ICSI

Institute for Clinical Systems Improvement

Technology Assessment Report

Institute for Clinical Systems Improvement

Technology Assessment Update Abstract

Cardiac Rehabilitation

Prepared under the direction of the
Technology Assessment Committee
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Description of Treatment/Procedure

For at least the past two decades, risk factor modification programs for cardiac patients, commonly referred to as cardiac rehabilitation, have evolved into a comprehensive management strategy. Originally focusing on exercise training, these programs have evolved to emphasize overall risk factor and behavioral modification. There are four phases of cardiac rehabilitation. Phase I is the inpatient days. Phase II is the outpatient days immediately after hospitalization which usually lasts about 2-12 weeks. Phase III is the late recovery period with a minimum duration of 6 months beyond phase II. Phase IV is the maintenance program that patients should continue indefinitely.

Potential Uses

Comprehensive outpatient programs which contain all phases of stress reduction, blood pressure control, lipid control, lifestyle management, and supervised exercise with continuous EEG monitoring are indicated for those selected patients who are at increased risk for adverse cardiac events during exercise, and should be discontinued after patients reach pre-set goals.

Contraindications

The following are absolute contraindications to exercise training: unstable angina pectoris; dangerous arrhythmias; overt cardiac failure; severe obstruction of the left ventricular outflow tract; dissecting aneurysm; myocarditis or pericarditis (acute); serious systemic disease; thrombophlebitis; recent systemic or pulmonary embolus; severe hypertension; overt psychoneurotic disorders; uncontrolled diabetes mellitus; severe orthopedic limitations.

Efficacy of Treatment/Procedure

In a randomized controlled trial (RCT) of 3,335 patients receiving supervised cardiac rehabilitation (CR) and followed for 16 years, only 5 major cardiovascular events had occurred during exercise of which 1 resulted in death. There have been 5 RCTs and 1 systemtic review (meta-analysis) of comprehensive CR. These studies have shown reductions in the numbers of cardiac events and hospitalizations as well as improvements in individual risk factors up to four years after beginning CR. The meta-analysis of 32 RCTs showed a significant reduction in cardiac mortality for both exercise-only and comprehensive CR programs. No studies have demonstrated the benefit of supervised versus unsupervised exercise in a CR program or exercise-only versus comprehensive CR programs.

Committee Summary

With regard to cardiac rehabilitation, the ICSI Technology Assessment Committee finds that:

1. Outpatient cardiac rehabilitation (CR) programs (Phase II, III, and IV) are safe for selected patients in stable condition with a diagnosis of atherosclerosis, acute myocardial infarction, percutaneous transluminal coronary angioplasty, coronary bypass surgery, or cardiac valve surgery including programs with an aerobic and/or strength training component.
2. CR programs with various components have been shown to be efficacious (Conclusion Grade I), however no gold standard CR program has been established. No studies have analyzed exercise-only versus comprehensive CR programs and it is unclear whether exercise only or comprehensive CR is more beneficial. Comprehensive CR programs including multifactorial coronary artery risk factor assessment and reduction have shown reductions in the number of cardiac events and hospitalizations as well as improvements in individual risk factors such as lipids, weight, and exercise capacity up to four years after beginning CR. One meta-analysis of 32 randomized controlled trials has shown a significant reduction in cardiac mortality for both exercise-only and comprehensive CR programs.
3. No studies have demonstrated the benefit of supervised versus unsupervised exercise in a CR program.
4. The Committee did not evaluate Phase I CR, as it is seen as part of the hospital care for these patients.

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Technology Assessment Update

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Technology Assessment Committee

Reason for Update

The original technology assessment report *Cardiac Rehabilitation* (CR) was approved in 1994. Since that original technology assessment report, there have been several published reports and reviews of this topic. Thus, an update including this more recent evidence is needed.

Previous Conclusion (1994)

The ICSI Technology Assessment Committee finds outpatient cardiac rehabilitation (Phase II, III, and IV) to be safe and effective for selected patients in stable condition with a diagnosis of acute myocardial infarction, coronary bypass surgery, or cardiac valve surgery; however, most patients free from serious complications may achieve the same results without a supervised program. The Committee did not evaluate Phase I cardiac rehabilitation, as it is seen as part of the hospital care for these patients.

Phases of Cardiac Rehabilitation

Phase	Type of program	Duration
I	Inpatient	Days
II	Outpatient, immediately after hospitalization	2-12 weeks
III	Late recovery period	Minimum of 6 months beyond phase II
IV	Maintenance	Indefinite

The inpatient exercise program (*Phase I*) starts as soon as the patient is medically stable following a cardiac event and an initial assessment has been completed. Goals include:

1. preventing the deleterious effects of bed rest;
2. assessing the hemodynamic response to exercise;
3. managing the psychosocial issues of cardiac disease; and
4. educating the patient and the family. (Brannon, Geyer, and Foley, 1993)

In general, *Phase I* consists of four components: 1) early assumption of the upright posture; 2) a progressive exercise and self-care program based on individual tolerance (gauged by heart rate, blood pressure response and presence of symptoms); 3) education; and 4) risk factor identification and initial attempts at modification (Levine, Friedman, and Williams,1992).

Outpatient exercise training and risk-factor modification (*Phase II*) is usually initiated within a few weeks after hospital discharge, and may provide continuous ECG monitoring, emergency equipment, medically supervised exercise, and risk-factor modification and education. These programs are usually recommended for patients with medical characteristics that place them at increased risk for cardiac events during exercise. Goals of Phase II cardiac rehabilitation are outlined below:

1. supervised exercise training to maximize functional capacity, teach safe exercise practices, and identify patients at risk for complications;
2. risk factor modification, including smoking cessation, stress reduction, weight loss, and improvement in cholesterol profile; and
3. education about medications, signs and symptoms of heart disease and its progression, sexual relations, dietary modifications and activity guidelines (Levine, Friedman, and Williams,1992).

For *Phase III*, patients who no longer need medical supervision while exercising may embark on a long-term program of exercise and health maintenance. Such programs are usually undertaken at home or in a fitness center.

Phase IV of rehabilitation is the maintenance program (consisting of efforts to modify risk factors and a routine program of physical activity) that patients should continue indefinitely (Squires, Gau, Miller, Allison, and Lavie,1990; ICSI, 1994).

Recent Evidence (1994-2001)

Comprehensive Cardiac Rehabilitation

In the Stanford Coronary Risk Intervention Project (SCRIP) randomized controlled trial (RCT), 300 patients with angiographically defined atherosclerosis were randomly assigned to usual care by their own physician (145 control patients) or multifactorial risk reduction (155 treatment patients). The risk reduction protocol involved programs for a low fat and cholesterol diet, exercise, smoking cessation, and lipoprotein medications. Four-year follow-up showed there were 3 deaths in each of the two groups but fewer nonfatal MIs (4 vs 10), coronary artery bypass graft (CABG) surgeries (6 vs 14), and primary percutaneous transluminal coronary angioplasties (PTCA) (13 vs 17) in the treatment group. The treatment group had significantly less narrowing (47% less change in minimal diameter) of the diseased coronary artery segments than the control group (-0.024 mm/y vs -0.045 mm/y, $p<0.02$). There were 25 hospitalizations for cardiac events in the treatment group and 44 in the control group ($p=0.05$). The treatment group had significant improvements in LDL cholesterol ($p=0.0001$), apolipoprotein ($p=0.0008$), HDL cholesterol ($p=0.001$), plasma triglycerides ($p=0.002$), body weight ($p=0.0001$), and exercise capacity ($p=0.001$) as compared to the control group. The number of smokers was not significantly different in either group at 4 year follow-up (Haskell, Alderman, Fair, et al., 1994).

The Lifestyle Heart Trial 5-year follow-up included 35 patients who were initially randomized to treatment and control groups. The treatment group (20 patients) was prescribed intensive lifestyle changes that included a vegetarian diet with 10% of calories from fat, moderate aerobic exercise, stress management, smoking cessation, and group psychosocial support. The control group (15 patients) was asked to follow the advice of their personal physician regarding lifestyle changes. There were 2 deaths in the treatment group and 1 among controls at 5 years. The treatment group had fewer cardiac events (25 vs 45, $p<0.001$) than controls at 5-year follow-up including fewer MIs (2 vs 4, $p=0.26$), PTCAs (8 vs 14, $p<0.05$), CABG (2 vs 5, $p=0.14$), and cardiac hospitalizations (23 vs 44, $p<0.001$). Chest pain (frequency, duration, and severity) was not significantly different between the two groups. In the treatment group, the average percent diameter stenosis at baseline decreased 1.75 (4.5% relative improvement) and 3.1 (7.9% relative improvement) absolute percentage points after 1 and 5 years, respectively. The controls had average percent diameter stenosis from baseline increases of 2.3 (5.4% relative worsening) and 11.8 (27.7% relative worsening) absolute percentage points after 1 and 5 years, respectively ($p=0.001$ between groups). HDL, LDL, total cholesterol, triglycerides, and apolipoprotein B were not significantly different in the two groups at 5-year follow-up, but apolipoprotein A was significantly lower in the treatment group ($p=0.04$) (Ornish, Scherwitz, Billings, et al., 1998).

In a RCT of 228 patients less than 65 years of age who underwent elective CABG, 119 patients received rehabilitation along with standard care and 109 patients received hospital based treatment along with standard care. In the 5 year follow-up, 12 patients in the rehabilitation group and 12 patients in the control group died either perioperatively or during follow-up. Standard postoperative care consisted of 5 visits to the cardiac outpatient center in the five-year follow-up. Visits lasted 30 minutes in which a physical exam was performed and progress of recovery was discussed along with the importance of physical activity and lipid-lowering diets. Drug treatment for hyperlipidemia was initiated by the patient's personal physician. The cardiac rehabilitation component consisted of 4 phases. Phase I started 2-3 weeks prior to surgery for 2 days and Phase II continued 6-8 weeks post-surgery for 3 weeks. Phase II consisted of various exercises while encouraging exercise outside of the program. Dietary counseling was initiated in Phase I with a goal of daily fat intake <30% of total calories, cholesterol intake <300 mg/day, P/S (polyunsaturated/saturated fat) ratio of > 1.0, and increased use of vegetable fiber. Phase III started 8 months post-surgery for 2 days emphasizing previous exercise and diet as well as giving patients an opportunity to exchange experiences. Phase IV was a 1 day refresher course at 30 months post-surgery in which spouses were invited. The proportion of patients exercising regularly increased similarly in both groups and the number of smokers was also similar. There was a beneficial change in serum lipid levels in both groups but the intergroup changes were not significantly different. In patients <55 years of age, the increase in HDL cholesterol was significantly greater ($p=0.02$) in the rehabilitation group (from 39 to 43 mg/dl) than in the control group (from 36 to 38 mg/dl) during the first year of follow-up, but disappeared in later follow-up (Engblom, Korpilahti, Hamalainen, Puukka, and Ronnemaa, 1996).

Another publication from the same RCT reported on the quality of life parameters and return to work among the same group of patients. Patient reported scores of heart symptoms, use of medication, exercise capacity, and depression did not differ between the two groups. At five-year follow-up, patients in the rehabilitation group reported less restriction in physical mobility than controls (p=0.005) and more patients in the treatment group perceived their health (p=0.03) and overall life situation (p=0.02) as good compared to controls. The proportion of patients working at 3-year follow-up was higher in the treatment group as compared to controls (p=0.02) but was not significantly different at other follow-up times (Engblom, Korpilahti, Hamalainen, Ronnemaa, and Puukka, 1997).

In another RCT, 585 patients <70 years of age hospitalized for acute MI were randomized to receive a nurse managed, home-based, multifactorial risk reduction program (293 treatment patients) or usual care (292 control patients). The risk reduction program included smoking cessation, nutritional counseling, lipid-lowering drug therapy, exercise training, and relaxation tapes for high levels of stress. Patients in the treatment group also received nurse initiated phone calls every month for the first 6 months to assess the patient's mood, coping, depression, and extreme distress. At 12-month follow-up, 29% of treatment and 37% of control patients had data missing and were not included in the analysis. The 13 (4%) patients in the treatment group and 10 (3%) in the control group that had died were not included in the analysis as well. There were no significant differences in depression scores, stress, anxiety among patients with high levels of psychological distress, and anger frequency among patients with low levels of psychological distress between the two groups. Anxiety among patients with low levels of psychological distress (p<0.05) and anger frequency among patients with high levels of psychological distress (p<0.05) were significantly improved in the treatment group as compared to the control group (Taylor, Miller, Smith, and DeBusk, 1997).

A Cochrane systematic review analyzed RCTs of patients receiving exercise only and comprehensive cardiac rehabilitation. Patients who have previously had myocardial infarction, CABG, PTCA, angina pectoris or coronary artery disease (CAD) defined by angiography were included. A total of 32 trials were included in various analyses. Total mortality was significantly reduced by 27% in the exercise only group (OR 0.73, 95% CI 0.54-0.98) and reduced (p=NS) by 13% in the comprehensive group (OR 0.87, 95% CI 0.71-1.05). Total cardiac mortality was significantly reduced by 31% in the exercise only group (OR 0.69, 95% CI 0.51-0.94) and by 26% in the comprehensive group (OR 0.74, 95% CI 0.57-0.96). Neither CR group had a significant effect on the occurrence of non-fatal myocardial infarction. In the comprehensive CR group there was a significant net reduction in total cholesterol (-0.57 mmol/l, 95% CI –0.83 to –0.31) and LDL (-0.51 mmol/l, 95 CI –0.82 to –0.19). No significant effect on sudden cardiac deaths was seen in either group. It was noted that patients who may have benefited most from CR were often excluded from studies based on age, sex, or co-morbidity. All of the comprehensive CR studies cited above were included in the systematic review (Jolliffe, Rees, Taylor, Thompson, Aldridge, and Ebrahim, 2002).

<u>*Exercise Alone*</u>

Belardinelli, Georgiou, Cianci, and Purcaro (1999) randomized 99 patients with chronic heart failure into exercise and non-exercise groups. The exercise group was to receive exercise training at 60% of peak oxygen consumption (VO2), initially 3 times per week for 8 weeks, then twice a week for one year. Exercise training resulted in significantly fewer deaths (9 vs 20, p=0.01) and significantly fewer hospital readmissions for heart failure (5 vs 14, p=0.02) as compared to the non-exercise group. Peak VO2 and thallium activity scores improved in the exercise group at 2 months (18% and 24%, respectively; p<0.001 for both) and did not change further after 1 year.

In a RCT by Wosornu, Bedford, and Ballantyne (1996), 81 male patients were randomized after coronary artery surgery to receive aerobic exercise, strength exercise, or no exercise (27 patients in each group). Patients in the two exercise groups received 12-40 minute sessions 3 times per week supervised by a physician, nurse, and physiotherapist. At 6-month follow-up, significantly higher increases in treadmill times were seen in the aerobic (196.4 minutes) and strength (122.7 minutes) exercise groups as compared to the control group (27 minutes, p=0.002 and p=0.03, respectively). There were no significant changes in lipid or lipoprotein levels. There were also no deaths or cardiac arrests in any of the exercise sessions.

Pierson, William, Norton, et al. (2001) analyzed 20 patients who completed either an aerobic exercise (10 control patients) or an aerobic plus resistance exercise (10 treatment patients) program. Patients were included in the analysis if they had >70% attendance record. Sixteen (16) of 36 patients initially randomized were excluded from analysis due to low attendance (4 patients), inability to finish the 6-month exercise program (11 patients) or change in prednisone therapy (1 patient). Strength gain was greater in the treatment group on 6 of 7 resistance machines (p<0.05) as compared to the control group. Resting and submaximal heart rate as well as rate-pressure product were lower (p<0.01) in the treatment group as compared to controls. The treatment group increased lean mass in arm, trunk, and total body regions (p<0.01) and the control group increased lean mass only in the trunk region (p<0.01). Percent body fat was significantly reduced (p<0.05) in the treatment group but not significantly reduced in the control group.

Daub, Knapnik, and William (1996) looked at 57 low-risk men 6-16 weeks after infarction. Patients were randomized into 4 groups all receiving aerobic exercise training 3 times per week for 12 weeks. A control group received only aerobic exercise. The 3 other groups received an additional strength training protocol of either 20 reps of 20% of 1 repetition maximum (Group 20), 10 reps of 40% of 1 repetition maximum (Group 40), or 7 reps of 60% of 1 repetition maximum (Group 60). Maximum strengths were significantly increased in the 3 strength-training groups (20, 40, and 60) as compared to controls (p<0.001) but were not significantly different from each other. Among the three strength-training groups, 30 of 42 patients had 1 or more cardiovascular complications during aerobic exercise but only 1 patient had complications during strength training (p<0.01).

In another RCT, 23 patients within 6 weeks of acute MI were randomly assigned to receive combined weight and cycle training (12 patients) or cycle training alone (11 patients) for 10 weeks. Maximal oxygen consumption (VO2 max [14%]) and cycling time (10%) were significantly increased in the combined exercise group (p<0.01 for both) but not significantly increased in the control group (8% for both). Both groups significantly increased arm and leg strength from baseline (p<0.01 for all) but greater increases were seen in the combined exercise group. No significant changes were seen in either group for resting hemodynamics, body weight and composition, left ventricle (LV) wall segment motion, LV fractional shortening, and early diastolic function. No adverse clinical events or exercise-related complications were seen in either group (Stewart, McFarland, Weinhofer, Cottrell, Brown, and Shapiro, 1998).

Beniamini, Rubenstein, Faigenbaum, Lichenstein, and Crim (1999) analyzed 34 patients already enrolled in a 12-week outpatient cardiac rehabilitation aerobic exercise program and randomized them to receive additional high-intensity strength training (18 patients) or flexibility training (16 patients). Strength training patients had greater increases in mean strength (p<0.0001) and local muscle endurance (p<0.0001) compared to the flexibility-trained group. The strength-training group lost significantly more body fat (p<0.01) and had significantly greater improvements in treadmill times (p<0.02) as compared to the flexibility trained group. There were no significant differences in joint flexibility between the two groups and none of the patients had evidence of cardiac ischemia or arrhythmia during training.

Lipids

Ades, Savage, Poehlman, Brochu, Fragnoli-Munn, and Carhart (1999) analyzed the effect of a lipid lowering protocol in a cardiac rehabilitation program. The intervention group consisted of 187 patients who entered the cardiac rehabilitation program from 1996 to 1997 and received a systematic lipid lowering intervention. The control group consisted of 51 patients who entered the cardiac rehabilitation program in 1995 and agreed to have their serum lipids measured but did not receive a systematic lipid lowering intervention. The intervention consisted of a fasting lipid profile and a 3-day food diary reviewed with the patient immediately after the entry stress test. Individualized therapy recommendations were based on the National Cholesterol Education Program (NCEP) guidelines and collaborative clinical judgment. Medical therapy was usually recommended for patients with baseline LDL cholesterol from 130-160 mg/dL and almost always recommended for patients with LDL cholesterol greater than160 mg/dL. Primary physicians were consulted to agree upon medical therapy. All intervention patients also participated in two classroom sessions on heart-healthy diets. Therapy was modified in 18% (4 of 22) of control patients compared to 52% (35 of 68) intervention patients ($p<0.05$) whose LDL cholesterol was greater than 129 mg/dL. In patients whose LDL cholesterol was greater than 159 mg/dL, therapy was modified in 22% (2 of 9) of control patients compared to 72% (18 of 25) intervention patients ($p<0.01$). The lowering of LDL cholesterol was significantly greater in the intervention group as compared to controls for both the greater than 129 mg/dL (-20% vs –8%, $p<0.01$) and greater than 159 mg/dL (-32% vs –17%, $p<0.01$) stratas.

Verges, Patois-Verges, Cohen, and Casillas (1998) looked at 52 hyperlipidemic men who had recently experienced myocardial infarction or coronary bypass surgery and were not known to be receiving any drugs known to affect lipid metabolism. Patients were separated (not randomized) into two groups (26 patients each) based on whether or not they had participated in the comprehensive cardiac rehabilitation program. Mean age, body mass index, triglycerides, and total, HDL, LDL, and LDL/HDL ratio cholesterol levels were all similar between the two groups at baseline. Both groups were referred to a dietitian and the same lipidologist to begin hypolipidemic treatment. At 3-month follow-up, patients in the cardiac rehabilitation group had significantly greater reductions of total cholesterol, LDL cholesterol, LDL/HDL ratio and triglycerides as compared to the non-cardiac rehabilitation group. It was proposed that the cardiac rehabilitation group's significantly better response to hypolipidemic treatment could be attributed to the extensive educational program on secondary prevention which may have enhanced the potential for improved diet and drug adherence.

Safety
The safety of cardiac rehabilitation exercise therapy was studied by Franklin, Bonzheim, Gordon, and Timmis (1998). They analyzed 3,335 patients who were referred for exercise-based cardiac rehabilitation between 1982-1998. Seventy percent of the patients were male and the average age was 61.6 years. Patients were referred typically 1-6 weeks after discharge from the hospital for MI, an acute coronary syndrome, or revascularization surgery. Phase II consisted of 50-minute aerobic exercise 3 times per week for 4-8 weeks with continuous ECG and blood pressure monitoring and Phase III was similar but included supervised exercise with spot checks of ECG and blood pressure as well as additional exercise machine choices. At 16-year follow-up, 5 major cardiovascular complications had occurred (all during Phase III) of which one resulted in death during the related hospitalization. Overall rates of major cardiovascular complications per patient exercise hours were 1 per 49,315 for Phase II and 1 per 58,451 for Phase II and III combined.

Safety of Treatment or Procedure

The evidence (or lack thereof), as cited in the literature, pertaining to:

a. mortality rate – *in a 16-year follow up of 3,335 cardiac rehabilitation patients only one death had been reported after a major cardiac event during an exercise session; other studies have indicated no increase in mortality due to cardiac rehabilitation*

b. morbidity rate (side effects) – *no significant increase in angina, adverse clinical events, or other adverse effects have been reported due to cardiac rehabilitation*

c. training and experience required to perform the procedure safely – *nothing reported*

d. where the procedure should be performed (e.g., volume or procedures, skilled support team, location/need for follow-up visits, etc.) – *no studies have proven the safety or benefit of supervised versus unsupervised exercise in a CR program*

e. co-morbidities that increase the risk associated with the procedure – *active ischemia, uncontrolled heart failure, sustained or symptomatic arrhythmias, high-grade heart block, hemodynamic or respiratory instability may increase the risks of cardiac rehabilitation*

f. potential for inappropriate use of the technology – *none reported*

Updated Conclusion

The ICSI Technology Assessment Committee finds:

1. Outpatient cardiac rehabilitation (CR) programs (Phase II, III, and IV) are safe for selected patients in stable condition with a diagnosis of atherosclerosis, acute myocardial infarction, percutaneous transluminal coronary angioplasty, coronary bypass surgery, or cardiac valve surgery including programs with an aerobic and/or strength training component.
2. CR programs with various components have been shown to be efficacious (Conclusion Grade I based on Class A & M evidence, see Appendix), however no gold standard CR program has been established. No studies have analyzed exercise-only versus comprehensive CR programs and it is unclear whether exercise only or comprehensive CR is more beneficial. Comprehensive CR programs including multifactorial coronary artery risk factor assessment and reduction have shown reductions in the number of cardiac events and hospitalizations as well as improvements in individual risk factors such as lipids, weight, and exercise capacity up to four years after beginning CR. One meta-analysis of 32 randomised controlled trials has shown a significant reduction in cardiac mortality for both exercise-only and comprehensive CR programs.
3. No studies have demonstrated the benefit of supervised versus unsupervised exercise in a CR program.
4. The Committee did not evaluate Phase I CR, as it is seen as part of the hospital care for these patients.

References

Evidence is classed and graded as described below.

I. CLASSES OF RESEARCH REPORTS

Primary Reports of New Data Collection:

Class A:	Randomized, controlled trial
Class B:	Cohort study
Class C:	Non-randomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study
Class D:	Cross-sectional study Case series Case report

Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:	Meta-analysis Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
Class R:	Narrative review Consensus statement Consensus report
Class X:	Medical opinion

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in Section I, above, and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade IV: The support for the conclusion consists solely of the statements of informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

The symbols **+**, **–**, **ø**, and **N/A** found on the conclusion grading worksheets are used to designate the quality of the primary research reports:
+ indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;
– indicates that these issues have not been adequately addressed;
ø indicates that the report is neither exceptionally strong or exceptionally weak;
N/A indicates that the report is not a primary reference and therefore the quality has not been assessed.

Ades PA, Savage PD, Poehlman ET, Brochu M, Fragnoli-Munn K, Carhart RL Jr. Lipid lowering in the cardiac rehabilitation setting. *J Cardiopulm Rehabil*. 1999;19:255-60. (Class C)

Belardinelli R, Georgiou D, Cianci G, Purcaro A. Randomized, controlled trial of long-term moderate exercise training in chronic heart failure: effects on functional capacity, quality of life, and clinical outcome. *Circulation*. 1999;99:1173-82. (Class A)

Beniamini Y, Rubenstein JJ, Zaichkowsky LD, Crim MC. Effects of high-intensity strength training on quality-of life parameters in cardiac rehabilitation patients. *Am J Cardiol*. 1997;80:841-6. (Class A)

Brannon FJ, Geyer MJ, Foley MW: Cardiopulmonary rehabilitation: basic theory and application, 2nd ed. F.A. Davis Company, 1993; p. 2. (Class R)

Daub WD, Knapik GP, Black WR. Strength training early after myocardial infarction. *J Cardiopulm Rehabil*. 1996;16:100-8. (Class A)

Engblom E, Korpilahti K, Hamalainen H, Ronnemaa T, Puukka P. Quality of life and return to work 5 years after coronary artery bypass surgery. Long-term results of cardiac rehabilitation. *J Cardiopulm Rehabil*. 1997;17:29-36. (Class A)

Engblom E, Korpilahti K, Hamalainen H, Puukka P, Ronnemaa T. Effects of five years of cardiac rehabilitation after coronary artery bypass grafting on coronary risk factors. *Am J Cardiol*. 1996;78:1428-31. (Class A)

Franklin BA, Bonzheim K, Gordon S, Timmis GC. Safety of medically supervised outpatient cardiac rehabilitation exercise therapy: a 16-year follow-up. *Chest* 1998;114:902-906. (Class D)

Haskell WL, Alderman EL, Fair JM, et al. Effects of intensive multiple risk factor reduction on coronary atherosclerosis and clinical cardiac events in men and women with coronary artery disease: the Stanford Coronary Risk Intervention Project (SCRIP). *Circulation* 1994;89:975-990. (Class A)

Institute for Clinical Systems Improvement (ICSI). Cardiac Rehabilitation. Technology Assessment Report #12, 1994. (Class R)

Jolliffe JA, Rees K, Taylor RS, Thompson D, Aldridge N, Ebrahim S. Exercise-based rehabilitation for coronary heart disease (Cochrane Review). In: *The Cochrane Library* , Issue 1, 2002. Oxford: Update Software. (last substantive review 11/22/2000) Accessed at: www.cochranelibrary.com (Class M)

Levine BD, Friedman DB, Williams AN: Starting a cardiac rehabilitation program: theory and practice. Cardio 1992; 26-37. (Class R)

Ornish D, Scherwitz LW, Billings JH, et al. Intensive lifestyle changes for reversal of coronary heart disease. *JAMA* 1998;280:2001-2007. (Class A)

Pierson LM, Herbert WG, Norton HJ, Kiebzak GM, Griffith P, Fedor JM, Ramp WK,Cook JW. Effects of combined aerobic and resistance training versus aerobic training alone in cardiac rehabilitation. *J Cardiopulm Rehabil*. 2001;21:101-10. (Class A)

Squires RW, Gau Gt, Miller TD, Allison TG, Lavie CJ. Cardiovascular Rehabilitation: status, 1990. Mayo Clinic Proc 1990; 65: 731-755. (Class R)

Stewart KJ, McFarland LD, Weinhofer JJ, Cottrell E, Brown CS, Shapiro EP. Safety and efficacy of weight training soon after acute myocardial infarction. *J Cardiopulm Rehabil*. 1998;18:37-44. (Class A)

Taylor CB, Miller NH, Smith PM, DeBusk RF. The effect of a home-based, case-managed, multifactorial risk-reduction program on reducing psychological distress in patients with cardiovascular disease. *J Cardiopulm Rehabil*. 1997;17:157-62. (Class A)

Verges BL, Patois-Verges B, Cohen M, Casillas JM. Comprehensive cardiac rehabilitation improves the control of dyslipidemia in secondary prevention. *J Cardiopulm Rehabil*. 1998;18:408-15. (Class C)

Wosornu D, Bedford D, Ballantyne D. A comparison of the effects of strength and aerobic exercise training on exercise capacity and lipids after coronary artery bypass surgery. *Eur Heart J*. 1996;17:854-63. (Class A)

Appendix

See next pages

Conclusion Grading Worksheet

<u>Work Group's Conclusion</u>: Cardiac rehabilitation (CR) programs with various components have been shown to be efficacious.

<u>Conclusion Grade</u>: I

Author/Year	Design Type	Class	Quality +,–,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Haskell et al., 1994 Stanford Coronary Risk Intervention Project (SCRIP)	RCT	A	ø	-300 patients with angiographically defined atherosclerosis -multifactorial risk reduction protocol (155 treatment patients) included a low fat and cholesterol diet, exercise, smoking cessation, and lipoprotein medications -usual care (155 control patients) protocol was initiated by patients' primary physician -patients were followed for 4 years	-there were fewer nonfatal MIs (4 vs 10), CABG surgeries (6 vs 14), and primary PTCAs (13 vs 17) in the treatment group -treatment group had significantly less narrowing (47% less change in minimal diameter) of the diseased coronary artery segments than the control group (-0.024 mm/y vs -0.045 mm/y, p<0.02) -treatment group had significantly fewer hospitalizations for cardiac events (25 vs 44, p=0.05) -treatment group had significant improvements in LDL cholesterol (p=0.0001), apolipoprotein (p=0.0008), HDL cholesterol (p=0.001), plasma triglycerides (p=0.002), body weight (p=0.0001), and exercise capacity (p=0.001) as compared to controls	-Intensive multifactorial risk reduction conducted over 4 years favorably altered the rate of luminal narrowing in coronary arteries of men and women with coronary artery disease and decreased hospitalizations for clinical cardiac events.
Ornish et al., 1998 Lifestyle Heart Trial	RCT	A	ø	-35 patients initially randomized to treatment and control groups -treatment group (20 patients) was prescribed intensive lifestyle changes including: a vegetarian diet with 10% of calories from fat, moderate aerobic exercise, stress management, smoking cessation, and group psychosocial support -control group (15 patients) was asked to follow the advice of their personal physician regarding lifestyle changes	-treatment group had fewer cardiac events (25 vs 45, p<0.001), MIs (2 vs 4, p=0.26), PTCA (8 vs 14, p<0.05), CABG (2 vs 5, p=0.14), and cardiac hospitalizations (23 vs 44, p<0.001) than controls at 5-year follow-up -in treatment group, the average percent diameter stenosis had decreased 1.75 (4.5% relative improvement) and 3.1 (7.9% relative improvement) absolute percentage points after 1 and 5 years, respectively -controls had average percent diameter stenosis increases of 2.3 (5.4% relative worsening) and 11.8 (27.7% relative worsening) absolute percentage points after 1 and 5 years, respectively (p=0.001 between groups) -HDL, LDL, total cholesterol, triglycerides, and apolipoprotein B were not significantly different in the two groups at 5-year follow-up	-More regression of coronary atherosclerosis occurred after 5 years than after 1 year in the experimental group. In contrast, in the control group, coronary atherosclerosis continued to progress and more than twice as many cardiac events occurred.

Conclusion Grading Worksheet (cont)

Author/Year	Design Type	Class	Quality +,–,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Belardinelli et al., 1999	RCT	A	**ø**	-99 patients with chronic heart failure received exercise (50 patients) or no exercise (49 patients) -exercise group was to receive exercise training at 60% of peak oxygen consumption (VO2), initially 3 times per week for 8 weeks, then twice a week for one year	-exercise training had significantly fewer deaths (9 vs 20, p=0.01) and hospital readmissions for heart failure (5 vs 14, p=0.02) as compared to the no exercise group -peak VO2 and thallium activity scores improved in the exercise group at 2 months (18% and 24%, respectively; p<0.001 for both)	-Long-term moderate exercise training determines a sustained improvement in functional capacity and quality of life in patients with chronic heart failure. This benefit seems to translate into a favorable outcome.
Jolliffe et al., 2002 Cochrane review	Systematic review /meta analysis	M	**N/A**	-patients receiving exercise-only or comprehensive CR -patients who have previously had myocardial infarction, CABG, PTCA, or angina pectoris or CAD defined by angiography were included -total of 32 trials were included	-total mortality was significantly reduced by 27% in exercise-only group (OR 0.73, 95% CI 0.54-0.98) and reduced (p=NS) by 13% in the comprehensive group (OR 0.87, 95% CI 0.71-1.05) -total cardiac mortality was significantly reduced by 31% in exercise-only (OR 0.69, 95% CI 0.51-0.94) and 26% in comprehensive (OR 0.74, 95% CI 0.57-0.96) groups -comprehensive CR group had significant net reductions in total cholesterol (-0.57 mmol/l, 95 CI –0.83 to –0.31) and LDL (-0.51 mmol/l, 95 CI –0.82 to –0.19)	-Exercise-based CR is effective in reducing cardiac deaths. It is not clear from this review whether exercise only or a comprehensive CR intervention is more beneficial.

Institute for Clinical Systems Integration

Technology Assessment

Cardiac Rehabilitation

Prepared under the direction of the

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TA# 12

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Committee Summary

The ICSI Technology Assessment Committee finds outpatient cardiac rehabilitation (Phase II, III, and IV) to be safe and effective for selected cardiac patients in stable condition; however, most patients free from serious complications may achieve the same results without a supervised program. The Committee did not evaluate Phase I cardiac rehabilitation, as it is seen as part of the hospital care for these patients.

Scientific Criteria

- Phase II: While outpatient rehabilitation programs may help patients to return to an active lifestyle after a heart attack or cardiac surgery, many well-motivated patients free from serious complications may also be able to achieve these results without a hospital-based program.
- Phase III and IV: Secondary risk factor reduction programs aimed at patients becoming more independent and maintaining a health and exercise regimen on an ongoing basis may be safely carried out without medical supervision.

Treatment Alternatives

Patients without serious complications that warrant observation may safely embark on an exercise program at home or at a community center.

Government Approval

Medicare provides coverage of outpatient cardiac rehabilitation exercise programs for selected cardiac patients.

Description of Treatment/Procedure

Cardiovascular disease (CHD) remains the single most prevalent cause of death in the United States today, although death rates from the disease have been declining. Levy and others have observed that since the late 1960s, there has been an unprecedented decline in mortality from cardiovascular disease in the United States, especially from CHD and stroke.[1,2] This decline has been observed in all age groups, especially in the elderly.[3] The fall in CHD mortality has been associated with the development of specialized acute coronary care, potent cardiovascular drugs for the treatment of heart failure and ischemia, surgical techniques for coronary revascularization, accurate noninvasive 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 development of increasing risk factor awareness and modification.[4]

Over the past two decades, risk factor modification programs for cardiac patients, commonly referred to as cardiac rehabilitation, have evolved into a comprehensive management strategy. Originally focusing on exercise training, these programs have evolved to emphasize overall risk factor and behavioral modification.

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."[5] Major objectives of cardiac rehabilitation include not only an improved functional capacity and quality of life but also a reduction in mortality and morbidity.

Comprehensive cardiac rehabilitation specifically entails the modification of coronary risk factors, particularly the control of abnormal blood lipids levels (blood cholesterol) and excess weight. Other medical problems, such as musculoskeletal diseases, arthritis, peripheral vascular disease, diabetes mellitus, reaction to medications, emotional problems related to the cardiac event, and problems with aging, are also addressed within the comprehensive cardiac rehabilitation program. These programs are usually divided into three or four phases, which are described below. (See Table 1.)

Table 1. Phases of Cardiac Rehabilitation

Phase	Type of program	Duration
I	Inpatient	Days
II	Outpatient, immediately after hospitalization	2-12 weeks
III	Late recovery period	Minimum of 6 months beyond phase II
IV	Maintenance	Indefinite

Phase I

The inpatient exercise program (Phase I) starts as soon as the patient is medically stable following a cardiac event and an initial assessment has been completed. Goals include:

1. Preventing the deleterious effects of bed rest;
2. Assessing the hemodynamic response to exercise;
3. Managing the psychosocial issues of cardiac disease; and
4. Educating the patient and the family.[6]

In general, phase I consists of four components: 1) early assumption of the upright posture; 2) a progressive exercise and self-care program based on individual tolerance (gauged by heart rate, blood pressure response and presence of symptoms); 3) education; and 4) risk factor identification and initial attempts at modification.[7]

According to Levine and colleagues,[8] patients admitted to the hospital with acute MI or unstable angina or who have undergone revascularization procedures such as coronary artery bypass graft (CABG) surgery or angioplasty are potentially eligible to begin phase I cardiac rehabilitation. Those with uncomplicated disease may be enrolled as early as 12 hours after admission and participate in rapid progression of activity; this minimizes deconditioning and allows for early discharge. Patients admitted with other cardiovascular diagnoses (e.g., heart failure, valvular heart disease or peripheral vascular disease) may also be considered for cardiac rehabilitation on a case-by-case basis.

Levine and colleagues exclude patients from Phase I if they have one or more of the following conditions:

1. Active ischemia;
2. uncontrolled heart failure;
3. sustained or symptomatic arrhythmias, or high-grade heart block (greater than type I, second-degree atrioventricular block);
4. hemodynamic or respiratory instability (a supine systolic blood pressure <90 mmHg or >180 mmHg, a resting supine heart rate <40 beats/min or >100 beats/min, hypoxemia (Po2 < 60 mmHG), or a requirement for a ventilator or parenteral inotropic/pressor support); or
5. severe, uncontrolled coexistent medical problems (e.g., diabetic ketoacidosis, sepsis, disseminated intravascular coagulation).

Phase II

Outpatient exercise training and risk-factor modification (Phase II) is usually initiated within a few weeks after hospital discharge, and may provide continuous ECG monitoring, emergency equipment, medically supervised exercise, and risk-factor modification and education. These programs are usually recommended for patients with medical characteristics that place them at increased risk for cardiac events during exercise.

Goals of Phase II cardiac rehabilitation are outlined below:[9]

1. Supervised exercise training to maximize functional capacity, teach safe exercise practices, and identify patients at risk for complications;
2. Risk factor modification, including smoking cessation, stress reduction, weight loss, and improvement in cholesterol profile;
3. Education about medications, signs and symptoms of heart disease and its progression, sexual relations, dietary modifications and activity guidelines.

During phase II, patient education continues. Earlier, during the acute hospitalization, patients are just beginning to cope with the ramifications of their disease and often are not ready to learn.[10] In addition to education, a major emphasis in phase II rehabilitation is on exercise conditioning. Both aerobic and muscle strengthening exercise programs are utilized to increase cardiorespiratory fitness and muscle strength. At the beginning of the program the exercise prescription is established, based principally on the maximal exercise test. The target or training heart rate is usually set at 75-85% of maximal, as long as this workload remains below the ischemic threshold. Progressively over the course of the training program, the duration and intensity are increased as functional capacity improves. Patients are usually monitored by telemetry for heart rate and rhythm throughout phase II exercise sessions.

Patients may spend 12 weeks in the program, but in some patients, as little as two weeks of monitored exercise is sufficient, as long as they can demonstrate the ability to monitor themselves and perform exercise safely. Higher risk patients (poor left ventricular function, poor exercise capacity, myocardial ischemia at low work intensities) may require a longer duration of monitored exercise training.

Phase III

Patients who no longer need medical supervision while exercising may embark on a long-term program of exercise and health maintenance. Such programs are usually undertaken at home or in a fitness center.

Over the last decade, a number of studies have attempted to identify which patients are at sufficiently low risk to safely exercise at home. On the basis of clinical variables (absence of recurrent chest pain, heart failure, or life-threatening ventricular arrhythmias) and a symptom-limited exercise test at three to six weeks after infarction, approximately 50% of post-MI patients have a low (<2%) risk of recurrent cardiac events in the following one to two years.[11] These patients, or those who have more chronic cardiovascular disease without a recent acute cardiac illness, may be considered for unmonitored exercise training. In one study, researchers were able to demonstrate that, in carefully selected, relatively well-educated patients, home-based rehabilitative exercise could be performed safely and with the anticipated training effect.

Phase IV

Phase IV of rehabilitation is the maintenance program (consisting of efforts to modify risk factors and a routine program of physical activity) that patients should continue indefinitely.[12]

For some programs, phase IV rehabilitation is combined with phase III. All cardiac rehabilitation programs, however, recommend some form of indefinite maintenance for their patients.

Efficacy of Treatment/Procedure

Impairment in exercise capacity after myocardial infarction is due both to infarct-related damage to the myocardium as well as to the deconditioning effects of bedrest and physical inactivity. According to Greenland and Chu,[13] gradual improvement in physical exercise capacity after myocardial infarction typically occurs even in the absence of a formal exercise program.

A number of randomized and controlled studies have addressed the question of whether a supervised exercise training program improves physical work capacity more than would be expected spontaneously. (See Table 2, by Greenland and Chu.)[14] It is difficult to compare any one study to the others due to differences in the exercise treatment programs, the role of nonexercise treatments such as counseling and risk factor reduction, time of enrollment after infarction, and exercise testing protocols used to assess changes in work capacity. In every study reported, functional capacity improved from prerandomization to post therapy in all patient groups, whether randomly assigned to special care or usual care. In all studies, the exercise group had a greater functional capacity after the intervention than had the control group.

In the study by DeBusk and associates,[15] patients after an uncomplicated MI were randomly assigned to a gymnasium-trained group (n = 28) and were compared to a no-trained group (n = 30). A smaller number of patients (n = 12) was randomly assigned to a home-trained status; however, these patients has less ischemia on exercise testing at 3 weeks after myocardial infarction and were therefore not entirely analogous to patients in the other two groups. Peak workload was similar at 3 weeks (before the exercise program). At 7 weeks, all three groups improved in functional capacity, and differences were not statistically significant. By 11 weeks after infarction, there were statistically significant differences between groups, but differences were small and only marginally significant clinically. All three groups in this study of patients without complications showed physical work capacities at 11 weeks after infarction similar to those of healthy, sedentary, middle-aged men (approximately 9 or more METS). Moreover, a work capacity of approximately 9 METS should allow the majority of patients with cardiac disease to return to a variety of jobs by 11 weeks after myocardial infarction.

A recent randomized, controlled study by Schuler et al[16] compared 56 patients who participated in an intensive exercise and low-fat diet program to 57 patients who received "usual care." Angiograms obtained after 12 months did not show any overall change in progression of disease among patients in the program. In patients on usual care, however, there was considerable progression of disease.

Table 2. Effects of Supervised Exercise Programs Shortly after Myocardial Infarction on Physical Work Capacity in Controlled Studies

Study (Reference)	Patients	Capacity before Program (Weeks after Myocardial Infarction	P Value	Work Capacity after Program	P Value	Program Length
	n					
DeBusk et al.[17]						
Exercise	28	6.8 ± 1.7 METS*	Not significant	10.4 ± 2.2 METS*	<0.05	8 wk
Control	30	6.7 ± 1.4 METS*		8.9 ± 2.0 METS*		
Miller et al.[18]						
Exercise	61	6.5 METS*	Not significant	8.5 METS*	<0.001	8 wk
Control	34	6.0 METS*		7.0 METS*		
Carson et al.[19]						
Exercise	151	12.5 ± 0.5 min	Not stated~	17.5 min	"Significant"	3 mo
Control	152	11.5 ± 0.5 min		13.0 min		
Hung et al.[20]						
Exercise	23	607 ± 180 kpm/min+	Not significantψ	750 ± 164 kpm/min	<0.01	8 wk
Control	30	596 ± 162 kpm/min		626 ± 139 kpm/min		
Wilhelmsen et al.[21] β						
Exercise	114	"20% increase in cycle time from 3 mo-12 mo"	...	...	...	9 mo
Control	88	"No change in cycle time, 3-12 mo"	...	...	...	...
Paterson et al.[22]						
High-intensity exercise	37	15% increase in VO_2 max in high-intensity group after 1 yr.	...	...	...	1 yr
Low-intensity exercise	42	No change in VO_2 max after 1 yr in low-intensity group	...	...	...	...
Marra et al.[23]						
Exercise	84	673 kg min^{-1}	Not significant	883 kg min^{-1}	<0.001	8-9 wk
Control	83	635 kg min^{-1}		673 kg min^{-1}		
Roman et al.[24]						
Exercise	93	11 L/min	Not significant	15 L/min	"Significant"	4 mo
Control	100	11 L/min		12 L/min		

* A MET is a multiple of the resting energy expenditure; 1 = 3.5 mL O_2/kg body weight x min.

~ Cycling.

+ kpm/min kilopond meters/minute (kilogram-weight · meter/minute).

ψ Bicycling.

β Men only.

Table 3 (adapted from Greenland and Chu)[25] lists the approximate energy requirements of some selected self-care, occupational, and physical conditioning activities. A workload of 7 to 9 METS is rated as heavy and translates into activities such as sawing wood, carrying moderately heavy objects (60 to 90 lb), digging ditches, climbing mountains, or jogging. Studies such as those by DeBusk and associates[26] indicated that the average uncomplicated patient after myocardial infarction may achieve a maximum capacity of 9 METS even without participation in a formal exercise program. Assuming that patients with cardiac disease should not plan to work consistently at a workload exceeding 80% of their maximal capacity,[27] a patient whose maximal load is 9 METS should safely be able to perform workloads requiring 7 METS or less in occupational or recreational activities. Many occupational and recreational tasks will therefore be within the limits of the uncomplicated patient by 11 weeks following infarction, with or without a formal training program.

Table3. Approximate Energy Requirements of Selected Activities.[28]

Category	Self-Care or Home	Occupational	Physical Conditioning
Very light			
< 3 METS*	Washing, shaving, dressing	Sitting (clerical)	Walking (2 mph)
<10 mL/kg x min	Desk work, writing	Standing (clerk)	Stationary bicycle
< 4 kcal	Washing dishes	Driving truck	(very low resistance)
	Driving auto	Operating crane	Very light calisthenics
Light			
3-5 METS	Cleaning windows	Stocking shelves	Walking (3-4 mph)
11-18 mL/kg x min	Raking leaves	(light objects)	Level bicycling (6-8 mph)
4-6 kcal	Painting	Golf (walking)	Light calisthenics
Moderate			
5-7 METS	Easy digging in garden	Carpentry	Walking (4.5 - 5 mph)
18-25 mL/kg x min	Level hand lawn mowing	Shoveling dirt	Bicycling (9-10 mph)
6-8 kcal	Climbing stairs (slowly)	Using pneumatic tools	Swimming (breast stroke)
	Carrying objects (30-60 lb)		
Heavy			
7-9 METS	Sawing wood	Tending furnace	Jog (5 mph)
25-32 mL/kg x min	Heavy shoveling	Mountain climbing	Swim (crawl stroke)
8-10 kcal	Climbing stairs (moderately)	Pick and shovel	Rowing machine
	Carrying objects (60-90 lb)		Heavy calisthenics
Very heavy			
> 9 METS	Carrying loads upstairs	Lumberjack	Running (> 6 mph)
>32 mL/kg x min	Carrying objects (> 90 lb)	Heavy laborer	Bicycle (> 13 mph)
>10 kcal	Shoveling heavy snow		Rope jumping

* A MET is a multiple of the resting energy expenditure; 1 MET = approximately 3.5 mL/kg x min.

According to Greenland et al,[29] the patient who would benefit most from an exercise training program in terms of functional benefit would be the patient who is initially most limited.[30] Ironically, these patients are often excluded from exercise programs or choose not to participate. One study reported that the greatest improvements in functional capacity in association with a cardiac exercise program were seen in patients who initially showed the lowest levels of physical fitness. In this study, 146 patients with coronary artery disease were randomly assigned to a year-long supervised exercise program or to a control (usual care) group. Data on the 59 people completing the year of exercise formed the basis for this report. Various measures confirmed that exercise capacity improved over the one year, and the average estimated maximum oxygen consumption increased by approximately 15%. Although the correlation was small, the best predictor of improvement in exercise performance was a low initial state of physical fitness.

A recent randomized, controlled study by Hambrecht et al[31] found that patients with stable coronary artery disease willing to devote their leisure time partly to intensive physical exercise for one year are regularly rewarded with an upward shift of their anaerobic threshold during submaximal exercise. To achieve this goal, a minimum of 1,400 kcal/week must be expended. Lower levels of exercise failed to change the position of the anaerobic threshold. Regression of coronary morphology was found to occur only in motivated patients who were willing to spend an average of 2,200 kcal/week in leisure time physical activity, amounting to 5 or 6 hours per week of regular exercise. However, progression of coronary artery disease was observed in some patients despite high activity levels and excellent compliance.

Changes in psychosocial function

According to Greenland et al,[32] patients with cardiac disease commonly suffer significant psychological, vocational, and social disabilities. Fifteen percent of patients do not return to work after myocardial infarction, many of whom seem physically capable of resuming employment.[33] The economic costs of myocardial infarction are estimated to be as high as 30 billion dollars yearly, primarily due to vocational disability.

A randomized, controlled study by Gulanick[34] studied the effects of rehabilitation plus exercise testing on perceived self-efficacy for and performance of daily activities as compared with and without exercise training. The study showed that in a sample of 40 uncomplicated, motivated patients who had participated in a phase 1 inpatient rehabilitation program, substantial improvements in self-efficacy and performance of daily activities were made early in recovery, before the onset of phase 2, formalized outpatient therapy. After 9 weeks, all groups had made improvements; there were no significant differences in self-efficacy scores or performance of physical activity among the three groups.

Effect on morbidity and mortality

The difficulty in determining whether cardiac rehabilitation can increase survival after myocardial infarction, has been due, to a large extent, to the fact that most studies have focused intervention efforts predominantly on low-risk patients. Because of the relative infrequency of events in either the study or control groups, a very large sample size has been necessary to achieve statistical significance. Table 4, by Greenland and Chu,[35] summarizes the principal characteristics of the controlled and randomized trials that have reported morbidity and mortality results. Most of these controlled studies showed a trend in favor of the special treatment group, but sample sizes have been small and statistically significant differences have been unusual.

Table 4. Main Features of Controlled, Randomized Trials Assessing Morbidity or Mortality After Myocardial Infarction in Cardiac Rehabilitation Programs.

Study	Patients Randomly Assigned	Essential Trial Features	Total Mortality Rates: Rehab Patients	Total Mortality Rates: Control Patients	*P* Value	Cardiac Morbidity (Nonfatal Myocardial Infarction): Rehab Patients	Cardiac Morbidity (Nonfatal Myocardial Infarction): Control Patients	*P* Value
	n		*n(%)*			*n(%)*		
Carson et al.	303	Intervention group exercised 2 times per week for 12 wk beginning approx. 6 wk after myocardial infarction; dropout rate in exercise group was 31%; mean follow-up = 2.1 yr.	12(8)	21(14)	NS*	11(7.3)	10(6.6)	NS
Rechnitzer et al.	733	Majority of patients enrolled 2-12 mo after myocardial infarction (median 6.2 mo); randomly assigned to a high-compared with low-intensity exercise group; high dropout rates same (45%) for both groups; mean follow-up =3.3 yr.	15(4.0)	13(3.7)	NS+	39(10.3)	33(9.3)	NS
Shaw et al.	651	Patients randomly assigned up to 26 mo after myocardial infarction; rehab and usual care patients were equivalent.	15(4.6)	24(7.3)	NS	15(4.6)	11(3.3)	NS
Wilhelmsen et al.	315	Training began 3 mo after myocardial infarction; exercise rehab only was compared with usual care; 4-yr follow-up.	28(17.7)	35(22.3)	NS	25(15.8)	28(17.8)	NS
Kallio et al.	375	Multifactorial intervention (including exercise) beginning early after myocardial infarction was compared with usual care; 3-yr follow-up.	41(21.8)	56(29.9)	<0.10	34(18.1)	21(11.2)	<0.10
Marra et al.	167	Exercise rehab compared with usual care; low-risk patients, randomly assigned at 45 d after myocardial infarction; average follow-up = 55 mo.	6(7.4)	5(6.3)	NS	5(6.1)	9(11.2)	NS
Roman et al.	193	Randomized during hospitalization to receive cardiac rehab or usual care; exercise rehab 3x per wk for 30 min beginning 2 mo after myocardial infarction; average follow-up = 55 mo.	16(3.6 per yr)	27(5.8 per yr)	NS	16(3.6 per yr)	23(4.9 per yr)	NS
Vermeulen et al.	98	Rehab program 6-8 wk duration, beginning 4-6 wk after myocardial infarction; intervention not clearly described; first attempt at long-term follow-up made at 5 yrs after myocardial infarction.	2(4.3)	5(9.8)	NS	2(4.3)	4(7.8)	NS
Kentala et al.	298	Home rehab compared with usual care; not supervised rehab.	…	…	…	…	…	…
Palatsi et al.	380	Not strictly randomized and groups not comparable medically at baseline.	…	…	…	…	…	…

*NS = not significant
+ Cardiac mortality only.

Risk factor modification during cardiac rehabilitation programs

In randomized trials of cardiac rehabilitation after infarction, several investigators have studied whether cardiac risk factors are more favorably affected by special interventions. Studies of cardiac rehabilitation interventions have not been uniform, and frequently, reports do not adequately describe intervention efforts other than the exercise program itself. In the 1992 study by Schuler et al,[36] improvement of physical work capacity, myocardial oxygen consumption, and reduction of stress-induced myocardial ischemia was observed in nearly all patients participating in regular physical exercise and low-fat diet. In the control group, metabolic and hemodynamic variables remained essentially unchanged.

Table 5, by Greenland and Chu,[37] summarizes some of the randomized trials and the effects on risk factors that have been noted. On the basis of the data presented in Table 5, an exercise program alone seems unlikely to produce better risk factor outcomes when applied to unselected patients following myocardial infarction.

Table 5. Risk Factor Modification in Randomized Trials of Cardiac Rehabilitation

Study (Reference)	Trial Features	Risk Factor Changes Reported
Kallio et al.	Multidisciplinary intervention beginning 2 wk after myocardial infarction	Intervention group had lower body weight, serum cholesterol, triglycerides, systolic and diastolic blood pressures; smoking decreased 50% in both groups
Vermeulen et al.	Intervention unclear from report	Lower cholesterol in intervention group; no difference in other risk factors
Carson et al.	Intervention: 12 wk exercise twice a week	Smoking decreased in both groups; no changes in body weight or cholesterol
Oberman et al.[38]	National Exercise and Heart and Disease Project; primarily an exercise program without other specific risk factor reduction components	No change in smoking; blood pressure, small decrease in diastolic blood pressure in exercise group over control; triglycerides, slightly lower in exercise group; cholesterol, slightly increased in both groups
Wilhelmsen et al. both	Training began 3 mo after myocardial infarction	Cholesterol and triglycerides decreased in groups (difference = not significant); systolic blood pressure slightly lower in exercise group compared to control
Marra et al.	Exercise four times a week for 7-9 wk	No difference between groups in smoking and cholesterol; triglycerides significantly lower in exercise group

Safety

There is little doubt that vigorous exercise itself is an important risk factor for sudden death, particularly in unfit individuals. However, this risk is outweighed by the overall benefits of habitual exercise.[39] The risk of exercise-induced cardiac arrest is also directly related to the intensity of the exercise, leading to the conclusion that lower intensity exercise is safer than vigorous exercise, particularly in the unsupervised patient.

A study by Squires and colleagues[40] of 20 consecutive patients who had had a myocardial infarction and had resting left ventricular ejection fractions of less than 25% (mean, 21%) reviewed the outcome of participating in an outpatient cardiac rehabilitation program. No serious complications of exercise training occurred during the 8-week supervised program.

Surveys of large numbers of programs and reviews from individual programs have studied the safety of cardiac exercise programs.[41] A report by Van Camp and Peterson[42] described the cardiac risks in 51,303 patients who exercised between 1980 and 1984 in 167 randomly selected cardiac rehabilitation programs that were surveyed by questionnaire. The authors concluded that current cardiac rehabilitation practices permited the delivery of prescribed, supervised exercise to patients who have cardiovascular disease with a low risk for cardiovascular complications.

According to Schuler et al,[43] intensive physical exercise is associated with an increased risk of cardiac arrest, particularly in young, well-motivated patients who frequently exceed their training recommendations during supervised exercise and on their own. The risk of life-threatening arrhythmias associated with exercise therapy needs to be carefully weighed against the benefit of less progression of coronary disease, improved physical work capacity, and reduced myocardial ischemia.

Indications

Phase I

Phase I inpatient programs are indicated for patients in stable condition with a cardiac diagnosis including the following: acute myocardial infarction, coronary artery bypass surgery, cardiac transplantation, or cardiac valve surgery.

Phase II

Comprehensive Phase II outpatient programs which contain all phases of stress reduction, blood pressure control, lipid control, lifestyle management, and supervised exercise with continuous EEG monitoring are indicated for those selected patients who are at increased risk for adverse cardiac events during exercise, and should be discontinued after patients reach pre-set goals.

Patients with the following characteristics should be trained in a medically supervised setting:[44]

- Low maximal functional capacity
- Severely depressed left ventricular function
- Complex ventricular arrhythmias
- Exercise-induced hypotension
- Exertional angina
- Inability to self-monitor exercise heart rate

Phase II cardiac rehabilitation programs which do not offer comprehensive risk-factor modification strategies have not been shown to be more effective than usual care, and are not indicated. Most well-motivated patients who are not at increased risk for adverse cardiac events during exercise may safely embark on a home program without medical supervision.

Phase III, IV

Phase III and IV programs are secondary risk factor reduction programs aimed at patients becoming more independent and maintaining a health and exercise regimen on an ongoing basis. Lifelong modification of the risk factors of hyperlipidemia, tobacco use, obesity, hypertension, and sedentary lifestyle is the goal of such programs. As such, they are highly desirable and should be encouraged. However, the exercise training component may be safely carried out without medical supervision.

Contraindications

The following are absolute contraindications to exercise training:[45]

- Unstable angina pectoris
- Dangerous arrhythmias
- Overt cardiac failure
- Severe obstruction of the left ventricular outflow tract
- Dissecting aneurysm
- Myocarditis or pericarditis (acute)
- Serious systemic disease
- Thrombophlebitis
- Recent systemic or pulmonary embolus
- Severe hypertension
- Overt psychoneurotic disorders
- Uncontrolled diabetes mellitus
- Severe orthopedic limitations

Risks and Limitations

According to Squires et al, exercise training in patients with coronary artery disease is not without risk.[46] Because cardiac patients may have a limited coronary reserve, the increase in myocardial oxygen demand during exercise may result in ischemia and may potentially precipitate a lethal arrhythmia or myocardial infarction. Reported complication rates for cardiac exercise sessions are low,[47] and typically are caused when patients choose to exceed their prescribed upper limit heart rate during exercise.[48]

Alternative Forms of Treatment

Patients without serious complications that warrant observation may safely embark on an exercise program at home or at a community center. Aggressive lipid lowering with medications[49] or lifestyle changes[50] have been demonstrated to influence the progression or even induce regression of coronary disease in some patients.

Costs

One non-randomized Swedish study compared patients who participated in an outpatient rehabilitation program to patients who were receiving standard care.[51] It is unclear whether the patients in the control group participated in any form of exercise whatsoever. The study found that, over a 5-year period, inpatient cardiac rehabilitation did not place any additional economic demands on the health-care budget. This was mainly due to the observed lower cost of readmission in the intervention group, which may be explained by a lower rate of recurrence of non-fatal MI, and a lower rate of total cardiac events.

Outpatient (Phase II) cardiac rehabilitation is generally limited to 12 to 18 visits, at $90 to $125 per visit. Total Phase II cardiac rehabilitation costs for one patient, therefore, can range from $1,080 to $2,250.

Experience/Epidemiology

There were approximately 530 patients (from both the staff and groups divisions of HealthPartners) with acute myocardial infarctions who were hospitalized in 1993.

Group Health, Inc.

Phase I programs of medically supervised exercise and patient education programs have been covered as a part of the patient's inpatient hospital charges.

Phase II programs are covered only where true medical indications are present or where the mental state of the patient (i.e., severe anxiety or depression) may limit the patient's recovery.

Phase III programs are not a covered benefit.

MedCenters

Phase I and II programs are generally covered for patients with a documented medical need, subject to limits and indications. The rehabilitation program must include both a supervised exercise program and a patient education component.

Coverage is generally discontinued when the patient has achieved a stable level of exercise tolerance because, at this point, the program becomes maintenance care.

Summary

The ICSI Technology Assessment Committee finds outpatient cardiac rehabilitation (Phase II, III, and IV) to be safe and effective for selected cardiac patients in stable condition; however, most patients free from serious complications may achieve the same results without a supervised program. The Committee did not evaluate Phase I cardiac rehabilitation, as it is seen as part of the hospital care for these patients.

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