Impact of program duration and contact frequency on efficacy and cost of cardiac rehabilitation: Results of a randomized trial

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Background Secondary prevention through cardiac rehabilitation (CR) has been recommended for most patients with coronary artery disease (CAD). Although generally reimbursed for 3 months, to date, optimal CR program duration and frequency of patient contact has yet to be identified. This study compared standard (33 sessions for 3 months) versus distributed (33 sessions for 12 months) CR for effects on exercise variables, risk factors, health-related quality of life (HRQL), depressive symptoms, and direct costs to the cardiac health care system.

Methods We randomly assigned 392 patients to either standard CR (n = 196) or distributed CR (n = 196). Outcomes were cardiorespiratory fitness, daily physical activity, coronary risk factors, generic and heart disease HRQL, and depressive symptoms, measured 12 and 24 months after program intake. Secondary outcomes included these variables measured after 3 months. Costs to the cardiac health care system were determined 2 years after program initiation.

Results Both groups showed improvements over time in cardiorespiratory fitness, daily physical activity, low-density lipoprotein cholesterol, generic and heart disease HRQL, and depressive symptoms. Over time, blood pressure and body mass index values worsened. Smoking status, high-density lipoprotein cholesterol, and triglyceride levels remained unchanged. There were no clinically meaningful or statistically significant between group differences for outcomes at 12 or 24 months. The costs of the programs to the cardiac health care system were not different.

Conclusions From a clinical standpoint, this study indicates that both standard and distributed program formats serve patients with CAD equally well over the longer term. Programs could use either program delivery model (standard or distributed) depending on patient or program needs. Costs to the cardiac health care system are similar. (Am Heart J 2005;149:862-8.)

Secondary prevention through cardiac rehabilitation (CR) has been recommended for most patients with coronary artery disease (CAD).[1] Cardiac rehabilitation programs typically include medical evaluation, prescribed exercise, behavioral change; cardiac risk factor modification, education, counseling, and psychosocial support.[1]

To date, optimal CR program duration and frequency of patient contact has yet to be identified. In the United States, programs are usually limited by third-party reimbursement to 36 contacts over a 12-week period.[2] In Canada, program parameters are highly variable, with programs lasting from 2 months to an indefinite period,[3] and frequency of patient contact ranging from 1 to 3 sessions per week.

Participation in a standard 12-week CR program is known to result in positive changes in health-related quality of life (HRQL), cardiac risk factors such as blood lipids and cigarette smoking, and cardiorespiratory fitness.[1,4] It has been suggested that CR outcomes might be improved by extending patient contact over longer periods.[2,5] This would allow more time to establish and consolidate new lifestyle patterns (eg, smoking cessation, healthy eating, regular physical activity), to address patient-specific issues (eg, stress management, vocational counseling), and to maximize medical manage-

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ment with cardiovascular risk-reducing medications (eg, antiplatelet agents, β-blockers, lipid-lowering agents, angiotensin-converting enzyme inhibitors [ACE]). Our aim is to test this hypothesis.

The purpose of the present study was to compare the efficacy of standard (SCR; 33 sessions for 3 months) versus distributed (DCR; 33 sessions for 12 months) CR for effects on exercise-related variables, cardiac risk factors, HRQL, depressive symptoms, the use of risk-reducing medications, and costs to the cardiac health care system.

Methods

Patients with diagnosed CAD, referred to CR between September 1999 and March 2001, at one center (University of Ottawa Heart Institute), who were willing to give written informed consent, were eligible for enrollment. Diagnosis of CAD was based on documented acute myocardial infarction (MI), coronary artery bypass graft surgery (CABG), percutaneous coronary intervention (PCI), or clinical diagnosis of angina pectoris. Patients with a history of heart failure due to left ventricular systolic dysfunction were included in the study, unless they had heart failure that was not compensated.[6] People referred after cardiac transplantation or valve surgery and those with contraindications to exercise were excluded. Potential study participants were recruited at the orientation session for new CR participants.

At baseline assessment, a medical history (including current medication use) was obtained and participants completed questionnaires concerning generic and heart disease HRQL[7,8] and depressive symptoms.[9] Height, weight, and blood pressure were measured and a fasting blood sample was collected. Smoking status[10] and preprogram physical activity level[11] were established via self-report and semistructured interview, respectively. Participants returned on a separate day for an exercise stress test to assess cardiorespiratory fitness.[12] After baseline testing, participants were randomly allocated to treatment.

Randomization, performed using a table of random numbers, was stratified according to sex. The interventions were SCR or DCR. Treatment allocation was concealed until completion of the baseline testing and stratification. No blinding of participants was used; they were immediately informed of their group assignment. Blinding was used for various aspects of the data collection. Questionnaire responses were computer scored and technicians with no knowledge of group assignment conducted exercise stress tests and blood analyses.

During intervention, 4 types of CR contacts were provided to all participants: educational workshops, case manager contacts, physician visits, and supervised exercise classes. Both groups received the same number of contacts (total of 33); however, the schedule varied depending on group assignment. Within 2 weeks of baseline, all participants attended two 3-hour educational workshops that provided information on behavior change, nutrition, and psychosocial and vocational recovery from heart disease. For participants receiving SCR, case manager visits occurred at weeks 2 and 8 after randomization. Telephone contact occurred at week 4. A physician visit occurred at week 7. Supervised exercise classes were held twice weekly for a 13½-week period. For participants receiving DCR, case manager visits occurred during weeks 2 and 26. Telephone contact occurred at week 8. The physician visit occurred at week 7. Supervised exercise classes were held once per week for 14 weeks, once every 2 weeks for 14 weeks, and once every 4 weeks for 24 weeks.

Case manager contacts (2 in person and 1 by telephone) were used to triage participants into optional program components (eg, smoking cessation, stress management, vocational counseling, psychosocial counseling, nutrition counseling) and to develop and monitor personal goals. The physician visit was intended to ensure adequate risk factor control according to recognized guidelines.[13-15] Comorbid conditions that might impair progress (eg, depression, respiratory or musculoskeletal problems) were also addressed. Follow-up physician visits were conducted as necessary. Supervised exercise visits consisted of 27, hour-long, group exercise classes. Participants received an exercise prescription and home exercise guidelines to help achieve target levels of 6300 to 8400 kJ/wk (1500-2000 kcal/wk). The frequency, intensity, duration, and mode of exercise was consistent with guidelines for patients with CAD recommending 30 to 60 minutes of moderate intensity physical activity 3 or 4 times weekly supplemented by an increase in daily lifestyle activities.[16] Electrocardiogram telemetry monitoring was used only for high risk patients.[13] Heart rate intensity was established using the Karvonen formula (ie, resting heart rate plus 50%-80% of heart rate reserve)[17] based on results obtained from cardiopulmonary exercise testing. If there was evidence of ischemia, the heart rate just before the onset of ischemia (based on symptoms or electrocardiogram criteria) was used as the training intensity. Intensity guidelines were also provided as rating of perceived exertion targets.

Measurements were repeated after 3, 12, and 24 months.

Heart disease HRQL was measured using the 27-item MacNew instrument,[7] which measures 3 quality of life domains (emotional, physical, and social). A global heart disease HRQL score was calculated as the average response across all questions. Generic HRQL was assessed by the SF-36 questionnaire,[8] which provides 2 component subscales: a physical component subscale (PCS) and a mental component subscale (MCS). Levels of plasma total cholesterol and high-density lipoprotein cholesterol (HDL-C) and triglycerides (TGs) were determined using standard laboratory procedures.[18] Depressive symptoms were measured using the Centre for Epidemiological Studies depression scale (CES-D).[9] Cardiorespiratory fitness was determined during treadmill testing using a ramp protocol with direct measurement of peak oxygen uptake, expressed in metabolic equivalents (METs).[12] Physical activity level was assessed using the 7-day physical activity recall. Reports of time spent in moderate, hard, and very hard activities are computed to provide the mean kilojoules (kcal) per week of energy expenditure related to activity.[11] Fatal and nonfatal events were recorded over the 24-month study period.

Costs were measured from the perspective of the cardiac health care system, assessed in 2002 Canadian dollars, and converted to 2004 U.S. dollars using an exchange rate of Can $1.30 for each US $1 and applying a 5% discount rate. Per patient costs of CR program delivery were measured using bottom-up cost calculations where unit costs for program contacts were multiplied by actual resource usage. Cardiac health care costs (for physician visits, hospitalizations, diag-

nostic tests) were calculated using case costs from the Ontario Joint Policy and Planning Committee[19] and the Ontario Health Insurance Plan schedule of benefits.[20]

The sample size required to detect a minimal clinically important difference for each of 4 main outcome measures (MacNew score, depression score, peak METs, and low-density lipoprotein cholesterol [LDL-C]) was calculated.[21] Two-tailed tests were used with 80% power. Calculations were based on data from previously published studies and consideration of minimal clinically important differences for each outcome.[4,15,22,23] The largest sample size (2n = 272) was required to detect a difference of 0.5 points (SD = 1.3) on the MacNew HRQL instrument and this was selected as the study sample size. The sample size was increased by 30% to account for attrition at 24 months, giving a final sample size of 388.

All analyses were conducted on an intent-to-treat basis. Groups were compared at baseline using independent-sample *t* tests and χ^2 tests. In the primary analyses, continuous variables were compared using a 2-way repeated measures analysis of variance (ANOVA) with the between component being group assignment and the within component being assessments at baseline and the 12- and 24-month time points. If data were missing because of loss to follow-up, it was replaced according to the last observation carried forward principle. For costs, program delivery and health care utilization costs were summed over the entire 2-year period for each participant. Total costs were compared between groups using a *t* test.

To provide an additional comparison of program effectiveness, we also compared the distribution of benefit by minimal important difference (MID) between groups. To do this, we first determined the MID empirically or, when necessary, estimated it statistically.[24] Empirical data were available for the MacNew and the SF-36 instruments. We used a change score of 0.50 points as the MID for the MacNew.[7] We used a change score of 5 points as the MID for both the PCS and MCS scales of the SF-36.[8] For all other outcomes, the MID was determined using standardized effect size benchmarks, specifically the standardized response mean.[25-27] The numerator of the standardized response mean is the mean change in score over time (24 months to baseline) and the denominator is the SD of the change.[27] We chose a moderate effect size (0.50) as our estimate of the MID for peak METs, physical activity, blood lipids, blood pressure, body mass index (BMI), and the CES-D.[28] The proportions of participants in each group who improved by at least the MID, stayed the same, or deteriorated by at least the MID were compared using χ^2 tests.

Results

Participant flow and follow-up

Six hundred and five patients with CAD referred to CR between September 1999 and March 2001 were asked to participate in the study and 396 (66%) agreed to do so. Four participants were excluded from the study when additional testing established they were free of CAD. Compared to those who refused participation, study participants were slightly younger (58 vs 60 years; $P = .02$) and less likely to be current smokers (7% vs 13%; $P = .03$). Participants and nonparticipants were similar in sex, education, BMI, and clinical event precipitating referral. In total, 392 participants (196 to SCR and 196 to DCR) were randomly allocated to treatment. Completion rates for scheduled contacts (ie, case manager visits and telephone calls, physician office visits, and supervised exercise training sessions) were similar for the 2 groups. Participants completed 26.5 (80.2%) and 25.4 (77.0%) of 33 schedule contacts with the SCR and DCR interventions, respectively. Complete data were available for 344 (87.8%), 314 (80.1%), and 252 (64.2%) of 392 participants at the 3-, 12-, and 24-month assessment points, respectively.

Table I. Baseline characteristics of volunteers participating in CR study

Variable	SCR group (n = 196)	DCR group (n = 196)
Age (y)	58 (10)	58 (11)
Sex (%)		
Male	84	85
Female	16	14
Education level (y)	15 (4)	15 (4)
BMI (kg/m^2)	29 (5)	29 (5)
Current cigarette smokers	6	8
Clinical event precipitating referral (%)		
MI	14	13
CABG	41	45
PCI	40	32
AP	5	10

Continuous values are expressed as means (SD). There were no statistically significant baseline differences between groups.
PCI, percutaneous coronary interventions; *AP*, angina pectoris.

Baseline characteristics

Baseline demographic and clinical variables are shown in Table I. Groups were balanced with respect to age, education, BMI, smoking status, and clinical event precipitating referral.

Outcomes at 12 and 24 months

A summary of the repeated measures ANOVA examining the effects of group assignment and time on continuous outcome measures is shown in Table II. Both groups demonstrated improvements over time in cardiorespiratory fitness, daily physical activity, LDL-C, generic and heart disease HRQL, and depressive symptoms. Systolic blood pressure (SBP), diastolic blood pressure (DBP), and BMI worsened over time, while HDL-C and TG remained unchanged. There were no significant effects of group assignment for any of these outcomes. There were few changes in smoking status during the study (data not shown). Of the participants who smoked cigarettes at the start of the study (n = 27), only one participant in each group was abstinent after 24 months.

Table II. Summary data from repeated measures ANOVA examining the effects of group assignment and time for exercise-related variables, blood lipids, blood pressure, BMI, HRQL, and depressive symptoms

	SCR (n = 196)			DCR (n = 196)			*P*		
	Baseline	12 m	24 m	Baseline	12 m	24 m	Program effect	Time effect	Program × time effect
Exercise related									
Peak METs	6.7 (1.8)	6.9 (1.8)	6.8 (1.9)	6.4 (1.7)	6.7 (1.8)	6.5 (1.7)	.14	.03	.60
Activity (kcal/wk)	1940 (2001)	2419 (3127)	2484 (2248)	2129 (2226)	2441 (2446)	2647 (2533)	.53	<.01	.92
Activity (kJ/wk)	8117 (8372)	10,121 (13,083)	10,393 (9406)	8908 (9314)	10,213 (10,234)	11,075 (10,598)	.53	<.01	.92
Coronary risk factors									
LDL-C (mmol/L)	2.4 (0.7)	2.2 (0.7)	2.3 (0.6)	2.5 (0.8)	2.3 (0.6)	2.5 (0.7)	.17	.03	.79
HDL-C (mmol/L)	1.2 (0.3)	1.2 (0.3)	1.2 (0.3)	1.2 (0.3)	1.2 (0.3)	1.2 (0.3)	.71	.47	.84
TG (mmol/L)	1.7 (1.3)	1.6 (1.3)	1.7 (1.3)	1.8 (1.2)	1.7 (1.1)	1.7 (1.1)	.60	.19	.93
SBP (mm Hg)	131 (21)	132 (20)	134 (21)	130 (19)	130 (20)	132 (19)	.33	.01	.89
DBP (mm Hg)	74 (10)	77 (10)	79 (10)	74 (10)	74 (11)	77 (11)	.08	<.01	.19
BMI (kg/m^2)	28.8 (4.6)	28.9 (4.6)	29.0 (5.2)	29.0 (5.2)	29.0 (4.9)	29.2 (5.0)	.69	.06	.98
HRQL									
SF-36 PCS	39.3 (9.9)	46.1 (10.2)	45.3 (10.3)	39.3 (8.9)	45.0 (9.3)	44.6 (10.2)	.51	<.01	.54
SF-36 MCS	48.9 (11.5)	50.0 (7.4)	50.6 (7.4)	45.6 (12.2)	49.5 (8.1)	49.2 (8.5)	.16	<.01	.26
MacNew global	5.4 (1.1)	5.7 (1.2)	5.8 (1.1)	5.2 (1.1)	5.7 (1.2)	5.7 (1.2)	.79	<.01	.93
Psychological distress									
CES-D	11.3 (10.3)	10.2 (10.4)	9.8 (10.1)	12.2 (10.5)	10.3 (10.3)	10.7 (11.0)	.51	<.01	.93

Table III. Distribution of benefit by MIDs in outcomes measured in CR study

	SCR group (n = 196)			DCR group (n = 196)			
Variable	Improve (%)	Stay the same (%)	Deteriorate (%)	Improve (%)	Stay the same (%)	Deteriorate (%)	*P*
Peak METs	27	52	21	31	47	22	.59
Physical activity	31	54	15	30	57	13	.81
LDL-C	28	53	19	31	45	24	.27
HDL-C	25	56	19	23	53	24	.46
TG	22	63	15	24	60	16	.88
SBP	22	43	35	26	40	34	.71
DBP	19	41	40	16	34	50	.13
BMI	18	56	26	16	54	30	.60
SF-36 PCS	50	42	8	53	39	8	.85
SF-36 MCS	40	40	20	33	39	28	.17
MacNew global	42	48	10	43	48	9	.94
CES-D	32	51	17	34	50	16	.84

Distribution of benefit by MIDs in outcomes

The proportions of participants in each group who improved, stayed the same, or deteriorated in relation to the MID for each outcome variable are shown in Table III. There were no significant differences between groups for any of the outcomes. Patients gained the biggest benefits in HRQL. The outcome with the highest proportion of participants (>50%) improving over 24 months was the physical component subscale of the SF-36, followed by the MacNew global scale. Body mass index was the outcome with the fewest participants achieving a clinically important improvement.

Use of cardiovascular risk-reduction medications

Reported use of cardiovascular risk-reduction medications is shown in Table IV. There were no significant differences between groups in medication use at baseline or after 3, 12, or 24 months.

Table IV. Cardiovascular risk reduction medication use at baseline and after 3, 12, and 24 months

	Baseline		3 m		12 m		24 m	
Medications/ group	**SCR (n = 196) (%)**	**DCR (n = 196) (%)**	**SCR (n = 196) (%)**	**DCR (n = 196) (%)**	**SCR (n = 196) (%)**	**DCR (n = 196) (%)**	**SCR (n = 196) (%)**	**DCR (n = 196) (%)**
Lipid-lowering agents	84	78	92	87	91	86	92	86
Antiplatelet agents	92	93	96	93	94	92	93	92
β-Blockers	71	68	74	67	69	66	69	67
ACE inhibitors	53	50	55	56	59	58	59	58

There were no statistically significant differences in medication use between the intervention groups at baseline or after 3, 12, or 24 months.

Clinical cardiac events

In the 24-month period after baseline assessment, 6 participants died (SCR, 2; DCR, 4), with 1 cardiac death and 1 death from cancer in the SCR group and 3 cardiac deaths and 1 death from cancer in the DCR group. During the 24 months of follow-up, 5 participants suffered nonfatal MIs (SCR 4; DCR, 1), 13 underwent CABG surgery (SCR, 8; DCR, 5), and 22 were hospitalized for new PCI (not post-MI or restenosis within 6 months of index PCI; SCR, 9; DCR, 13). The total number of participants with a primary cardiac event (ie, cardiac death, or hospitalization for nonfatal MI, PCI, or CABG surgery) over the 2 years was 22 in the SCR group and 22 in the DCR group.

Costs

At 2 years, the total direct costs of DCR were $5267 ($759 for program delivery + $4508 for cardiac health care costs) versus $5132 for SCR ($681 for program delivery + $4451 for cardiac health care costs) ($P = .33$).

Discussion

The present study is the first to compare SCR (33 sessions for 3 months) to DCR (33 sessions for 12 months) in a randomized trial. We hypothesized that DCR would be more effective over a 2 year-period after program initiation since it would allow more time to establish and consolidate healthful lifestyle behaviors, to address patient-specific issues, and to optimize medical management. Our data did not support this hypothesis. Rather, we found that SCR had similar effects compared with DCR for a variety of outcomes including exercise-related variables, cardiac risk factors, HRQL, depressive symptoms, and reported use of cardiac risk reduction medications. Direct costs associated with both programs over the 2-year period were similar. Both program formats were acceptable to patients, and adherence to scheduled program contacts was close to 80% in both groups.

There are several possible explanations as to why we failed to detect differences between groups. First, the DCR intervention may not have been sufficiently different from SCR. While contacts with this group continued over 12 months, the intervention was still "front-end loaded," with more than half of contacts (58%) occurring within the first 3 months. Alternative designs that could be considered in future studies include distributing contacts evenly over the entire period (average, 2.75 contacts per month) or even "back-end loading" the intervention so that more contacts occur as time goes on. In this way, more assistance could be provided when motivation is waning and relapse to old behavior patterns is more common. The second explanation is that there were differences between the groups that affected responsiveness to the DCR intervention. For example, despite randomization, there were more patients with angina and smokers in the DCR group. Patients with angina typically have lower quality of life, while smokers may gain fewer benefits from exercise-based interventions. The third explanation is that the periodic measurement of outcomes may have been a form of intervention that contributed to the retention of intervention effects among participants in the SCR group. In future studies, we would recommend that outcomes be measured only when necessary. Fourth, we used a last observation carried forward strategy to replace missing data. This is a conservative approach that may have attenuated differences between groups.

Our findings are consistent with other trials assessing the impact of extended intervention after a standard 12-week program. Brubaker et al[29] randomly assigned patients exiting from a 12-week CR program to 1 of 3 groups: usual care, a home-based intervention, or ongoing participation in a center-based program. The investigators found that cardiorespiratory fitness, blood lipids, and body weight/composition were similar in all 3 groups 12 months after program initiation. In a trial of patients with heart failure randomized to 3 months of

supervised exercise training followed by 9 months of home-based training, McKelvie et al[30] found significant improvements in cardiorespiratory fitness and arm/leg strength in the exercise group compared with controls, however, there was little further improvement over the final 9 months of follow-up.

This study has a number of strengths including the randomized trial design, the use of a multifactorial SCR comparison group, the measurement of multiple outcomes of interest, the long-term follow-up of participants, and the measurement of cost data. The randomized trial design provides good control over potentially confounding variables and provides the strongest evidence regarding the effects of altering program design characteristics. Since the comparison group received CR in a program format that is widely used in North America, the results of this study are broadly generalizable. We measured a variety of outcomes of interest to CR practitioners and clinicians and found no clinically meaningful differences between these 2 intervention formats. Participants were followed for at least 12 months (DCR group) and up to 21 months (SCR group) after completion of their CR program. It is important that different approaches be tested for their long-term effects to ensure that observed benefits of any particular approach are durable.

Limitations are acknowledged. We compared 2 active interventions; there was no untreated control group. Because secondary prevention through CR has been recommended for most patients with CAD,[1] and given that their physician had referred participants in the trial to CR, we did not feel it was ethically defensible to deny participants treatment of known benefit. In addition, we compared only one alternative to SCR. It is possible that a different schedule of patient contacts may have yielded different results. Another limitation is that the follow-up contacts conducted for the purposes of collecting data may have contributed to the retention of intervention effects in the SCR group. Subjects in the SCR group were contacted for follow-up 4 times between the end of their program and 24 months. This follow-up could be construed as an extension of the SCR intervention. These results apply only to center-based CR and are not necessarily relevant to case-managed approaches to CR and secondary prevention.[31-33]

This study provides some interesting insights into the role of multifactorial CR in patients receiving contemporary therapy for CAD. Participation in either program format was associated with clinically meaningful changes in level of physical activity and generic and heart disease HRQL. Effects on blood lipids were modest, probably because most patients (>80%) were already prescribed lipid-lowering medications before their referral to the CR program. The interventions may have, however, ensured patients continued using risk-reducing medications over the long term. At 24 months, reported use of antiplatelet agents, β-blockers, lipid-lowering agents, and ACE inhibitor medications was 92%, 68%, 89%, and 58%, respectively. These results are superior to the EUROASPIRE II study of preventive therapy use where antiplatelet agent, β-blocker, lipid-lowering agent, and ACE inhibitor use was 84%, 66%, 63%, and 43%, respectively, 6 months after an index cardiac event.[34] Medication use was also better than that reported by Gordon et al in a comparison of the effectiveness of 3 models for comprehensive cardiovascular disease risk reduction.[33] Cardiorespiratory fitness levels increased only slightly (+3%). Over time, blood pressure and BMI values worsened, suggesting that CR programs need to focus greater attention toward these risk factors.

This study provides original information on the efficacy of different CR program durations and frequencies of patient contact. Our data indicate that there are no clinically meaningful or statistically significant differences between a standard 3-month, 33-session program of CR and one that has the same number of contacts distributed over a 12-month period, as measured by differences in cardiorespiratory fitness, daily physical activity, coronary risk factors, generic and heart disease HRQL, or depressive symptoms 12 and 24 months after program intake. Costs from the perspective of the cardiac health care system are similar for both programs. From a clinical standpoint, program administrators can be confident that either one of these program designs will produce similar long-term effects on patient-related outcomes, and can decide which approach is most appropriate for their situation on the basis of patient or program needs.

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