

Cardiac Rehabilitation—An Effective and Comprehensive but Underutilized Program to Reduce Cardiovascular Risk in Patients with CVD

a report by

Edwin E Ferguson, MD

American Association of Cardiovascular and Pulmonary Rehabilitation



Edwin E Ferguson, MD, is Professor of Medicine and Staff Physician in the Section of Preventive Cardiology, Division of Cardiovascular Medicine, at the University of Wisconsin School of Medicine and Public Health in Madison. He is co-director of the out-patient cardiac rehabilitation program. He has been in practice as an internist for 28 years, and a preventive cardiologist for 12 years. Dr Ferguson is a member of the Scientific Advisory Council of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) and co-editor of the AACVPR's "Medical Director's newsletter". Dr Ferguson received his medical degree at the George Washington University of Medicine, and completed his residency in internal medicine at the University of Wisconsin School of Medicine.

Cardiac rehabilitation (CR) refers to coordinated multifaceted interventions designed to optimize a cardiac patient's physical, social, and psychological functioning, with the additional goals of stabilizing, slowing, or even reversing the progression of the underlying atherosclerotic processes, thereby reducing morbidity and mortality. CR is a comprehensive secondary prevention program that currently includes baseline and on-going patient assessments designed to reduce future cardiovascular risk. As a multifaceted treatment program, CR provides in-depth patient management, including nutritional counseling, aggressive risk factor management (i.e. lipoproteins, hypertension, weight control, diabetes mellitus, and smoking cessation), psychological and vocational counseling, and physical activity counseling and exercise training. Cardio-protective drugs are used that have evidence-based efficacy.

Traditionally, candidates for CR have been patients who had recently suffered a myocardial infarction (MI) or who had undergone coronary artery bypass graft (CABG) surgery, or who had stable angina pectoris. Candidacy then began to broaden to include patients who had undergone percutaneous coronary interventions; heart transplantation candidates or recipients; patients with stable congestive heart failure; patients with peripheral vascular disease with claudication, and patients who had undergone surgical procedures for valvular heart disease.

Until March 2006, payment for CR services for most patients was determined by Medicare policy guiding coverage, which had been limited to patients following a recent MI, those who had undergone recent CABG, or those patients with stable angina pectoris. This policy was detailed in Section 35-25 (now 20.10) of the Center for Medicare and Medicaid Services (CMS) Medicare Coverage Issues Manual on CR. Last year, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the American College of Cardiology (ACC), and the American Hospital Association (AHA) encouraged CMS to update the coverage policy to provide services to patients who had recently had

percutaneous coronary intervention (PCI), heart valve surgery, cardiac transplantation, and congestive heart failure. On March 22, 2006, CMS published revised language for Section 20.10 to include the following—Out-patient (phase II) CR, as described by the US Public Health Service, is a comprehensive, long-term program including medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. Phase II refers to out-patient, medically supervised programs that are typically initiated one to three weeks after hospital discharge and provide appropriate electrocardiogram (ECG) monitoring. Effective for services performed after March 22, 2006, Medicare coverage for CR are now considered reasonable and necessary for patients who:

- have a documented diagnosis of an acute MI within the preceding 12 months;
- have had CABG;
- have stable angina pectoris;
- have had heart valve repair or surgery;
- have had PCI (percutaneous coronary angioplasty or coronary stenting); and
- have had heart or heart/lung transplantation.

CMS determined that the evidence is not adequate to conclude that CR is reasonable and necessary for congestive heart failure (CHF) and therefore will not cover this indication. Reconsideration may be made when the results of the heart failure trial—A Controlled Trial Investigating Outcomes of Exercise Training (HF-Action)—are released in 2008.

CMS also approved longer-term coverage for CR services at the discretion of the contractor/fiscal intermediary. Services provided may be considered reasonable and necessary for up to 36 sessions and patients may receive two to three sessions per week for 12 to 18 weeks. Coverage may extend beyond 18 weeks, but may not exceed 72 sessions for 36 weeks.

The CMS description of comprehensive cardiac rehabilitation is based on the Core Components of Cardiac Rehabilitation/Secondary Prevention Programs AHA Scientific statement.

Thus, in summary, the CMS Decision Memo allows healthcare providers to refer patients with recent valve surgery, heart or heart/lung transplants, and PCI into phase II CR programs, in addition to patients post-MI, post-CABG, and patients with stable angina pectoris. Patients will also benefit from expanded duration of coverage since there will be more time available to follow-through on lifestyle changes and aggressive modification of risk factors.

The American Heart Association Heart Disease and Stroke Statistics 2004 indicate that more than 13 million people in this country have coronary artery disease (CAD) and more than five million have a diagnosis of CHF. CHF is the most common discharge diagnosis for hospitalized Medicare patients. Paul Dudley White, MD, President Eisenhower's cardiologist, was a pioneer who championed the benefits of exercise in patients with CAD and as a means to prevent premature coronary death. His work led to the inclusion of cardiac rehabilitation programs in cardiovascular care and the safety of the program has been firmly established. Two recent comprehensive reviews have been published that summarize the benefits of exercise training in patients with CAD and CHF. Smart and Marwick reviewed 81 studies of exercise training in patients with CHF (ejection fraction <40%). These included 30 parallel-group randomized clinical trials (RCTs) comparing exercise training versus no exercise training which included 1,197 patients. Among these RCTs, training duration ranged from 15 minutes three times a week for eight weeks to 100 minutes seven times a week for eight weeks. Follow-up ranged from four weeks to 192 weeks. The groups did not differ for either adverse events (incidents causing withdrawal from the program, or hospitalization), or all-cause mortality.

For all included trials, no exercise-related deaths occurred in any patient during >60,000 hours of exercise training. In 57 trials that measured maximum oxygen uptake, exercise training showed a mean increase of 17%.

Taylor et al. reviewed 48 RCTs in patients with CAD (8,940 patients, mean age 55 years of age) comparing exercise-based cardiac rehabilitation (alone or combined with educational or psychosocial interventions) with usual care that did not include any form of structured exercise training or advice. The mean intervention was three months and the median follow-up was 15 months. Patients who received exercised-based cardiac rehabilitation had less all-cause and cardiac mortality than did patients who received usual care. Groups did not differ for rates of non-fatal MI, CABG, or PCI. Cardiac

rehabilitation was associated with improvement in total cholesterol and triglyceride levels, systolic blood pressure, and patient-reported smoking. Health-related quality of life (HRQOL) was assessed in 12 RCTs—all trials showed an improvement in HRQOL in both cardiac rehabilitation and usual care groups, with greater improvement seen in cardiac rehabilitation in two RCTs.

Benefits of exercise training in patient populations with CAD or CHF include improved peak rate of oxygen consumption and cardiac output and efficiencies in oxygen consumption. Thus, exercise capacity improves and the threshold for developing cardiac symptoms increases. Additionally, decreased levels of aldosterone, angiotensin, natriuretic peptides, and vasopressin are seen.

A meta-analysis by Clark et al. of 63 studies of CR and secondary prevention programs that emphasize risk factor modification (including lipid-lowering, management of hypertension, smoking cessation, and dietary changes) shows that CR programs give many survivors of MI better and longer lives, regardless of whether the programs include supervised exercise. Since exercise training confers substantial psychological benefits and activity levels are inversely proportional to cardiovascular mortality, it is not surprising that trials of exercise programs found positive effects on survival. What was less clear, however, was whether programs focused on modification of other coronary heart disease risk factors could offer benefits similar to those conferred by exercise in terms of survival, quality of life, and healthcare costs.

To dissect the answers, the meta-analysis included a total of 21,295 patients with coronary disease. The studies were grouped into those examining risk factor modification with and without an exercise component, and supervised exercise programs alone. The investigators found that the summary risk ratio for all-cause mortality was 0.85 (95% confidence interval, 0.77 to 0.94), ranging from 0.97 (95% CI 0.82 to 1.14) at one year to 0.53 (95% CI, 0.35 to 0.81) at two years. When considering possible reasons for the lack of a significant reduction in mortality risk at one year, the authors suggested that 12 months is probably too short to show a clear effect on mortality given the natural history of atherosclerotic coronary artery disease (that is, changes in coronary risk factors would not be expected to produce immediate improvements in atherosclerotic plaque stability or coronary artery diameter).

Alternatively, the patients included in the studies may have been at relatively low-risk to begin with, meaning

that it would require more time for noticeable effects of interventions to appear. A third possibility was that the quality of care given to controls was sufficiently high to blunt the additional benefits for patients who underwent cardiac rehabilitation. Although the mortality benefit was slow to take effect, it was apparently durable, as seen by pooled data from seven trials with long follow-up, showing that secondary prevention programs reduced the risk of death from all cause by 23% at five years. In addition, among all patients enrolled in trials that looked at risk of recurrent MI (11,723 patients), the summary risk ratio for a second event at one year was 0.83 (95% CI, 0.74 to 0.94). This benefit did not differ over time in any of the three types of programs.

Taken as a whole, the programs reduced the risk of a second myocardial infarction within the first year by 17%, and all-cause mortality by nearly 50% two years after a first heart attack.

Evidence suggests the inclusion of CR as a standard performance measure for the care of patients with coronary heart disease. The clinical evidence for a net health benefit from CR in patients with heart disease is conclusive, with meta-analyses of clinical trials demonstrating a 25–30% reduction in total and cardiovascular mortality for CR participants compared with non-participants. Medically supervised CR programs reduce cardiovascular risk factors, including sedentary lifestyle and low physical fitness, obesity, blood hypercoagulability, abnormal sympathetic nervous system tone, inflammation, and improve abnormal lipid levels and endothelial function, in men, women, and the elderly. HRQOL in CR participants, including the elderly, is also significantly improved.

Out-patient CR results in substantial improvements in morbidity and mortality among CR participants in this era of aggressive present-day therapy including coronary revascularization and pharmacological treatments shown to improve outcome of patients with coronary disease.

Unfortunately, cardiac rehabilitation programs remain underutilized in this country, with an estimated participation rate of only 10 to 20% of the more than two million eligible patients per year who experience acute MI or undergo coronary revascularization. Contributing to the vast underutilization of these services are a low patient referral rate (particularly of women, the elderly, and racial and ethnic minorities); poor patient motivation; inadequate third-party reimbursement for services; and geographic limitations to accessibility of program sites. There is also a lack of visibility and recognition by the public and by healthcare providers of the importance of cardiac rehabilitation services.

Randomized clinical trials are needed to more clearly define the role of exercise therapy to improve quality of life, functional capacity, and to reduce cardiovascular symptoms and event rates, especially among older, female, and racial and ethnic minority patients with cardiovascular disease. The role of exercise also needs to be better clarified in patients with chronic stable angina pectoris, diabetes mellitus, left ventricular dysfunction, cardiac transplantation, or an implanted cardioverter defibrillator.

A multicenter randomized clinical trial of comprehensive cardiac rehabilitation and secondary prevention for patients with coronary disease should be explored in which interventions with or without an exercise component are compared to demonstrate a significant reduction in cardiac mortality in the exercise group. Secondary end-points should include non-fatal cardiovascular events, need for revascularization, and the rate of progression or regression of atherosclerosis as assessed by various imaging techniques.

Additional studies are needed to clarify the impact of much overlooked and underemphasized beneficial effects of comprehensive lifestyle modification as a first-line approach to secondary prevention, and to clarify additive benefits of lifestyle modification in combination with other interventions (pharmacologic and interventional) in preventing recurrent cardiovascular events.

Areas of future research include evaluating community, home, and Internet-based interventions, and care management by non-physician healthcare professionals to complement physician services. The cost-effectiveness of traditional supervised programs versus these alternative interventions related to improving patients' functional capacity, independent living, risk factor modification, long-term adherence to therapy, re-hospitalization rates, and QOL will need to be compared: these studies could effect third-party reimbursement for out-patient CR services.

Research should evaluate the use of CR programs as centers for intensive life-style management for weight loss, physical activity, nutrition, and psychosocial support for patients with additional chronic medical conditions such as type 2 diabetes mellitus or the metabolic syndrome. Prevention of cardiovascular events in such patients would be economically beneficial as well as lifesaving. ■

A version of this article containing references can be found in the Reference Section on the website supporting this briefing (www.touchcardiology.com).



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