI + PCI + CABG	17 (3%)
PCI + CABG	8 (2%)
LVEF, %	55 ± 11
LVEF < 40%, *n*	35 (7%)
Persons with diabetes, *n*	106 (21%)
Persons with hypertension, *n*	242 (48%)
Smokers at the time of event, *n*	86 (17%)
Smoking history, *n*	297 (59%)

Abbreviations: BMI, body mass index; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; LVEF, left ventricular ejection fraction; MI, myocardial infarction.

The goal of the disease manager was to optimize secondary-prevention efforts. At each meeting, the following factors were addressed:

- *Measured variables*: blood lipids, blood pressure, and body weight.
- *Patient report variables*: tobacco use, cardiac medications, exercise and physical activity, nutrition (assisted by registered dietitians), and cardiopulmonary symptoms.

Physicians were readily accessible for medical decision-making purposes, including adjustment of cardioprotective medications. Treatment of diabetes was deferred to the patients' primary healthcare providers. Communication with the primary and other healthcare providers was accomplished via an electronic medical record. American Heart Association (AHA) guidelines for secondary prevention served as the goals for disease management.[9] We were more aggressive than these guidelines in one respect: we recommended statin medications in all subjects unless intolerance was present.

Follow-up appointments with disease managers were scheduled through the existing institutional advance-appointment system according to the instructions of the disease manager. Standard appointment letters were mailed to the patient's home address. A telephone number was provided if patients needed to reschedule their appointment. Patients who missed their appointment were contacted by the appointment office staff. Patients and/or their insurance plans were billed for the laboratory tests and consultations by our institutional business office. Blood lipids were measured in the institution's clinical laboratory in the morning after a 12-hour fast. Laboratory results were available when the patient was seen in consultation, usually later the same day or the next day. Appointments were scheduled within the normal business hours of 8 AM to 5 PM, Monday through Friday. The face-to-face time required for each consultation was approximately 20 to 30 minutes. Risk factors, medications, symptoms, and exercise habits were addressed and discussed in detail. The data were collected on paper forms and transferred to a database. One or 2 PhD-level exercise physiologists and 1 registered nurse saw patients in consultation each day.

The AHA recently acknowledged that disease-management programs are widely heterogeneous and lack a common definition.[8] The AHA has recommended an 8-point taxonomic system to facilitate comparisons of different disease-management programs and to identify specific factors associated with success. Table 2 contains the AHA classification factors with our study's specific components.

The following outcome measures were assessed after 3 years of disease management:

1. Appropriate use of cardioprotective medications: aspirin and statins for all patients; β-blockers for patients with myocardial infarction as the index event; and angiotensin-converting enzyme inhibitors or receptor blockers for patients with left ventricular ejection fractions below 40%.
2. Selected coronary risk factors (AHA[9] risk factors minus hemoglobin A1c in diabetics): blood lipids, blood pressure, smoking, and body mass index (BMI).
3. Amount of regular exercise training.
4. All-cause mortality.

Comparison of selected continuous variables was accomplished using a 2-tailed *t* test. The chi-square test was used for nominal variables. The McNemar test was used for comparison of the percentage of patients at the AHA risk-factor goals at years 1 and 3 of disease management. SAS software (version 9.1 for Windows, SAS Institute, Cary, North Carolina) was used for the analysis and a $P < .05$ was selected for statistical significance. Descriptive statistics were calculated as the mean ± SD.

Table 2 • AMERICAN HEART ASSOCIATION TAXONOMIC DISEASE MANAGEMENT DOMAINS WITH THE CURRENT STUDY'S INFORMATION

Intervention recipient	Patients
Patient population	Acute coronary event, excluded if unavailable for long-term disease management
Intervention content	Patient meetings with disease manager Assessment of cardioprotective medications Assessment of coronary risk factors Assessment of exercise training Assessment of symptoms
Delivery personnel	PhD-level exercise physiologists Registered nurses Physicians (support role)
Method of communication	Face-to-face: individual
Intensity and complexity	Patients meet with disease managers every 3 to 6 months for 3 years High level of complexity
Environment	Outpatient clinic
Clinical outcomes	Use of cardioprotective medications Coronary risk factors Amount of habitual exercise training All-cause mortality.

RESULTS

During the 3 years of follow-up, the total number of face-to-face meetings of disease managers with each patient averaged 6.9 ± 2.1. The total number of disease-management visits per workday averaged 4.6.

After 3 years of disease-management efforts, appropriate usage of cardioprotective medications was as follows for the entire cohort of patients: aspirin 91%; statins 91%; β-blockers 78%; and angiotensin-converting enzyme inhibitors or receptor blockers 76%. With the exception of BMI, coronary risk factors were reasonably controlled: total cholesterol, 164 ± 29 mg/dL; high-density lipoprotein (HDL) cholesterol, 46 ± 11 mg/dL; LDL cholesterol, 90 ± 23 mg(dL; triglycerides, 145 ± 74 mg/dL; systolic blood pressure, 126 ± 19 mm Hg; diastolic blood pressure, 70 ± 11 mm Hg; smoking, 45 patients (9%); and BMI, 29.0 ± 5.1 kg/m^2. The amount of habitual exercise training averaged 139 ± 123 minutes per week.

Medication usage and coronary risk factors after 1 and 3 years of disease management are shown in

Table 3 • COMPARISON OF CARDIOPROTECTIVE MEDICATION USAGE, SELECTED CORONARY RISK FACTORS, AND EXERCISE TRAINING AMOUNT FOR THE ENTIRE COHORT AFTER 1 YEAR (*n* = 499) AND 3 YEARS (*n* = 474) OF DISEASE MANAGEMENT

	Year 1	Year 3	*P*
Aspirin	90%	91%	.86
ACE inhibitors/ARBs[a]	75%	78%	.32
β-Blockers[b]	77%	78%	.29
Statins	90%	91%	.85
Total cholesterol, mg/dL	165 ± 31	164 ± 29	.13
HDL cholesterol, mg/dL	45 ± 13	46 ± 11	.55
LDL cholesterol, mg/dL	91 ± 24	90 ± 23	.11
Triglycerides, mg/dL	142 ± 79	145 ± 74	.98
SBP, mm Hg	129 ± 58	126 ± 19	.28
DBP, mm Hg	71 ± 11	70 ± 11	.05
BMI, kg/m^2	28.1 ± 5.2	29.0 ± 5.1	.01
Exercise, min/wk	134 ± 122	139 ± 123	.66

Abbreviations: ACE, angiotensin-converting enzyme; ARBs, angiotensin receptor blockers; BMI, body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.
[a]Patients with left ventricular ejection fraction < 40%.
[b]Patients with myocardial infarction.

Table 3. Medication usage and most risk-factor values were similar at both time points. Diastolic blood pressure was minimally lower at 3 years. BMI was higher at 3 years by approximately 1 kg/m^2.

Figure 1 shows the percentage of patients achieving the AHA risk-factor goals after 1 and 3 years of follow-up. There was a significant increase in the achievement of the LDL cholesterol goal from year 1 to year 3 (69% vs 74%, $P = .03$). At 3 years, a favorable percentage of patients achieved the goals for not smoking (95%), systolic (75%), diastolic (95%), and both blood pressures (73%). After 3 years of disease management, 48% of patients were not smoking and were at goal for both systolic and diastolic blood pressures and for LDL cholesterol. Fifty-seven percent of patients achieved the physical activity goal at year 3. The percentage of patients at the goal for BMI was extremely poor and decreased from year 1 to year 3 (21% vs 17%, $P = .02$).

As shown in Table 4, cardioprotective medication use was similar for men and women at 3 years. Women had higher total cholesterol level, HDL cholesterol level, triglycerides, and systolic blood pressure. Men exercised more minutes per week than did women. LDL cholesterol, and BMI were similar for men and women.

There were no significant differences in medication usage, exercise training amount, or LDL cholesterol

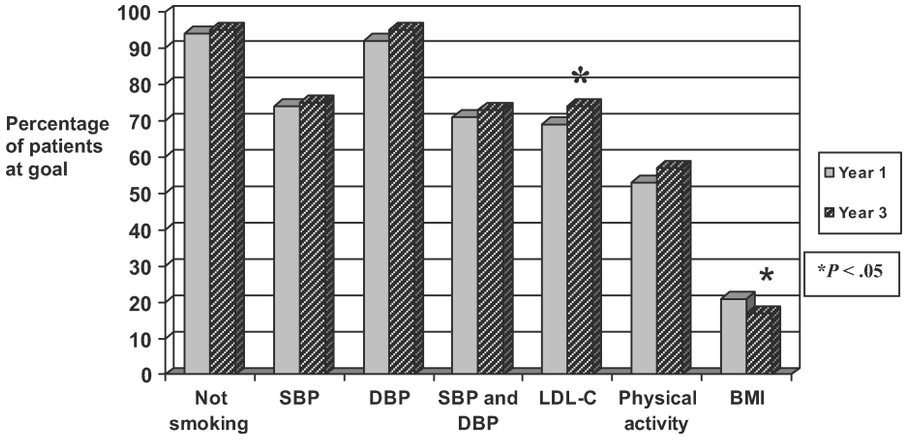

Figure 1. Percentage of patients achieving the American Heart Association risk factor goals for persons with atherosclerotic cardiovascular disease[9] at year 1 and year 3 of follow-up.
Abbreviations: BMI, body mass index, 18.5–24.9 kg/m^2; DBP, diastolic blood pressure < 90 mm Hg; LDL-C, low-density lipoprotein cholesterol < 100 mg/dL; physical activity, >120 min/wk; SBP, systolic blood pressure < 140 mm Hg; SBP and DBP, both systolic and diastolic blood pressures < 140/90.

Table 4 • COMPARISON OF CARDIOPROTECTIVE MEDICATION USAGE, SELECTED CORONARY RISK FACTORS, AND EXERCISE TRAINING AMOUNT AFTER 3 YEARS OF DISEASE MANAGEMENT IN MEN (*n* = 350) AND WOMEN (*n* = 124), AND IN YOUNGER (*n* = 227) AND OLDER (*n* = 247) SUBJECTS WITH CORONARY DISEASE

	Men	Women	*P*	<65 y	≥65 y	*P*
Aspirin	91%	88%	.35	92%	89%	.33
ACE inhibitors/ARBs[a]	78%	70%	.61	80%	74%	.71
β-Blockers[b]	80%	71%	.15	80%	76%	.51
Statins	90%	92%	.72	92%	89%	.31
Total cholesterol, mg/dL	161 ± 27	173 ± 32	.01	166 ± 31	162 ± 27	.29
HDL cholesterol, mg/dL	44 ± 9	52 ± 14	.01	43 ± 10	48 ± 12	.01
LDL cholesterol, mg/dL	90 ± 22	89 ± 25	.64	92 ± 25	88 ± 20	.07
Triglycerides, mg/dL	139 ± 72	160 ± 76	.02	156 ± 87	134 ± 60	.01
SBP, mm Hg	125 ± 18	129 ± 20	.03	125 ± 17	127 ± 19	.16
DBP, mm Hg	70 ± 10	70 ± 11	.91	73 ± 11	67 ± 10	.01
BMI, kg/m^2	30 ± 6	27 ± 7	.39	31 ± 6	29 ± 6	.01
Exercise, min/wk	153 ± 113	91 ± 82	.01	127 ± 126	149 ± 120	.22

Abbreviations: ACE, angiotensin-converting enzyme; ARBs, angiotensin receptor blockers; BMI, body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.
[a]Patients with left ventricular ejection fraction < 40%.
[b]Patients with myocardial infarction ACE.

level for younger patients versus older patients at 3 years (Table 4). Older patients had higher HDL cholesterol and lower triglycerides, diastolic blood pressure, and BMI.

Over the 3 years of the intervention in 503 subjects, there were 29 deaths (25 in men and 4 in women) yielding an annual all-cause mortality of 1.9%. This compares favorably to the Centers for Disease Control and Prevention's expected annual mortality of 1.6% for average Americans, in the general population, of similar ages as our patients.[10] Annual mortality over 3 years for the 102 patients who enrolled in CR, but who were not available for disease management, was 6.5%.

DISCUSSION

The major finding of the current study was that a 3-year coronary disease-management program for a large cohort of patients in routine clinical practice using CR staff was both feasible and generally effective in assisting patients in secondary prevention. Patients, in general, continued to take aspirin, angiotensin-converting enzyme inhibitors or receptor blockers, β-blockers, and statins, as indicated for their clinical status. A favorable percentage of patients achieved the AHA goals for most risk factors. Unfortunately, an excessive BMI remained a persistent and prevalent risk factor. All-cause mortality was low and compared favorably to the expected death rate for average Americans of the same age. Primary healthcare providers were provided ongoing feedback on their patients' performance and the program was well accepted by them.

The benefits of disease-management programs for coronary heart disease patients were established in 1994 with the publication of 2 groundbreaking randomized trials. Haskell et al[6] randomized 274 patients with coronary artery disease to usual care or risk-factor management directed by registered nurses with physician support. Patients in the risk-factor management group had less angiographic progression of their disease and fewer hospitalizations than did the usual care group. DeBusk et al[7] randomized 535 patients with myocardial infarction to usual care or registered nurse disease management. After 1 year, intervention patients exhibited a better smoking cessation rate, lower LDL cholesterol, and a better exercise capacity than usual care subjects.

Results from the present study compare favorably to contemporary-randomized trials with CR-type interventions lasting at least 1 year. After a 4-month standard CR program, the extensive lifestyle management trial randomized coronary heart disease patients to usual care versus risk-factor intervention.[11,12] Of the population of CR graduates who were screened for the study, only 29% were randomized. After 1 year, there was a nonsignificant trend in favor of risk-factor intervention in reduction of a global risk score. The authors speculated that the lack of difference between the usual care and intervention groups might have resulted from self-selection bias (willingness to participate may indicate heightened health consciousness).

Patients with a history of an acute-coronary event underwent baseline testing and subsequent randomization to either usual care or risk-factor intervention in the Vestfold Heartcare Study.[13] After 2 years, intervention subjects had a better diet, were less likely to smoke, and performed more regular exercise than did usual care subjects. Aspirin, β-blocker, and statin medication usage were similar for both groups. Intervention subjects experienced a 22% reduction in estimated relative coronary risk according to the West of Scotland Coronary Prevention Study algorithm.

Reid et al[14] randomized coronary patients to a standard 3-month versus a prolonged 12-month CR program. At 1 year, there were no significant differences between the 2 groups for risk factors, exercise capacity, or cardioprotective medication usage. The authors speculated that the lack of differences between the 2 study groups may have been due to insufficient differences in the interventions, baseline differences between groups (more patients with angina and more current smokers in the prolonged rehabilitation group), or that periodic outcome assessment for both groups may have constituted a form of intervention that contributed to improved secondary prevention in both groups.

The GOSPEL study,[15] a large randomized trial involving coronary patients carried out in 78 CR centers in Italy, was published in abstract form. After completion of a standard CR program, patients were randomized to usual care versus an intensive approach for 3 years. After 3 years, the intensive group exhibited better lifestyle habits, better adherence to cardioprotective medications, and a 12% lower combined endpoint of cardiac death, recurrent myocardial infarction, stroke, revascularization, heart failure, and angina pectoris.

Our results were similar to those from trials utilizing nurse disease-management approaches in multisite medical practices without a specific CR program. Murchie et al[16] reported results from a randomized trial of nurse-directed secondary-prevention programs in general medical practices. Patients with coronary disease were randomized to either usual care versus secondary prevention. After 1 year, subjects in the secondary-prevention group were better when compared with usual care in terms of medication use (eg, aspirin use: 81% vs 66%), blood pressure, blood lipids, exercise, and diet. The groups were similar in smoking rates. Annual total mortality was lower for secondary prevention than for usual care (3.1% vs 4.0%, $P < .05$) after 4 years of observation.

The recently published COURAGE trial was a multicenter study of patients with angiographic coronary artery disease and evidence of myocardial ischemia during stress testing.[17] Patients were randomized to percutaneous coronary intervention and intensive secondary prevention versus intensive secondary prevention only. Percutaneous intervention did not reduce the risk of death, myocardial infarction, or other major cardiovascular events when compared with intensive secondary prevention only. After 3 years, the same length of intervention as in the present study, annual all-cause mortality was 1.7% versus 1.9% in the present study. With the exception of lower LDL cholesterol in COURAGE, medication usage and other risk factors were similar to those in our study, although the intensity of intervention was greater in COURAGE than in the present study (more frequent clinical visits, lower LDL-cholesterol goal). Table 5 provides summary data from contemporary clinical trials compared with the present study.

In light of these randomized-controlled trials, we believe that our study provides new and important information regarding the role of CR in long-term secondary prevention. The disease-management intervention used in the current study was part of the

Table 5 • COMPARISON OF CONTEMPORARY RANDOMIZED TRIALS TO THE PRESENT STUDY

Study	*n*	Age, y	Length	LDL-C, mg/dL	BMI, kg/m^2	Annual all-cause mortality	Other
Present study	503	66	3 y	90	29	1.9%	
Lear[12]	302	64	1y	94	28	...	
Vestfold[13]	197	55	2 y	...	...	...	↓Risk est
Reid[14]	392	58	1 y	87	29	0.8%	↑HRQL
GOSPEL[15]	3,241	...	3 y	...	...	...	↓Events
Murchie[16]	1,343	66	4 y	...	...	3.1%[a]	
COURAGE[17]	2,287	62	3 y[b]	75	29	1.7%	

Abbreviations: BMI, body mass index; HRQL, health-related quality of life; LDL-C, low-density lipoprotein cholesterol; Risk est, estimated cardiovascular risk.
[a]Mortality in the intervention subjects.
[b]COURAGE also reported 5-year outcomes.

routine clinical work for the CR staff and was not difficult to develop and implement. It did require physician support and guidance, although the amount of time required of physicians was minimal. We have demonstrated that 3 years of intervention in routine clinical practice was generally effective in achieving secondary-prevention goals. In our study, as well as in many of the randomized trials, overweight appears to be the most difficult modifiable risk factor in terms of achieving long-term control.

Our study has several limitations. Exercise training and medication usage was determined via self-report. There were no baseline data on medications and risk factors. We did not have data on the frequency of change in medications or medication dosage. We did not have quantifiable data regarding recurrent hospitalizations and dietary or psychosocial variables. The study was a retrospective analysis and no contemporary control group was available for comparison. Patients were willing to participate in long-term disease-management activities and this may have introduced selection bias, although a high percentage of patients participated in disease management (83%). The 17% of patients who enrolled in CR, but were not available for disease management, experienced a 3.4-fold higher annual mortality than subjects in disease management. However, these patients may have been different in important characteristics than disease-management participants and should not be considered an adequate control group. Our program is somewhat unique. It is the only CR program in the city. We are part of a large group practice that facilitates a high enrollment rate of eligible patients and facilitates follow-up.[18] The results may not be applicable to patients who choose not to enroll in CR programs. We have previously reported that such patients tend to be older and sicker than are the participants in our program and are more likely to be female.[18]

In summary, long-term disease management of typical patients with coronary disease in routine clinical practice by CR program staff is feasible and effective in achieving and maintaining secondary-prevention goals. We advocate expansion of CR into long-term coronary disease-management programs.

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