

Predicting Long-Term Mortality, Morbidity, and Survival Outcomes Following a Cardiac Event: A Cardiac Rehabilitation Study

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Rehabilitation Process and Outcome
Volume 8: 1–8
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DOI: 10.1177/1179572719827610



ABSTRACT

BACKGROUND: Cardiac rehabilitation (CR) has been shown to decrease mortality and morbidity but estimations vary. While there is significant literature supporting short-term benefits, there is not a similarly body of research as to long-term (LT) benefits. Low participation rates in CR are due to several causes and evidence demonstrating positive LT outcomes could be a catalyst to increased participation rates.

OBJECTIVE: To predict LT mortality, readmission, and survival benefits associated with CR participation in a nationally certified program.

METHODS: Investigators collected mortality and hospital readmission data in a retrospective study to examine a cohort of cardiac patients following a myocardial infarction (MI), MI/percutaneous coronary intervention (PCI), and coronary artery bypass graft (CABG) up to 14 years ago. Hospital electronic medical record (EMR; $n = 207$) were used to measure hospital readmission outcome and State Health Department records ($n = 361$) for mortality and survival outcomes. Participation in CR, age, gender prior history of cardiac event, and diagnosis were used to predict readmission, mortality, and survival.

RESULTS: Approximately half (52.1%) the sample participated in CR. Participants included 72% males, average age 68 years (38–91 years), and were predominantly Non-Hispanic white. CR participants attended an average of 20 sessions. CR group differed in diagnoses MI (58.5%), CABG (57.4%) and in prior history of heart disease (25.4%) from the non-cardiac rehabilitation (NCR) group (83.2%, 25.4%, 42.2%, respectively) ($P < .05$). After controlling for the covariates in logistic regression analyses, the CR group independently predicted lower all-cause mortality (odds ratio, $OR = 0.22$, 95% CI 0.12 to 0.39) and decreased hospital readmissions ($OR = 0.48$, 95% CI 0.24 to 0.96). After controlling for the covariates in survival analysis, the CR group significantly contributed to decreased likelihood of death hazard (hazard ratio = 0.36, 95% CI 0.24 to 0.54). Median survivor time for the participants was 5.91 years, $SD = 3.81$ years.

CONCLUSIONS: Participation in CR for middle age and elderly patients is associated with increased survival, a marked decrease in all-cause mortality, and a decrease in cardiovascular-related hospital readmission. A referral to a nationally certified outpatient CR program prior to hospital discharge and early enrollment may improve LT outcomes.

KEYWORDS: cardiac rehabilitation, mortality, hospital readmission, survival, long term, outcomes

RECEIVED: December 20, 2018. **ACCEPTED:** January 4, 2019.

TYPE: Original Research

FUNDING: University of Colorado, Colorado Springs Committee for Research and Creative Work Faculty Grant.

DECLARATION OF CONFLICTING INTERESTS: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Introduction and Purpose

The consequences of coronary heart disease (CAD) are many with premature death a potential reality.¹ Outpatient phase II cardiac rehabilitation (CR) is a non-invasive health care intervention that assists in the management of modifiable CAD risk factors. In the United States, Centers for Medicare and Medicaid Services (CMS) and third-party payers reimburse for CR. Historically, patients were enrolled within 3 months following hospital discharge² whereas today patients are enrolled earlier. Participants in CR demonstrate significant physical and psychosocial benefits.^{3–6} Although a referral to CR is a Class 1A recommendation following an acute cardiac event programs are underutilized.^{7,8}

Mortality and morbidity are two outcomes studied to determine the effectiveness of CR services. Considered a secondary

health prevention intervention,⁹ CR is associated with reductions in mortality and morbidity.^{3,10,11} In two seminal works published three decades ago, a 20% to 25% reduction in mortality was observed.^{12,13} O'Connor and colleagues¹² in 1989 analyzed 22 randomized controlled trials (RCTs) of myocardial infarction (MI) patients and found CR effective in reducing all-cause mortality and cardiovascular (CV)-related mortality (odds ratio, $OR = 0.80$ and $OR = 0.78$, respectively). Subsequent studies including a number of reviews continue to support CR as an effective and efficient health care intervention.^{10,11,14} In a 2012 overview of 6-independent CR meta-analyses including 13,824 patients, Oldridge¹⁵ identified reductions in mortality and hospitalizations outcomes similar to results from their 1988 review.¹³ The results for reduced



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mortality are consistent; however, results for morbidity are less consistent.^{14,16–18}

Cardiac rehabilitation studies typically measure outcomes 12 months following CR program completion¹¹ and fewer studies examine mortality, morbidity, and survival benefits beyond 10 years of program completion.^{19–23} Long-term studies are one approach toward investigating lasting benefits associated with secondary preventive interventions. In a 10-year follow-up study, Pack et al¹⁹ identified a reduction in all-cause mortality associated with CR attendance and Beauchamp et al²⁰ observed a 58% reduction in their 14-year follow-up study. Dorn et al²¹ in a 19-year follow-up of 651 men enrolled in exercise training following an MI (mean age 51 years), found no protective effect from the program but observed increases in physical work capacity consistent with reduction in mortality throughout the 19-year follow-up period.

While long-term studies are sometimes criticized for issues related specifically to design and missing data, they offer a broad perspective of health-related benefits associated with CR and provide researchers and practitioners with valuable information.^{24,25} Predicting positive long-term survival may offer hope to cardiac patients and health care providers. The purpose of this study was to investigate the long-term mortality, readmission, and survival benefits associated with early CR enrollment in a nationally certified CR program and to identify specific patient characteristics that could predict survival rates in CAD patients.

Methods and Data Collection

Study design and sample

A retrospective study was done at a 450-bed Joint Commission accredited acute care hospital located in the Rocky Mountain Region of the United States. In December 2015, two investigators using hospital electronic medical record (EMR) and State Health Department Records collected readmission and mortality data on patients hospitalized 12–14 years prior for a cardiac event (November 2001 through February 2003). Male and female patients, 18 and older, admitted with a MI with or without an invention of percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) were consecutively identified using the hospital daily admission sheet. Elevated biomarkers and electrocardiogram changes confirmed diagnosis of MI and surgeons' post-operative report confirmed CABG surgery. Patients with serious comorbidities including advanced heart failure (Stages III and IV), Chronic Obstructive Pulmonary Disease (COPD), cancer, physical mobility problems, acute complications during hospitalization, and stroke were excluded. Patients attending fewer than 8-CR sessions, residing greater than 50 miles from the hospital or discharged directly to a skilled nursing facility or long-term care facility, were excluded. Approval for the study was received from the Institutional Review Boards from the participating university and hospital. Patient consent was not required for the follow-up record review.

Intervention cardiac rehabilitation

Patients in both groups received standard education from the CR Phase I nurse educator and a physician referral to the outpatient CR prior to hospital discharge. Automatic CR referrals were generated directly from the Heart Cath Lab and from surgical orders sets. Inpatient CR nurses encouraged patients to attend CR 3 times/week for up to 3 months. The comprehensive CR program included aerobic and resistance exercise with extensive cardiac education. A team of nurses, exercise personnel, and dietary interns staffed CR under the leadership of the medical director. Initial CR appointment included 1-h history/ physical assessment and program orientation. Patients were enrolled in one of six CR classes. Certified in 1999, the CR program met rigorous criteria required by American Association of Cardiopulmonary Rehabilitation (ACVPR).

Exercise prescriptions approved by the physician at program entry were updated each session. Exercise monitoring included continuous telemetry monitoring, blood pressure, and heart rate/rhythm monitoring throughout the hour session. Multiple forms of media were used for group and individual patient/family education. Lectures, written handouts, and videos from the American Heart Association (AHA) were included. Educational materials included managing coronary artery disease risk factor, medications, nutrition, smoking cessation, and exercise. Patients turned in home exercise logs weekly recording of type of exercise, duration, frequency, and intensity. Referrals for counseling, smoking cessation, and weight loss were available. With each session, attendance was recorded. Following CR completion, CR patients were offered the option to continue with exercise at a local gym for minimal fee. Patients not enrolled in CR were identified as the non-cardiac rehabilitation (NCR) group. The NCR group received standard care from their physician, which included a follow-up visit within 3 months of discharge and medication management.

Outcomes

Mortality considered the primary outcome and was defined as all-cause mortality or CV-related mortality. Mortality was measured as 6 months following the cardiac event to the time of study follow-up. Mortality records dating from November 2001 to December 2015 were reviewed for 361 patients. Vital Statistics were abstracted from State Health Department Records to identify deceased patients. Mortality identified by primary cause of death was coded as either all-cause mortality or CV-related death. Myocardial infarction, CAD, stroke, and congestive heart failure were defined as CV-related deaths.

Secondary outcomes included hospital readmission and survival rate. Readmission was defined as an inpatient hospital admission of greater than 24 h for an acute non-fatal cardiac event including unstable angina, hypertensive crisis, MI, stroke, congestive heart failure, or other CV-related event following the index event to time of follow-up. Patients admitted to and

discharged directly from the emergency department or patients scheduled for elective scheduled procedures were not included as a readmission. Hospital EMR was used to collect readmission data, date at time of readmission, age at readmission, chief complaint, and billing codes to confirm the admission diagnosis. Date of birth correctly identified patients in EMR with like surnames.

Survival information is useful in health care because of the information provided for duration of a specific condition or state of being, and unlike mortality outcomes, allows providers to estimate how long patients can be expected to survive following a significant cardiac event.²⁶ To determine survival, investigators used State Health Department records to determine the number of patients deceased from hospital discharge for the index event up to time of follow-up. Age from time of the event to survival or death was used to determine survival trends for patients in the CR and NCR groups.

Analysis

For analyzing the covariates, chi-square, analyses, and *t* tests were used to determine proportional and mean differences of the covariates as a function of the CR with NCR groups. Three statistical models involving logistic regression analysis and survival analysis served as the main analyses to identify predictors contributing to hospital readmission, mortality, and survival.

First, to explain hospital readmission for a CV-related event, a binary logistic regression analysis was estimated using the following from the index event as predictors: the intervention (CR vs NCR), gender, and prior history of cardiac event, age at time of index event, diagnosis of MI, PCI, Stent, and CABG. The same set of eight variables was incorporated into a logistic regression model to predict mortality (from the time of the index event to the 14-year follow-up). The main parameter interpreted in the logistic regression model is the odds ratio (OR).

Finally, survival analysis was pursued using Cox proportional hazards regression with the same set of aforementioned predictors to explain years of survival following the index event. The statistical parameter interpreted in survival analysis is the hazard ratio. Analyses were performed using SPSS Software (version 23; SPSS Inc., Chicago, IL). Confidence intervals were reported and statistical significance was determined using a *P* value of $<.05$ for all tests.

Results

State Health Department Records ($N=361$) and hospital EMR medical records ($N=207$) were reviewed in December 2015. Approximately half the patients ($n=188$) participated in CR and 48% did not participate ($n=173$). Patients were 72% male and 98% Caucasian. At the time of CR participation, patient ages ranged from 38 to 91 years ($M=67.5$, $SD=11.6$). Participation in the CR program was by self-selection process. Patients in the NCR group declined the program due to

co-payments, lack of transportation, time, or interest and received no CR sessions. Patients in the CR group participated in 8 to 36 sessions (mean = 20, $SD=9.4$). Thirty-three percent of the patients completed over 25 sessions and 55% completed greater than 20 sessions.

Outcome results for mortality and survivability were based on records for 361 patients; however, due to patients no longer registered in the new EMR system at time of follow-up, results for readmission data were based on the 207 patients who continued to be registered (CR: $n=127$; NCR: $n=79$). Because of the inability of the researchers at time of follow-up to access hospital records between 2001 and 2007, readmission outcomes are from 5 years and beyond discharge from the index event.

Following the index event, 28% of the total sample (NCR 39.2% vs CR 21.1%) had been readmitted for a cardiac-related event and 35% of the patients were identified as deceased (NCR 46.8% vs CR 21.8%). Average length of time between index event and hospital readmission was 7.28 years ($SD=1.38$). The CR group compared with NCR had a greater proportion of females, were less likely to have a prior history of heart disease (CAD), more likely to have CABG, and less likely to have a myocardial infarction and PCI. Bivariate *t* test and chi-square analyses involving each variable as a function of CR vs NCR groups are presented in Table 1.

The logistic regression model simultaneously controlling for the set of eight predictors in explaining readmissions is presented in Table 2. The only one of the eight predictors determined to be significant in this model was the CR intervention, with the CR group significantly less likely than NCR group of being readmitted (OR = 0.41, $P < .05$; adjusted OR = 0.48, $P < .05$).

Based on the mortality records reviewed, 46.8% ($n=81$) patients from NCR and 21.8% ($n=41$) from CR were deceased at the time of follow-up. The average patient age at time of death was 80 years ($SD=9.4$). When CR as the intervention variable was entered as the sole predictor of all-cause mortality in a logistic regression model, the CR group had a subsequently lower rate of mortality compared with patients in NCR (OR = 0.30, $P < .05$; adjusted OR = 0.22, $P < .05$). Table 3 shows the estimates for the logistic regression model controlling for the eight covariates. Specifically, prior history of heart disease, older age at the time of the index event, and participation in the NCR group, each independently and significantly contributed to greater likelihood of all-cause mortality at the 14-year follow-up.

Survival analysis was also performed to identify factors responsible for explaining variations in the trajectory of survival after the index event. Death (vs non-death) was specified as the hazard event in the mortality model. Among the deceased participants at the final measurement, the average length of survival was 5.91 years ($SD=3.81$ years, median = 5.95) following the index event. Survival rates across the entire sample are presented in Figure 1. The survival rates for all patients as

Table 1. Chi-square and *t* test for covariates as a function of NCR and CR group (N=361).

VARIABLE	NCR (N= 173)	CR (N= 188)	TEST	P VALUE
Gender				
Male	76.9%	67.0%	$\chi^2=4.32$.038*
Female	23.1%	33.0%		
Prior history of heart disease	42.2%	24.5%	$\chi^2=12.81$	<.001*
Myocardial infarction	83.2%	58.5%	$\chi^2=26.41$	<.001*
CABG	25.4%	57.4%	$\chi^2=37.88$	<.001*
Stent	32.4%	24.5%	$\chi^2=2.78$.096
PCI	40.5%	27.7%	$\chi^2=6.60$.010*
Age at index event	M=68.24 (SD= 12.13)	M=66.82 (SD= 11.06)	<i>t</i> test= 1.16	.248

Abbreviations: CABG, coronary artery bypass graft; CR, cardiac rehabilitation; NCR, non-cardiac rehabilitation; PCI, percutaneous coronary intervention.
**P* value < .05.

Table 2. Logistic regression: predicting hospital readmission for cardiac event (N=207).

PREDICTOR	LOG ODDS	WALD TEST	ADJUSTED ODDS RATIO (95% CI)	P VALUE
Gender	-0.26	0.45	0.77 (0.36, 1.64)	.502
Prior history of heart disease	0.35	0.92	1.41 (0.70, 2.87)	.338
Age at index event	0.01	0.12	1.01 (0.98, 1.04)	.731
MI at index event	0.32	0.42	1.38 (0.52, 3.69)	.518
CABG at index event	-0.01	0.00	0.99 (0.35, 2.76)	.981
Stent at index event	0.71	0.67	2.02 (0.37, 10.95)	.413
PCI at index event	-0.85	0.98	0.43 (0.08, 2.29)	.322
Cardiac rehabilitation	-0.74	4.36	0.48 (0.24, 0.96)	.037*

Abbreviations: CABG, coronary artery bypass graft; MI, myocardial infarction; PCI, percutaneous coronary intervention.
Reported are adjusted odds ratios (AOR), after controlling for all other covariates in the model.
**P* value < .05.

estimated by the model are as follows: 93% survival for 3 years, 87% survival for 6 years, 80% for 9 years, and 74% for 14 years after index event. As detailed in Table 4, prior history of heart disease, older age, at the cardiac event, along with not participation in CR each significantly contributed to the increased likelihood of death hazard. Notably, even after controlling for all other predictors in the model, the CR intervention was significantly related to increased survival duration (*adjusted hazard ratio* = 0.36, *P* < .05). Survival curves for the CR and NCR groups are presented in Figure 2. Specifically, the CR group exhibited a significantly higher survival trajectory than the NCR group (see Figure 2).

Discussion

In this long-term follow-up study, CR participation was associated with improved health outcomes. Similar to other CR studies,¹⁹ this study included more males, average age 68 years,

and mainly Non-Hispanic white patients. The CR group included fewer, patients with a prior history of heart disease, and more CABG patients than NCR (see Table 1). Reduced risk for the occurrence of all-cause mortality and CV-related readmission were observed for the CR group. An increase in CV related death was observed for the NCR group but was not significant. A benefit in long-term survival was observed for the CR group after adjusting for the covariates. The long-term all-cause mortality benefit associated with CR participation is similar to findings from other original studies and reviews.^{3,10,14,20,27,28}

Comprehensive services in CR are likely to contribute to mortality and morbidity benefits. In two long-term (LT) studies by Pack et al¹⁹ and Beauchamp et al's²⁰ CR attenders received education in addition to exercise training and outcomes were favorable. Few studies, although finding no reduction in all-cause death did identify a reduction in CV-related

Table 3. Logistic regression predicting mortality (N=361).

PREDICTOR	LOG ODDS	WALD TEST	ADJUSTED ODDS RATIO (95% CI)	P VALUE
Gender	0.17	0.32	1.19 (0.65, 2.15)	.574
Prior history of heart disease	0.54	3.92	1.72 (1.01, 2.92)	.048*
Age at index event	0.09	40.51	1.09 (1.06, 1.12)	<.001*
MI index event	-0.75	2.87	0.47 (0.20, 1.12)	.090
CABG index event	-0.19	0.16	0.83 (0.34, 2.06)	.689
Stent index event	-0.33	0.32	0.72 (0.23, 2.25)	.574
PCI index event	-0.46	0.65	0.63 (0.21, 1.92)	.419
Cardiac rehabilitation	-1.53	26.16	0.22 (0.12, 0.39)	<.001*

Abbreviations: CABG, coronary artery bypass graft; CI, confidence interval; MI, myocardial infarction; PCI, percutaneous coronary intervention. Reported are adjusted odds ratios (AOR), after controlling for all other covariates in the model.
*P value < .05.

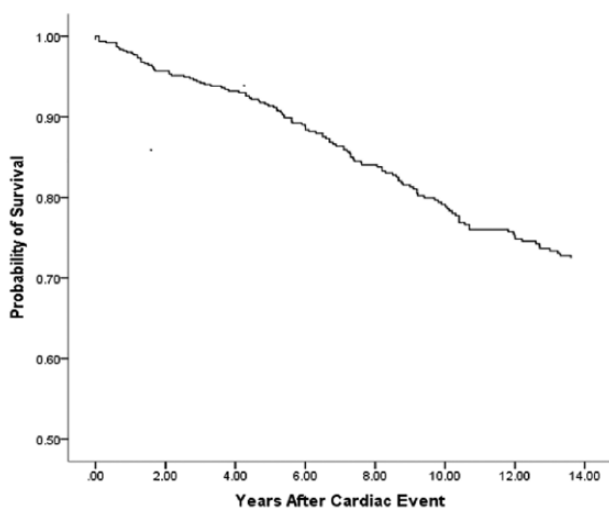


Figure 1. Survival probability as a function of years after index cardiac event (N=361). Graph has statistically controlled for the covariates in Table 4.

mortality, different to⁴ the large multicenter RCT, where no significant difference in mortality risk was found.²⁹ Conclusions from the RCT (RAMIT) have since been criticized by the British Association for Cardiovascular Prevention and Rehabilitation for including out-of-date programs.³⁰

Differences in the type of programs studied and length of follow-up time may account for outcome differences. Studies have included inpatient and home-based CR programs in addition to traditional outpatient programs¹⁰ and many include outcomes measured 12 to 15 months post CR.⁴ How much programs vary between countries and population characteristics are another important consideration.^{10,20,28} Taylor et al⁴ found 63% of the programs analyzed were from Europe.

Morbidity is less studied than mortality and the findings have been less consistent. Variations in definitions are wide, as are methods of measurement.⁵ In one contemporary

comparative study morbidity was defined as all-cause and CV related, and included emergency room visits.² Fewer hospital readmissions were observed for CR participants; however, results were not significant for emergency room visits.² The definition for morbidity in the current study was repeat readmissions for CV event, whereas definition of Heran et al¹⁰ included fatal MI and scheduled total revascularization. Unlike the LT readmission benefit identified in this study, Heran et al¹⁰ found CR associated with decreased hospital readmission in the short term (<12 months), but not for the long term.

Several points differentiate our study from others. Unlike some, which define CR as attending one or more sessions of CR,^{19,27,31} this study excluded patients attending fewer than eight sessions to ensure greater exposure to the rich educational and exercise components of the program. Another distinction included early enrollment. The program enrolled patients within 2 weeks of hospital discharge rather than within 3 months and for some programs up to 6 months following hospital discharge.³² Re-vascularized patients, including CABG patients, are less studied compared with MI patients and in one review, 60% of the studies did not include CABG patients.^{3,4,10,14,16,32} Although CABG and PCI patients were not exclusively studied, these diagnoses were included, and hopefully, the findings will contribute to limited long-term evidence associated with CABG, CR, mortality, and morbidity.^{19,33}

Future Implications

The evidence for long-term benefits,^{20,28,32} similar to short-term benefits,^{31,33,34} have overall been positive.³⁵ While referrals to CR are increasing, programs continue to be underutilized, particularly among females and minorities.³⁶ In a study by Li et al,³⁶ hospitalized women and minorities receiving a referral to CR had lower mortality compared with those not receiving a referral. Cardiac rehabilitation also improves survival in older

Table 4. Survival analysis: predicting years of survival—death hazard across 14 years (N=361).

PREDICTOR	LOG HAZARD	WALD TEST	ADJUSTED HAZARD RATIO (95% CI)	P VALUE
Gender	0.06	0.01	1.01 (0.68, 1.50)	.975
Prior history of heart disease	0.39	4.51	1.48 (1.03, 2.13)	.034*
Age at index event	0.06	47.95	1.07 (1.05, 1.09)	<.001*
Myocardial infarction	-0.56	2.87	0.57 (0.30, 1.09)	.090
CABG	-0.36	1.15	0.70 (0.36, 1.35)	.283
Stent	-0.34	0.68	0.71 (0.32, 1.60)	.410
PCI	-0.34	0.79	0.71 (0.34, 1.51)	.374
Cardiac rehabilitation	-1.02	25.71	0.36 (0.24, 0.54)	<.001*

Abbreviations: CABG, coronary artery bypass graft; CI, confidence interval; PCI, percutaneous coronary intervention. Reported are adjusted hazard ratios, after controlling for all other covariates in the model.

*P value < .05.

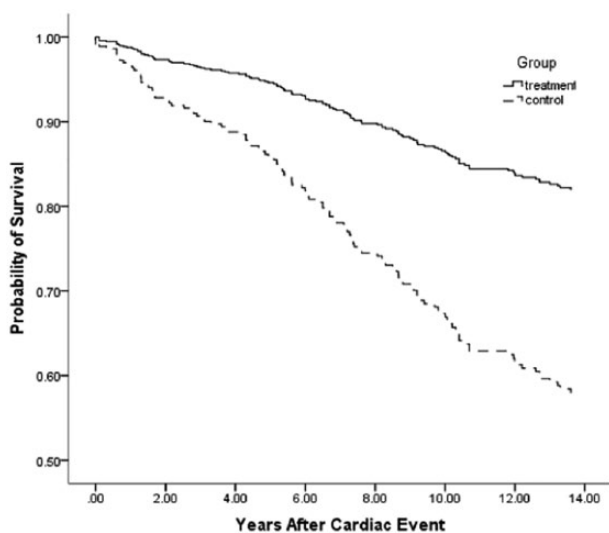


Figure 2. Treatment group and control group—survival probability as a function of years after the index cardiac event. Graph has statistically controlled for the covariates in Table 4.

adults^{27,37} and yet CR is underused among the elderly.³⁸ Concentrated efforts can be made to increase CR enrollment among special populations. It is imperative that referral rates and attendance in CR programs increase and special attention is given to disparities found between groups who do and do not participate.^{8,39} Access to CR using automatic referrals and expediting program entry within 1 to 2 weeks following hospitalization are needed for all patients who meet program entry criteria. Early program entry for CAD and cardiac surgical patients is safe and results in positive outcomes.^{32,37,40}

In the future, once more programs achieve national accreditation, researchers will have greater opportunities to objectively compare program outcomes based on services and staffing that are more equitable. Continued support from governing health care organizations as the AHA and American College of Cardiology⁷ are critical in promoting and funding CR research. Access to

sufficient funding to research creative innovative CR programs designed to meet the needs of the 21st Century patient population should be a priority.

Strengths and Limitations

The study was limited to one site; females and minorities were under-represented. Because of the selection bias, it is possible that the positive findings are overstated and the effects of personality and character traits on the outcomes are difficult to determine. Inclusion criteria were carefully defined and patients with serious comorbidities including heart failure, COPD, and other conditions were excluded, while history of diabetes and hypertension were not reported. Baseline differences between groups were statistically controlled; however, it is not known how much the variables in this model were adequate. Another limitation includes reliance on the availability of patient medical records for morbidity outcomes over 10 years following the index event. Following the hospital's conversion to EMR in 2007, 43% of the patient records were no longer available for morbidity follow-up.

The study site program offered a number of features, which may have resulted in the measure of positive outcomes observed. It was an early adopter of automatic referrals and early enrollment, a practice not commonly observed a decade ago^{2,3,41} and now increasingly endorsed.^{7,32,41-43} The providers believed an inpatient referral to outpatient CR for all patients was the best time to capture the interest of patients and families since it was the time when diet education, risk factor management, and exercise were most needed.⁴⁴ In addition to the standard services offered, close communications were maintained between program staff, cardiologists, and primary physicians to ensure prompt reporting and treatment for symptoms and medication issues. Since early 2000, the study site program continued to maintain over a 90% referral rate to CR, a rate well above the 30% to 50% referral rates obs

erved.^{7,17,43,45,46} The above average referral rate, early enrollment, and certification are program strengths, which ultimately may have contributed to the positive outcomes observed for the CR participants. These findings provide relevant information for the study site program and its providers however; results are not generalizable to other CR programs. A recommendation for a future study includes determining whether an association existed between the number of sessions attended in relationship to mortality and readmission outcomes.

Conclusions

Outcome benefits for a group of patients attending a comprehensive CR program up to 14 years previously were predicted. Early entry into a nationally certified CR program showed a reduction in long-term risk for all-cause mortality, CV-related readmission, and an increase in survival rate for CR participants. Age at the time of the index event, prior cardiac history, and CR participation independently predicted increased survival. Given today's emphasis on health promotion and providing quality interventions that are safe, CR is such a program, which offers long-term survival, and readmission benefits following an acute cardiac event. Finally, based on these findings, health care providers are encouraged to continue referring patients and to urge patients to regularly attend CR until program completion is accomplished.

Author Contributions

Design of the work: HG and AL

Data Collection: HG

Data Analysis and Interpretation: AL and HG

Drafting the article: HG and AL

Critical Revision: HG, AL, HL and MB

Final Approval of Version to be published: HG, AL and MB.

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