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Current Concepts in Cardiac Rehabilitation Medical Considerations and Outcomes Evaluations

W. Benzer, N. B. Oldridge¹

The concept of cardiac rehabilitation and secondary prevention can be defined as the effort toward cardiovascular risk factor reduction designed to lessen the chance of a subsequent cardiac event and to slow and perhaps stop the progression of the cardiovascular disease process. A multifactorial and multidisciplinary approach is imperative nowadays in order to meet the challenges of reducing the progression of CAD, the rate of cardiovascular events and of improving the quality of life in patients with proven CAD. A long-term comprehensive cardiac care program involves a close follow up, risk factor modification, patient education, and psychological guidance. Contemporary cardiac rehabilitation programs should incorporate tailored modifications and motivational strategies to enhance participant interest and adherence. Individual cardiac rehabilitation and exercise training studies have demonstrated improved exercise capacity, reduced various CAD risk factors, improved health-related quality of life and reduced subsequent hospitalisation costs. However, the findings in three meta-analyses of cardiac rehabilitation showed that exercise-based cardiac rehabilitation is effective in reducing cardiac deaths but there is insufficient evidence to make conclusions on benefit in terms of risk factors and health-related quality of life. Unfortunately, patients who could have benefited most were in fact excluded from the randomized controlled trials on the basis of age, gender, or comorbidity. There is little evidence on which to base a choice between exercise-only and comprehensive cardiac rehabilitation, suggesting that it would be rational to consider both cost and local access to available services to determine practice. *J Clin Basic Cardiol 2001; 4: 211–219*.

Key words: cardiac rehabilitation, concepts, practice, outcome

The World Health Organization (WHO) has defined cardiac rehabilitation as the "sum of activity required to ensure cardiac patients the best possible physical, mental, and social conditions so that they may, by their own efforts, regain as normal as possible a place in the community and lead an active life"[1]. Implicit in this definition is the concept of secondary prevention, which can be defined as the effort toward risk factor reduction designed to lessen the chance of a subsequent cardiac event and to slow and perhaps stop the progression of the disease process. A conceptual model of cardiac rehabilitation is depicted in Figure 1.

Secondary prevention goals are embedded in the overall goal of cardiac rehabilitation. Each component of a cardiac rehabilitation program is shown by the rectangles. For example, a formal exercise program has approximately equal benefits for secondary prevention and rehabilitation alike. Rehabilitation "end points" from the exercise program might be less depression, greater confidence for resumption of normal



Figure 1. Components of cardiac rehabilitation. Relative contribution to rehabilitation versus secondary prevention goals (modified from Pashkow FJ and Dafoe WA (Editors): Clinical Cardiac Rehabilitation; a Cardiologist's Guide; Williams & Wilkins 1999) activities, improved health-related quality of life (HRQL), and so forth. Secondary prevention "end points" from this same modality could be the effects that exercise has on risk factors (increased high-density lipoprotein (HDL) cholesterol, improved weight control). Another program component, such as smoking cessation, would have most of its benefits directed toward secondary prevention.

Since the early 1970s, an increasing number of working groups evaluated different components of rehabilitation. Some of the emerging concepts included the following:

- 1. Physical exercise should be only one part of rehabilitation
- 2. Rehabilitation is only one part of secondary prevention
- Non-cardiologic aspects psychological, social, and vocational – play an important role in the success or failure of rehabilitation
- 4. Nearly all existing attempts to assess sustained regular physical exercise in MI patients have failed because of the high drop-out rates of initial participants.

By its very nature, cardiac rehabilitation is heterogeneous and involves health care practitioners from various disciplines. The American Heart Association (AHA) and the American College of Cardiology (ACC) have recurrently developed and published standards and guidelines. The American College of Sports Medicine (ACSM) has supported cardiac rehabilitation by offering certification procedures for personnel involved with the exercise training of cardiac patients. The ACSM has two references pertinent to cardiac rehabilitation: The Guidelines for Exercise Testing and Prescription [2] and The Resource Manual for Exercise Testing and Prescription [3].

Policy Statements on Cardiac Rehabilitation

The WHO formed an expert committee on the prevention of coronary artery disease (CAD) in 1981. The Expert Committee recommended that, for every CAD patient, planned preventive measures should be part of the usual care. The expec-

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For personal use only. Not to be reproduced without permission of Krause & Pachernegg GmbH. Homepage Journal of Clinical and Basic Cardiology: http://www.kup.at/JClinBasicCardiol tation of long-term benefit is unlikely to be less, and could well be more, than in primary prevention. Their general statement regarding the prevention of the recurrence and progression of CAD is as follows [4]. "A substantial proportion of CAD deaths occur in people already known to have the disease; measures to influence the course of already recognized CAD might help significantly to reduce the total attributable mortality. The long-term prognosis after a heart attack is influenced by many of the same risk factors that provoked the first attack, suggesting that atherosclerosis continues to progress, and hence that preventive measures are still relevant".

The AHA and ACC in 1996 published guidelines for the management of patients with acute myocardial infarction (MI). These guidelines for long-term management stated: "The patient should be instructed to achieve an ideal weight and educated about a diet low in saturated fat and cholesterol. The patient with a low-density lipoprotein cholesterol measurement greater than 130 mg/dl (3.36 mmo/L) despite diet should be given drug therapy with the goal of reducing LDL to less than 100 mg/dl (2.59 mmol/L). Smoking cessation is essential. Finally, the patient should be encouraged to participate in a formal rehabilitation program.

The Canadian Cardiovascular Society in 1995 issued the following recommendations for cardiac rehabilitation after a consensus conference for the management of the post-MI patient: "The aim of rehabilitation is to relieve symptoms and to improve both cardiovascular performance and quality of life. Rehabilitation strategies should include services to help control weight, smoking, blood pressure, and lipid disorders; to help manage emotional stress and facilitate social support; and an exercise prescription to help increase exercise tolerance. The immediate and long-term aims of rehabilitation are to relieve symptoms and to improve both cardiovascular performance and quality of life."

In 1995, The Clinical Practice Guideline Panel applied the U.S. Public Health Service definition for cardiac rehabilitation. "Cardiac rehabilitation services are comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. These programs are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients."

Conflict with Traditional Medical Models

Until recently, in the United States and Europe at least, cardiologists have had total freedom with respect to decisions concerning subspecialization and allocation of time. More recently, significant internal and external trends have occurred that will affect the role of the cardiologist for the future. Externally, we are witnessing a significant aging of the population [5]. This will have a major impact on cardiologists, because, on average, their patients are considerably older. Government and insurance carriers are becoming more involved in the standardization of the delivery of care in an effort to control costs [6]. Whether there is increasing interest by business in rehabilitation and prevention services has a lot to do with the documentation of cost savings and benefits from such programs. With the need to cut health care costs, all outpatient services are under scrutiny. If physicians and administrators inappropriately deem cardiac rehabilitation as an unnecessary service, it will be difficult to overcome such an obstacle, and a real danger continues to exist that physicians and administrators will come to such a point [7].

Within the discipline of cardiology, we see important trends as well. Overall, there is an increasing supply of doctors. Close to 20,000 cardiologists are practicing in the United States in the year 2000, which will represent a 100 % increase from the number practicing in 1980 [8]. There is likely to be a shift toward group and salaried practice, with more competition among physicians, increased monitoring, and application of practice norms, distinct changes in the style of practice - for instance, more outpatient procedures, greater use of physician extenders, an expanding role of cardiologists as directors of programs and rehabilitation centres [8]. With these anticipated changes, no doubt a shift in reimbursement motive will occur, and cardiologists are likely to dedicate more of their efforts to preventive medicine [8]. Currently, little personal incentive exists to emphasize prevention in a system that mainly compensates practitioners on the basis of procedures performed [9] - but this is, in fact, in the process of change [10-12].

In addition to the reimbursement issues, there are compelling reasons that our practices have had a procedural versus a more lifestyle-enhancing or behaviour-modifying approach. The system has attributed greater prestige to the performance of invasive or other complex technical procedures [13] patients have demanded as instant a "fix" as possible for their coronary problems; and no prevalent infrastructure has arisen for the provision of alternative services. The tiny medical-industrial complex for rehabilitation (mainly a spinoff from the exercise equipment market) is dwarfed by the massive complexes that exist for medical imaging, interventional cardiology, and drug therapy.

At the same time, cardiologists are obliged to provide additional services and functions that seriously impinge an their available time. They are spending more hours producing ever increasing medical documentation, serving on more quality assurance and utilization surveillance committees, and responding to the increasing demands of patients and their families for more personalized attention [14]. A survey of internists was undertaken to ascertain the perceived problems with counselling for prevention (in particular for exercise training). The findings of this survey gave the following barriers to counselling: Lack of time, 55 %; Belief of inefficacy of counselling, 35 %; Need more counselling skills, 33 %; Patients not interested, 31 %; Unsure about content of counselling, 28 %; Lack of reimbursement, 22 %; Not convinced exercise helpful, 11%; Lifestyle matter of personal choice, 7 % [15]. Thus, lack of time was the major deterrent for initiating such preventive efforts.

Medical Considerations

Comprehensive cardiac rehabilitation: an issue to be readdressed

A multifactorial and multidisciplinary approach is imperative nowadays in order to meet the challenges of reducing the progression of CAD, the rate of cardiovascular events and of improving the quality of life in patients with proven CAD. As shown later, meta-analytical data from more than 4000 patients demonstrate that cardiac rehabilitation attained a reduction in cardiac and overall mortality of about 25 % during a 3-year follow-up period [16–18].

A crucial point is not to consider cardiac rehabilitation as exercise training, but as a program based on the individual's requirements, aiming at the improvement of the quantity and quality of life by means of. reduction (or abolition, when possible) of the classical risk factors, such as smoking and cholesterol levels, modification of dietary habits, increase and maintenance of endurance training, psychological support, and guidance on returning to work. According to previous data [19], the initial gain of cardiac rehabilitation is partially lost at mid-long term if the scheduled program is limited to the initial period after the index coronary event. This is particularly relevant in the elderly, whose physical activity is 'naturally' less than patients below the age of 65 years; therefore, continued organized training seems even more relevant for the preservation of the initial success. To further underscore this concept, we should remember that it could be demonstrated that the positive influence on mortality of cardiac rehabilitation is strongly influenced by the continuation of the program beyond the usual 8–12 weeks [16].

A long-term comprehensive cardiac care program involves a close follow up, risk factor modification, patient education and psychological guidance. The program should be utilized in coronary patients under medical therapy as well as in those who have had percutaneous transluminal coronary angioplasty (PTCA), surgical revascularization and transplantation. However, physical training can only be considered as one component of such a program. It has been demonstrated and established in a number of large historical and randomised trials that physical training has a beneficial effect on physiological and haemodynamic exercise variables, and that an effective training program will improve patients functional ability, physical work performance, as well as metabolic properties. On the other hand, it should be reiterated that exercise can only be considered within the framework of the total care program. It does not present a panacea nor is it indicated in every patient [20].

Contemporary cardiac rehabilitation services

Many uncomplicated post-myocardial infarction, and coronary artery bypass patients are now being discharged from the hospital in less than 5 days. These patients are likely to be motivated to participate in outpatient rehabilitation services. Accordingly, staff efforts must be intensified to ensure initial contact before hospital discharge, if possible. The potential for permanent risk factor modification may also be heightened with earlier intervention. A 71 % smoking cessation rate has been reported at 1 year for patients who received a nurse-managed behavioral intervention at the time of hospitalization compared with a 45% success rate in those receiving usual care [21].

Although hypertension, hyperlipidaemia, obesity, and diabetes mellitus may be favourably affected by regular physical activity [22] exercise alone should not be expected to alter global coronary risk status. Contemporary cardiac rehabilitation programs should provide a menu of multifactorial services to meet individual patient needs, including exercise training, education and counselling about coronary risk reduction, return-to-work, medical surveillance and emergency support (when appropriate), and interventions to improve psychosocial functioning. Staff members (eg, nurses, physiologists, physical therapists) may be assigned to a specific group of patients (a caseload), and comprehensive risk reduction plans should be formulated for every participant. Regression or limitation of progression of angiographically documented coronary atherosclerosis and/or significant reductions in cardiovascular morbidity and mortality has been achieved not only by drug therapy but by dietary intervention, disciplined exercise programs and behaviour modification as well [23].

Contemporary cardiac rehabilitation programs should incorporate tailored modifications and motivational strategies to enhance participant interest and adherence. These include assessing the patient's "readiness" for change, providing services that are designed to circumvent or attenuate common barriers to enrolment and adherence (eg, transportation to and from the program), keeping goals short-term and attainable, using incentives accruing to periodic exercise testing and risk factor assessment, recruiting spouse support of the program, and archiving for the patient his or her recorded goal achievements [24]. The exercise prescription should employ low-to-moderate intensity physical activity which has been shown to be as effective as more strenuous exercise in increasing functional capacity and high-density lipoprotein cholesterol, while reducing the risk of orthopaedic injury [25].

Although traditional supervised group programs are associated with increased cost and extended travel time, considerable data are available regarding the safety, efficacy, and costeffectiveness of this model. Such programs are also more appropriate for the growing medical complexity of candidates who may be at increased risk for future cardiac events. Further, supervised programs facilitate patient education both in regard to exercise and lifestyle changes for coronary risk reduction, provide variety and recreational opportunities, and offer staff reassurance and the potential for enhanced adherence, safety, and surveillance [26].

Home exercise rehabilitation should be promulgated as an alternative, however, because of its lesser cost, increased practicability, convenience; and potential to promote independence and self-responsibility [27]. For low-risk patients, medically directed, home-based rehabilitation and supervised group programs have shown comparable safety and efficacy. Dealing with smoking and hyperlipidemia can also be successfully achieved in a home-based rehabilitation setting [28]. A variety of techniques may be used to facilitate monitoring and/or communication between patients managed at home and rehabilitation staff, including regular telephone contact, mail (eg, completion of activity logs), fax; video recording, Internet, and transtelephonic ECG monitoring [27-29].

The treatment of CAD has evolved from simple lifestyle modification in the mid-to-late 60s, largely focused on early ambulation and exercise training, to an array of costly medical and surgical interventions that too often fail to address the underlying causes high-fat and cholesterol diets, cigarette smoking, hypertension, and physical inactivity. Intensive measures to control hyperlipidemia with diet, drugs, and exercise, especially in combination, have now been shown to stabilize or even reverse the otherwise inexorable progression of atherosclerotic CAD. Added benefits include a reduction in anginal symptoms, decreases in exercise-induced myocardial ischemia, fewer recurrent cardiac events, and diminished need for coronary revascularization [24].

Changing demographics and the impact of aging

The 20th century has seen prodigious growth in the number of people we identify as elderly, and projections indicate that there will be increases in both the absolute and relative proportions of the population who are older [30, 31]. This phenomenon is related to the current birth date and the decline in age-specific mortality. Because of the increasing population and its high component of elderly, we can expect an increase in the absolute numbers of patients who have CAD [32]. These demographic changes related to the aging population will inevitably have a huge impact on health care utilization and expenditures [5].

Levy and others [33, 34] have observed that since the late 1960s, there has been an unprecedented decline in mortality from cardiovascular disease in the United States, especially from CAD and stroke. The decline has been observed in all age groups, especially in the elderly [33]. The fall in CAD

mortality is attributable to the development of specialized acute coronary care, potent cardiovascular drugs for the treatment of heart failure and ischemia, surgical techniques for coronary revascularization, accurate non-invasive diagnostic methods such as echocardiography, and the identification of specific cardiovascular risk factors (including the major modifiable ones of cigarette smoking, hypertension, and blood lipids). The decline in mortality correlates with the increasing risk factor awareness and modification. Not only improved treatment regimens but also risk factor modification through lifestyle changes have played important roles in the reduction of cardiovascular mortality [33]. Because of the demographics of the growing population, however, we must not misinterpret the decline in cardiovascular mortality to imply a lower future prevalence of disease, at least not in the next decade or two. If anything, we should expect the prevalence of CAD to increase by about 30 % by the year 2015, even with 20 % to 25 % decreases in case fatality and incidence rates [32].

The gender gap

Cardiac rehabilitation and exercise training have now been shown to improve exercise capacity, reduce various CAD risk factors, improve quality of life, reduce subsequent hospitalisation costs, as well as reduce major CAD events, including fatal myocardial infarction, sudden death, and all-cause mortality [26]. Despite these well-proven benefits of outpatient cardiac rehabilitation and exercise training, limited data are available on the outcome of these treatments in women [35-37]. In addition, data indicate that women, especially older women, are not referred to cardiac rehabilitation programs as often as men [38, 39] and it is generally recognized - that even when referred, women are not as vigorously encouraged to enter these programs. These data all support a possible gender bias in the approach to women with CAD, despite the fact that the decline in CAD has been considerably less in women, than in men and that CAD is the leading cause of morbidity and mortality in middle-aged and older women. Because women have a lower exercise capacity, energy function score, and total quality of life score at baseline, the improvements after cardiac rehabilitation may be of greater clinical benefit to women than to men. These data reaffirm that women should be routinely referred to and vigorously encouraged to participate in outpatient cardiac rehabilitation and exercise training after major cardiac events [40].

Practice of Cardiac Rehabilitation

Exercise testing and exercise prescription

An exercise test is the primary means used to evaluate the safety of participating in an exercise program and to formulate the exercise prescription. Because of the wide scatter of maximal HR when plotted against age, it is much better to determine a person's maximal HR by testing to assign a target for training rather than to give a predicted value. In formal cardiac rehabilitation programs an exercise test can be used to advance a patient safely to a higher level of performance. Also, the improvement in exercise capacity demonstrated by an exercise test can be an effective incentive and can encourage risk factor modification.

The exercise prescription should be individualized according to the results of the exercise test. In our laboratory we use the heart rate at the anaerobic or ventilatory threshold (AT) measured by cardiopulmonary exercise testing as the heart rate for intensity recommendation. Generally, however, one must be sure that the heart rate at AT is safe and that the patient does not exhibit symptoms of angina or moderate dyspnea at that level. Alternatively, a heart rate 10 beats per minute less than that at AT may be a reasonable starting point for patients with severe symptoms or marked debilitation. Exercise is recommended three times per week for 20 to 30 minutes at the assigned intensity. Initially, aerobic training modalities are advised [41].

Stress management training

"Stress management training" has been used in the literature to refer to a wide range of interventions [42]. Fortunately, research suggests that relatively simple stress management interventions can significantly improve outcomes in cardiac populations [43]. Protocols for structuring stress management programs have recently been published [42]. In addition to reducing distress during the formal rehabilitation period, stress management interventions should help patients cope with the long-range challenges they face. Ideally, such intervention should incorporate didactic discussion of the physical aspects of the stress response; self assessment exercises that help patients identify their most prevalent causes of stress and their typical coping reactions; training in a relaxation technique; modelling appropriate methods of communicating and dealing with interpersonal conflict; and coaching regarding ways to disrupt problem coping sequences. Information is best presented in a combination of modalities: video and audio tapes, brief discussions and brief instructions.

The efficacy of such a stress management program has recently been demonstrated [44]. Seventy-eight cardiac patients exposed to a 12-week multifaceted stress management program evidenced significant pre- to post-treatment reductions in anxiety and depression and improvements in psychological well-being, activities of daily living, social activity, and satisfaction with sexual relationship. Similar responses were noted in MI and coronary artery bypass graft patients.

Clinical experience suggests that "stress management" is a palatable frame of reference for introducing a variety of interventions. Individuals who view themselves as being strong, capable copers are likely to discredit their need for psychosocial intervention but respond to the notion that stress management training might be helpful [45].

Lipid management in the cardiac rehabilitation setting Cardiac rehabilitation has been validated as an effective model for secondary prevention of CAD. The Agency of Health Care Policy and Research published "Cardiac Rehabilitation: Clinical Practice Guidelines" [26]. Thirty-seven reports in the scientific literature describe improvement in lipid profiles resulting from multifactorial cardiac rehabilitation. The rehabilitation studies that reported the most favourable impact on lipid levels were multifactorial, that is, providing exercise training, dietary education, and counselling, and in some cases pharmacologic treatment, psychological support and behavioural training. The report, however, does not recommend cardiac rehabilitation as a sole intervention in the treatment of lipid disorders [26].

Cardiac rehabilitation programs predominantly focus on nonpharmacologic approaches to reducing cardiovascular risk. It is becoming more apparent that a combination of therapies individualized to the underlying disorder is more effective than a single therapy. The combination of comprehensive cardiac rehabilitation involving medical evaluation, prescribed exercise, cardiac risk factor modification, and education and nutrition counselling with a sophisticated approach for lipoprotein management can improve cardiovascular health and reduce health care costs [46].

Smoking cessation as a critical element of cardiac rehabilitation

Cigarette smoking is a major risk factor for the development of CAD and increased morbidity and mortality among people who have already developed CAD. Cessation of chronic cigarette smokers after a diagnosis of myocardial infarction or angina are reportedly between 20 % and 60 %, but a large portion of patients continue to smoke sooner or later [47]. Given the high risk from continued smoking for CAD patients, there is a need to provide empirically based smoking cessation interventions to these patients during their rehabilitation period. These interventions must be tailored to patients' characteristics (usually older and less thy individuals who may need to make multiple health-risk behaviour changes). It is also important to provide alternatives to group programs (which appeal only to a relatively small proportion of patients), and to provide programs that facilitate long-term abstinence given the high proportion of post-MI patients who stop smoking on their own but later relapse [48].

Cardiac rehabilitation providers are uniquely powerfully situated in their routine practice to educate patients about the relationship between lifestyle and CAD, and to help patients develop the skills necessary to make behavioural changes, decrease morbidity and mortality and improve quality of life. The continuity of care and extended contact between patients and the cardiac rehabilitation staff provides an excellent opportunity to provide smoking cessation interventions [49].

Program organisation

Phase I of cardiac rehabilitation is an inpatient program that is designed primarily for those recovering from myocardial infarction or coronary artery bypass grafting (CABG). To a lesser degree, phase I includes PTCA, valve surgery, cardiac transplant, stable angina, and CAD risk factor patients. The program combines low-level exercise and patient education, generally lasting from 3 to 6 days. The length of a typical program has decreased significantly in recent years because of shorter hospital stays. Currently, programs are often condensed to only a few days. Phase I is designed as the initial step in preparing the patient for a return to an active and productive lifestyle.

Phase II of cardiac rehabilitation is a supervised residential or outpatient program of individually prescribed exercise with continuous or intermittent ECG monitoring. It may be operated as a hospital-based or freestanding physician-directed facility. The exercise program is based on an individualized prescription of intensity, duration, frequency, and mode of activity. Patient education and lifestyle modification are integral parts of phase II.

Phase III and phase IV of cardiac rehabilitation are longterm programs. Patients who exit phase II should enter immediately into the long-term program. Low-risk patients who did not participate in phase II are also good candidates. Phase III usually lasts from 6 to 24 months and generally includes both clinical supervision by an exercise professional or nurse and intermittent ECG monitoring. The primary goals are to improve physical fitness, promote a feeling of well-being, and reduce the risk of a recurring event.

Phase IV is an ongoing long-term program beyond phase III that generally does not include clinical supervision or ECG monitoring. The goals of phase IV include continued improvement and maintenance of fitness, and the program may include both cardiac patients and healthy adults. It is not always necessary to enter phase III prior to IV. The professional staff decides which program is more appropriate.

Outcomes Evaluations

"The real challenge of the new millennium may indeed be to strike an appropriate balance between the pursuit of exciting new knowledge and the full application of strategies known to be extremely effective, but considered underused" [50]. We must acknowledge that increasing emphasis needs to be placed on reducing this treatment gap associated with regimens that have proven benefits [51, 52].

Based on rigorous evidence of treatment effectiveness, comprehensive risk reduction guidelines for patients with established heart disease have been promulgated by various scientific and policy agencies in North America and Europe [26, 53-55]. Despite this, evidence from the United Kingdom [56], Europe [57, 58], and from the United States [59-61] suggests that a large "treatment gap" exists between recommended therapies for patients with cardiovascular disease and the care that they are actually receiving [52, 60, 62-64]. For example, aspirin and beta-blockers are associated with lower mortality rates after MI in patients receiving these therapies than those not receiving them [59, 61] even though these and other cardiac medications are underutilized [59, 61, 65]. Further, there is little doubt that lifestyles such as tobacco smoking, a diet rich in saturated fats and little physical activity frequently associated with developed, Western countries play an important role in the development and progression of CAD. [55, 63]. Risk factor management in secondary prevention is especially important as adverse cardiac event rates in patients with documented CAD are 5- to 7-fold higher than that reported in persons with similar risks but without evidence of CAD [66]. There can be little doubt that this 'treatment gap' significantly decreases the potential effectiveness of proven interventions.

In support of optimal clinical practice, innovative evidence-based medicine (EBM) methodologies are emerging which integrate the best research evidence (clinical relevant patient-centered research into the efficacy and safety of therapeutic, rehabilitative, and preventive regimens, eg, cardiac rehabilitation) with clinical expertise (clinically skills and past experience) and patient values (as the unique preferences, concerns, and expectations of each patient) [67]. These innovations are based on the premise that patients who receive evidence-based therapies have better outcomes than those who do not. Meta-analysis is the most powerful and useful EBM methodology available, providing a summary of the medical literature using explicit methods to systematically search, critically appraise, and synthesize the available evidence to demonstrate the efficacy or effectiveness of a treatment [67]. The following guidelines can be used to determine the validity of the results of the meta-analysis.

- Is this a systematic review of randomized controlled trials (RCTs)? RCTs reduce bias (randomized allocation to treatment) and pooling them reduces random error (increased number of patients). When non-randomized trials are included, the problem of individually misleading trials can produce a lower quality of evidence.
- Does the systematic review have a methods section that describes how the relevant, including negative, RCTs were found? This includes hand-searches of the journals, which is the starting point for the Cochrane Collaboration, as well as searching conference proceedings and other data banks, and contacting authors of published articles for additional information.
- Does the systematic review describe how the validity of the RCTs was assessed? Was the assignment to treatment randomized? Were the outcome assessors blind to allocation? Was the follow-up of patients sufficiently long and

 Does the systematic review include a quantitative analysis of the combined data from the individual RCTs? Is there a summary statistic, usually expressed as an odds ratio (OR), a relative risk, or a number-need-to-treat?

The purpose of the second section of this review is to identify "best research evidence" for the efficacy of cardiac rehabilitation and secondary prevention services in persons who have documented CAD. Reviews of cardiac rehabilitation have varied considerably in their rigor and the studies they have included. The focus of this section will be on three published meta-analyses of cardiac rehabilitation using similar EBM methodologies [16-18]. Although new evidence from clinical research may invalidate previously accepted interventions replacing them with more efficacious and safer interventions, clinical research also may provide evidence substantiating the efficacy and safety of the intervention being evaluated.

Meta-analysis for evidence-based cardiac rehabilitation

Guidelines for the assessment of safety and health outcomes associated with a particular intervention generally include outcomes such as survival rates, symptoms and complications, HRQL, the experiences of patients and their care-givers, and the cost and use of resources to provide the service [68, 69]. The evidence for the safety of cardiac rehabilitation services is inferred from surveys of clinical experience [70, 71] and from aggregate analysis of studies [26]. Having been shown to be safe, cardiac rehabilitation needs then to be examined for efficacy (ie, can the intervention work in ideal circumstances such as the RCT?), effectiveness (ie, does the intervention work in routine clinical circumstances?), and efficiency (ie, is the intervention cost-effective?).

Methodology used to identify RCTs

Each of the three meta-analyses [16-18] includes a methods section specifically describing the search and statistical methodologies. The RCTs considered for inclusion in the metaanalyses were derived 1) from reviewing the published literature (English only) [16], no specific comment on language [17], and without regard to language [18]), 2) from computer-assisted searches, and 3) by canvassing the principal investigators of the RCTs and other experienced professionals for additional information. In the first two meta-analyses [16, 17], RCTs of exercise-based cardiac rehabilitation, with some risk factor management component, for patients with MI were considered. In the most recent meta-analysis [18], RCTs included patients with CAD, ie, MI, CABG, PTCA, angina, or angiographically-documented coronary artery disease. Further, this meta-analysis was designed specifically to examine separately the results of exercise-only RCTs and RCTs of exercise as part of comprehensive cardiac rehabilitation and to examine the quality of the data reported in the individual RCTs.

Trial characteristics

The numbers of RCTs and patients, and the diagnoses, age, and gender of patients included in each meta-analysis are summarized in Table 1. The overall number of separate publications in the most recent meta-analysis totaled 51 and the total number of comparisons is greater than the number of trials as in some trials patients could be randomized to more than one group [18].

Primary outcomes

The primary outcomes reported in the three meta-analyses examined in this review include all-cause mortality, cardiac mortality, non-fatal MI [16-18], sudden death and fatal MI [17], adverse events (mortality, non-fatal MI, and revascularization which includes CABG and PTCA), as well as HRQL [18]. The OR, with 95% confidence intervals (CI), is the summary statistic for dichotomous outcomes with the ORs in bold being significant as the 95% CI around the OR does not include 1.00 [16–18]. The primary outcomes in the meta-analyses are summarized in Table 2. The time period of the mean follow-up for the Oldridge meta-analysis was 42 months, for the O'Connor meta-analysis it was 36 months, and for the Jolliffe meta-analysis it was 27 months. The ORs (and 95 % CI) for total mortality in individual comprehensive cardiac rehabilitation RCTs are provided in Figure 2.

Health-related quality of life outcomes were measured in 11 of the RCTs and considered only in the meta-analysis reported by Jolliffe and colleagues [18]. In all, 18 different measures, including unvalidated ones, were used. Valid HRQL measures were used in only five RCTs; two generic HRQL measures were used in three RCTs with 806 patients and one specific HRQL measure was used in two RCTs with 651 patients. Pooling data was inappropriate because of the

differences in HRQL measures but there was an improved HRQL by the end of the intervention in each RCT although, in one RCT, this difference was trivial at 12 months even though both rehabilitation and usual care patients improved significantly [16].

Secondary outcomes

Secondary outcomes were reported only in the most recent of the meta-analyses and include blood lipid levels, blood pressure, and smoking behavior [18] and are summarized in Table 3. The summary statistic used for these continuous variables is the weighted mean change, with the standard deviation of the change, from baseline to follow-up.

Table 1. Randomized controlled trial numbers and patient characteristics

		Oldridge	O'Connor		Jolliffe	
				Exercise	CCR [‡]	All RCTs
RCTs	s [n] total patients [n] [range, n]	10* 4,347 98–1360	22** 4,554 98–1780	14 2,845 42–651	19 ^{***} 5,595 60–1479	33 8,440 42–1479
Diag	nosis [% RCTs] MI CABG PTCA mixed	100	100	86 7 7	68 4.5 4.5 23	79 6 3 12
Age	[mean years] [upper limit]	51.5 < 71	26 – 70 < 70	55.0	53.2	54.0
Gender – % male		97.1	96.8	95.6	89	91.1
	 Compret The WHC ** The WHC 	nensive cardiac D centers consi	rehabilitation dered as a single dered as 14 BCT	e RCT		

The WHO centers considered as 13 trials

 Table 2. The odds ratio (OR), 95 % confidence intervals (95 % Cl), and number of patients

 (n) for the separate primary outcome analyses in the three meta-analyses. Data in bold indicate a significant OR and the 95 % Cl.

	Meta-analyses			
	Oldridge	O'Connor	Jollif	ife
Outcome			Exercise	CCR [‡]
All-cause mortality OR 95 % Cl n	0.76 0.63, 0.92 3,614	0.80 0.66, 0.96 4,554	0.73 0.54, 0.98 2,582	0.87 0.71, 1.05 5,101
Cardiac mortality OR 95 % Cl n	0.75 0.62, 0.93 4,044	0.78 0.63, 0.96 N/A	0.69 0.51, 0.94 2,312	0.74 0.57, 0.96 2,903
Non-fatal MI OR 95 % Cl n	1.15 0.93, 1.42 4,347	1.09 0.88, 1.34 N/A	0.96 0.69, 1.35 2,104	0.88 0.70, 1.12 3,541
Sudden death OR 95 % Cl n		0.92 0.69, 1.23 N/A		
Fatal MI OR 95 % Cl n		0.75 0.59, 0.95 N/A		
CABG OR 95 % Cl n				0.83 0.60, 1.13 1,434
Pooled adverse events OR 95 % Cl n			0.81 0.65, 1.01 2,582	0.80 0.70, 0.93 5,101
[‡] Comprehensive cardia	c rehabilitation			

There were insufficient secondary outcome data in the exerciseonly RCTs for any comparisons to be made. Total cholesterol, LDL cholesterol, triglycerides, and diastolic blood pressure improved with comprehensive cardiac rehabilitation when compared to usual care. There was no effect on smoking in the three exercise-only RCTs and in the 5 comprehensive cardiac rehabilitation RCTs, only the larger RCTs showed favourable, but not significant, effects of intervention on smoking.

Trial quality

Examination of RCT quality was a specific aim in the metaanalysis carried out by Jolliffe and colleagues [18]. The meth-



Figure 2. Forest plot of total mortality with exercise-only cardiac rehabilitation randomized controlled trials with odds ratios (OR) and 95 % confidence limits (based on reference [18])

ods for randomization were unclear in 82 % of the RCTs, blind assessment occurred in only 8 % of the RCTs, and 29 % of the RCTs had a greater than 20 % loss to follow-up. The pooled estimate for RCTs with adequate randomization was significant with an OR of 0.78 (0.61, 0.99) compared to a lower but not significant OR of 0.53 (0.2, 1.4) in those RCTs with inadequate randomization. No evidence of publication bias was found.

Interpretation of the outcomes evaluations

While each of the meta-analyses considered in this report meets methodological guidelines for validity, the most recent meta-analysis [18] provides evidence on additional outcomes not considered in the two earlier meta-analyses [16, 17]. The latest meta-analysis increases the power of the evidence by adding 27 RCTs, most not published at the time of earlier meta-analyses, with the total number of patients increased from 4,347 [16] and 4,554 [17] to 8,440 patients, with 2,845 in the exercise-only RCTs and 5,595 in the comprehensive cardiac rehabilitation RCTs [18].

In the most recent meta-analysis, exercise-only cardiac rehabilitation RCTs were associated with a significant re-

duction in total mortality (OR= 0.73) compared to comprehensive cardiac rehabilitation RCTs where the reduction in mortality was less and not statistically significant (OR= 0.87) [18]. This is consistent with the meta-analysis reported by Oldridge and colleagues [16] but not with that reported by O'Connor and colleagues [17]. While the ORs for adverse events with exercise-only and comprehensive cardiac rehabilitation, reported only in the meta-analysis by Jolliffe and colleagues, were almost identical, the OR of 0.80 with com-

Table 3. The weighted mean difference (WMD), 95 % confidence intervals (95 % CI), and number of patients (n) for the separate secondary outcome analyses. Data in bold indicate a significant WMD and the 95 % CI.

	Meta-analysis: Jolliffe			
Outcome	Exercise	CCR [‡]		
Total cholesterol WMD 95 % Cl n	insufficient data	-0.57 -0.83, -0.31 1,198		
LDL* cholesterol WMD 95 % Cl n	insufficient data	-0.51 -0.82, -0.19 728		
Triglycerides WMD 95 % Cl n	insufficient data	- 0.29 - 0.42 , - 0.15 800		
Diastolic blood pressure WMD 95 % Cl n	insufficient data	-2.2 -3.6, -0.9 N/A		
Smoking OR 95 % Cl n	insufficient data	0.78 0.55, 1.11 1272		

Comprehensive cardiac rehabilitation

* Low density lipoproteins

prehensive cardiac rehabilitation was significant while the OR of 0.81 with exercise-only was not [18]. There was no impact on non-fatal recurrent MI with either exercise-only or comprehensive cardiac rehabilitation in the meta-analyses [16-18]. There is insufficient evidence to determine whether the differences between exercise-only or comprehensive cardiac rehabilitation in mortality and adverse events are significant, so limiting any conclusion about one being more effective than the other.

The meta-analysis reported by Jolliffe and colleagues is also the first to provide a methodologically sound examination of the effect of cardiac rehabilitation on established cardiac risk factors and HRQL [18]. Total and LDL cholesterol were significantly improved with comprehensive, but not exercise-only, cardiac rehabilitation when compared to usual care but a possible confounding effect of cholesterol-lowering medications, eg, statins, could not be ruled out. The observed differences in blood lipids and diastolic blood pressure were small and of questionable decision-making value for individual patients. There was insufficient data to make any conclusions about either mode of cardiac rehabilitation on smoking. In terms of HRQL, the diversity of measures used, the lack of valid measures specifically designed to assess HRQL, and the small number of RCTs which examined HRQL as an outcome means that valid conclusions can not be drawn about HRQL as an outcome of cardiac rehabilitation. This is unfortunate as HRQL is a research area which warrants serious attention. With increasingly effective invasive interventions and medications for patients with CAD, mortality and recurrent MI may not be the best outcomes for evaluating the effectiveness of cardiac rehabilitation and HRQL probably is a more important outcome from the patient's perspective.

Another objective of the meta-analysis conducted by Jolliffe and colleagues was to examine the impact of RCT quality [18]. It is clear that the majority of the RCTs were under-powered with poor methodological quality. It was also clear that better quality RCTs were associated with a lower, albeit significant, reduction in total mortality than the RCTs with questionable methodological quality.

Not surprisingly given the data base, the three meta-analyses each reported a preponderance of RCTs designed for patients with MI, who were most likely to be white, middleaged, and male, with few RCTs including patients with other presentations of CAD or comorbidities, or patients who belong to minority groups, are older, or are female [16–18,]. For example, many RCTs actively excluded patients with heart failure or diabetes and this exclusion rate may have applied to as many as 60 % of the patients considered for an RCT which certainly would have affected older patients disproportionately. A number of more recent RCTs have been published and have addressed some of the issues raised by each of the meta-analyses considered in this report. These include RCTs examining exercise-based rehabilitation in patients with heart failure [72, 73], patients with heart transplantation [74], elderly patients [75, 76], as well as examining the impact of rehabilitation on HRQL [77] and in the home setting [29].

In summary, exercise-based cardiac rehabilitation is effective in reducing adverse events including deaths. However, there is little evidence on which to base a choice between exercise-only and comprehensive cardiac rehabilitation, suggesting that it would be rational to consider both cost and local access to available services to determine practice. The population studied in each meta-analysis was predominately post-MI, middle-aged, male, and low risk. This means that it is possible that patients who could have benefited, ie, elderly, female, and high risk patients, were, in fact, excluded from the RCTs on the basis of age, gender, or co-morbidity. Larger scale, well-designed and well-conducted RCTs are needed to determine whether the effects of cardiac rehabilitation can be confirmed and extended to these and other patient populations. Finally, outcome measures that reflect patient- and family-perceived effects of cardiac rehabilitation need to be developed and used in RCTs and clinical practice. Some of these questions are addressed in on-going RCTs or in RCTs that have been published since the most recent of the metaanalyses was initiated.

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