Benefits of the First Pritikin Outpatient Intensive Cardiac Rehabilitation Program

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Purpose: Intensive cardiac rehabilitation (ICR) is a comprehensive, medically supervised exercise treatment program covered by Medicare for patients with approved cardiac diagnoses. The aim of this study was to determine the benefits of the first Pritikin outpatient ICR program.

Methods: This retrospective analysis included patients referred to ICR or traditional cardiac rehabilitation (CR) during the first 7 yr (2013-2019) at the first facility to implement Pritikin ICR. Intensive cardiac rehabilitation is composed of 36 education sessions on nutrition, exercise, and a healthy mindset, in addition to 36 monitored exercise sessions that comprise traditional CR. Assessments included anthropometrics (weight, body mass index, and waist circumference), dietary patterns, physical function (6-min walk test, [6MWT] Short Physical Performance Battery [SPPB: balance, 4-m walk, chair rise], handgrip strength), and health-related quality of life (Dartmouth COOP, 36-item Short Form Survey). Baseline and follow-up measures were compared within and between groups.

Results: A total of 1963 patients enrolled (1507 ICR, 456 CR, 66.1 ± 11.4 yr, 68% male, 82% overweight or obese); 1141 completed the program (58%). The ICR patients completed 22 exercise and 18 education sessions in 9.6 wk; CR patients completed 19 exercise sessions in 10.3 wk. ICR resulted in improvements (P < .001 pre vs post) in all anthropometric measures, dietary patterns, 6MWT distance, all SPPB components, grip strength, and health-related quality of life. The improvements in anthropometrics and dietary patterns were greater in ICR than in CR.

Conclusions: The Pritikin outpatient ICR program promoted improvements in several cardiovascular health indices. Critical next steps are to assess long-term health outcomes after ICR, including cardiac events and mortality.

Key words: cardiac rehabilitation • intensive cardiac rehabilitation • Pritikin

Cardiac rehabilitation (CR) is a medically supervised treatment program designed to promote optimal recovery after a cardiac event or procedure and to reduce the risk for future cardiac events in patients with cardiovascular disease (CVD). C Exercise is the central focus of CR, with additional instruction on healthy dietary patterns and lifestyle behaviors that impact cardiovascular risk. Cardiac diagnoses that are approved by the Centers for Medicare & Medicaid Services (CMS) for referral to CR include myocardial infarction, coronary artery bypass surgery, stable angina pectoris, heart valve repair or replacement, coronary angioplasty or coronary stenting, heart transplant, and heart failure with reduced ejection fraction. Cardiac rehabilitation has proven to be beneficial for reducing hospitalizations, rehospitalization, cardiac mortality, all-cause mortality, and improving daily function, depressive symptoms, and quality of life among patients with CVD.

Traditional CR typically includes up to 36 1-hr, supervised, monitored exercise sessions over 12-18 wk. In August 2010, the CMS expanded coverage for CR to include intensive cardiac rehabilitation (ICR) programs, based on demonstrated improvements in specific endpoints, including less progression of coronary heart disease, reduced need for coronary bypass surgery, and reduced need for percutaneous coronary interventions. Intensive cardiac rehabilitation includes all the components of traditional CR plus up to 36 additional 1-hr sessions, for a total of 72 sessions during a period of up to 18 wk.

Three ICR programs have been approved by the CMS; the Ornish Reversal Program, the Pritikin Program, and the Benson-Henry Institute Cardiac Wellness Program at Massachusetts General Hospital. The Pritikin-certified ICR program is a comprehensive lifestyle change program based on three pillars: safe and effective exercise, a healthy eating plan, and a healthy mindset. The Pritikin diet was designed by Nathan Pritikin in 1955 to mimic the diet of the Tarahumara Indians of Mexico, which was high in unprocessed, complex carbohydrates, fiber, and plant sterols and low in fat, cholesterol, and simple sugars. The original Pritikin program began in 1976 as a residential lifestyle change program to reduce the risk of recurrent cardiovascular events. Favorable outcomes of the Pritikin Longevity Center 3-wk residential program included clinically meaningful reductions in CVD risk factors (e.g., 23% decrease in total and low-density lipoprotein cholesterol, 33% decrease in triglycerides).
for triglycerides,18 5.1% for body weight,19 14% for blood pressure,20 and 26% for blood glucose21) and medications to manage those risk factors, as well as reductions in angina, morbidity, and cardiac mortality.22 These improvements formed the basis of the Pritikin outpatient ICR program, which is available nationwide. Heretofore, little was known about the benefits of the outpatient Pritikin ICR program. The objective of this study was to fill this gap in knowledge by assessing the short-term effectiveness of the Pritikin outpatient ICR program on improving CVD risk factors. The primary aim was to assess within-group changes in cardiovascular health metrics and dietary behaviors among patients in ICR; the secondary aim was to compare between-group changes in response to ICR and traditional CR.

METHODS
This was a retrospective, observational study to assess the benefits of the Pritikin outpatient ICR program during its first 7 yr of implementation at the first CR center to offer Pritikin ICR in the nation. Patients who enrolled in ICR or CR at the Washington University School of Medicine/Barnes-Jewish Hospital Heart Care Institute in St Louis, MO, as part of routine clinical care were included in the analysis. The ICR and CR programs were conducted in the same facility and run by the same clinical staff. The predominant factor determining whether patients enrolled in ICR or CR was their insurance plan. Patients whose insurance covered ICR were encouraged to enroll in ICR; the remainder were enrolled in traditional CR. This study was approved by the Washington University in St Louis Institutional Review Board.

TRADITIONAL CR PROGRAM
Patients in the traditional CR program had medical consultations with a cardiac nurse and a cardiologist, completed standardized assessments, and received individualized exercise prescriptions from exercise physiologists. Most patients had nutrition consultations with a registered dietitian, depending on insurance coverage. The primary focus of the program was a series of up to 36 1-hr exercise sessions that were supervised by exercise physiologists and CR nurses and during which the patients had continuous electrocardiogram monitoring. Heart rate and blood pressure were measured during exercise, and self-reported ratings of perceived exertion were recorded after each exercise mode. Several modes of exercise were used during each session and were tailored to patient exercise tolerance, cardiorespiratory fitness (CRF) level, orthopedic limitations, balance, and preferences. Exercise options included recurrent cross-trainers, treadmills, recurrent and upright cycle ergometers, elliptical cross-trainers, upper body ergometers, weight machines, dumbbells, and mats and bars for stretching and balance exercises. Patients were scheduled to attend 2-3 sessions/wk.

PRITIKIN ICR PROGRAM
Pritikin ICR is composed of the same exercise regimen and components as traditional CR. The distinguishing feature is an additional series of 36 Pritikin education sessions that address healthful eating, regular exercise, and healthy mindset. The education sessions were held on the same days as the exercise sessions, resulting in a 2-hr ICR visit composed of exercise plus education; two to three visits were scheduled each week. Pritikin education sessions are standardized, focus predominantly on nutrition, and consist of up to 36 videos, as well as cooking classes and nutrition workshops led by registered dietitians. Video topics include healthy eating, dining out, weight control, grocery shopping, hypertension, heart disease, metabolic syndrome, body composition, exercise, blood lipids, sleep, yoga, smoking cessation, stress management, and other topics related to heart health. The Pritikin diet emphasizes unprocessed foods that are high in fiber and low in fat, cholesterol, added sugars, and sodium. All ICR patients met with a registered dietitian; specific dietary recommendations were individualized based on patient comorbidities, weight classification, and personal goals.

ASSESSMENTS
Patients completed baseline assessments during the first visit and follow-up assessments after 24 visits, in accordance with the clinical protocol at this CR facility. Standardized assessments included anthropometrics, CRF, physical function, and questionnaires.

Anthropometric measurements included height with a wall-mounted stadiometer and body weight with a digital scale. Body mass index (BMI) was calculated to determine weight classification23; underweight (<18.5 kg/m²), healthy/normal weight (18.5-24.9 kg/m²), overweight (25.0-29.9 kg/m²), or obese (≥30.0 kg/m²). Waist circumference was measured at the superior border of the iliac crest over a single layer of clothing.

The 6-min walk test (6MWT)24 was used as an estimate of CRF, based on the distance traveled in 6 min. Higher values reflect greater walking velocity and higher CRF. Patients were instructed to walk briskly on an oval, indoor track at a consistent pace, stopping only if necessary. The number of laps completed and the precise stopping location were used to calculate the distance traveled.

The Short Physical Performance Battery (SPPB)25 includes three functional tests, each with a score ranging from 0 to 4: balance (standing with feet side-by-side, semi-tandem, and full tandem), walking velocity during a timed, 4-m walk, and chair rise (ability to rise from a chair five times within specified time limits). Higher scores reflect greater functional ability; the total score ranges from 0 (unable to complete any of the three tests) to 12 (reflecting the best score on all three tests). Grip strength is an important biomarker that reflects whole-body strength and health status and is predictive of mortality.26 Grip strength was assessed with a Jamar handheld dynamometer while the patient was seated with arms straight down at their sides. Three repetitions were completed on each hand, with rest between. The highest value was used for analysis.

Rate Your Plate is a 24-item questionnaire27 recommended by the American College of Cardiology to assess dietary patterns. Respondents choose A, B, or C for each food category to describe the way they usually eat; the corresponding point values are 3, 2, and 1, respectively, for a total score ranging from 24 (worst) to 72 (best). Higher scores reflect more healthful eating patterns. Three score ranges were assessed: 24-40 (“there are many ways to make eating habits healthier”), 41-57 (“there are some ways to make eating habits healthier”), and 58-72 (“many healthy choices”).

The Dartmouth COOP General Health Questionnaire28 asks respondents to rate nine items (physical fitness, feelings, daily activities, social activities, pain, change in health, overall health, social support, and quality of life) during the past 4 wk using a 5-point scale; 1 reflects the best health and 5 reflects the worst for each item. The total score ranges from 9 (if all responses are “1”) to 45 (if all responses are “5”). A lower score reflects better health.

The 36-item Short Form Survey (SF-36)29 asks respondents to rate their health status in eight domains: physical functioning, role limitations due to physical health problems, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, bodily
pain, and general health. Domain scores range from 0 (poorest health) to 100 (most favorable health).

**STATISTICAL ANALYSES**

Baseline characteristics were compared between groups using χ² tests or Fisher’s exact test for categorical variables. The distribution of continuous variables at baseline was examined via histograms. Continuous variables were reported as mean ± SD or as median (IQR) for data that were not normally distributed and compared between groups using Student’s t test or the Wilcoxon test. Within-group changes in response to ICR and CR were assessed by paired Wilcoxon tests or paired t tests for continuous variables and by McNemar’s test for categorical variables. Correlations between change in body weight and change in 6MWT distance were assessed using Spearman correlation coefficients. Between-group changes relative to baseline were assessed univariately by two-sample Wilcoxon tests or t tests for continuous variables and by χ² tests for categorical variables. In addition, changes in anthropometric measures and 6MWT distance were tested using a multivariate regression model, controlling for sex, age, and baseline BMI category (for 6MWT). To determine whether men and women responded differently, a sex-by-group (ICR vs CR) interaction was tested. Significance was accepted at P < .05. Analyses were performed using R version 4.0.3.

**RESULTS**

Our sample included 1963 patients enrolled in CR from April 2013 through December 2019: 1507 patients (77%) were in the ICR program and 456 patients (23%) were in traditional CR. The proportion of ICR patients relative to the overall sample each year ranged from 63-87% during the 7 yr in the analysis. As shown in Table 1, the majority of patients were male, White, and non-Hispanic; 95% did not smoke. The ICR group was older, less racially diverse, and had higher systolic blood pressure than the CR group, but there were no significant differences between groups in BMI, physical function, dietary patterns, or quality of life at baseline. The most common cardiac diagnoses for referral to CR were coronary angioplasty/stenting in the ICR group and coronary angioplasty/stenting and heart failure in the CR group (Table 1).

**PROGRAM COMPLETION**

A total of 1141 patients (58%) completed ≥24 visits and/or follow-up assessments (59% of ICR, 55% of CR patients, P = .092 between groups). The ICR patients completed more exercise sessions than CR patients (22 [11, 36] vs 19 [8, 35]; P < .001 between groups). The ICR group also attended 18 (8, 33) education sessions, for a total of 41 (21, 70) sessions. The ICR patients completed the program in less time than CR patients (9.6 [8.3, 12.0] wk vs 10.3 [8.4, 13.7] wk, P = .006 between groups). Among completers, 95% of ICR and 83% of CR patients completed ≥24 sessions (P < .001). Completers were older than dropouts (68 vs 64 yr, P < .001) and a higher proportion of men than women completed the program (60 vs 54%, P = .01). Reasons for attrition included schedule conflicts, transportation difficulties, return to work, transition to exercise facilities without medical oversight, insurance plans that approved <24 sessions, comorbidities, hospitalization, death, or dissatisfaction with the program. Attrition did not differ by referral diagnosis.

**ANTHROPOMETRICS AND PHYSICAL FUNCTION**

The majority of patients were categorized as overweight (38%) or obese (44%) at baseline, with 18% in the healthy weight range and no difference between groups (P = .326).

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**Table 1**

Demographic and Baseline Characteristics of Patients Enrolled in ICR or CR, 2013-2019

| Value          | All (N = 1,963) | ICR (n = 1,507) | CR (n = 456) | P Value |
|----------------|-----------------|-----------------|--------------|---------|
| Sex, male      | 68              | 69              | 68           | .817    |
| Race, Black/White/other | 13/85/2        | 12/86/2        | 15/80/5      | .002    |
| Ethnicity, Hispanic | 1              | 1               | 1            | 1.00    |
| Age, yr        | 66.1 ± 11.4     | 66.9 ± 10.9     | 63.6 ± 12.5  | <.001   |
| Resting heart rate, bpm | 75.6 ± 13.9    | 75.2 ± 13.7     | 77.1 ± 14.6  | .070    |
| Resting systolic BP, mm Hg | 125.5 ± 16.5   | 126.4 ± 16.1    | 122.0 ± 17.2 | <.001   |
| Resting diastolic BP, mm Hg | 72.5 ± 10.2    | 72.4 ± 10.1     | 72.8 ± 10.4  | .525    |
| Referral Diagnoses, Coronary angioplasty/stenting | 51             | 55              | 38           | .001    |
| Coronary artery bypass grafting | 19            | 22              | 12           | .011    |
| Heart failure  | 26              | 22              | 38           | <.001   |
| Heart transplant | 1              | 1               | 1            | 1.00    |
| Heart valve repair/replacement | 20           | 21              | 17           | .268    |
| Myocardial infarction | 28            | 29              | 23           | .184    |
| Stable angina  | 5               | 5               | 5            | 1.00    |

Abbreviations: BP, blood pressure; CR, cardiac rehabilitation; ICR, intensive cardiac rehabilitation.

**Notes:** Data are reported as % of sample or mean ± SD.

1 Race and ethnicity were known for 73% of the sample (76% ICR and 64% CR).

2 Referral diagnoses exceeded 100% because some patients had more than one qualifying diagnosis; diagnoses were known for 31% of the sample (32% ICR and 30% CR).

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Body weight and BMI decreased significantly in ICR, but not in CR, with significant differences between groups (Table 2). Figure 1 displays the weight changes by group and BMI category. Of the patients with obesity at baseline, the median weight changes were $-2.2$ kg ($-3.9$, $0.0$) in ICR and $-0.1$ kg ($-2.5$, $2.0$) in CR; 10% of ICR patients with obesity at baseline (31/305) transitioned to overweight status; 7% of patients with overweight (20/289) transitioned to healthy weight. The corresponding values in CR were 6% (4/72) from obese to overweight and 6% (5/77) from overweight to healthy weight. In a multivariate regression model, ICR and male sex were significant predictors of a greater decrease in BMI. The interaction between group (ICR or CR) and sex was not significant.

The 6MWT distance increased significantly in ICR and CR, with no differences between groups (Table 2), between men and women ($P = .308$), or by BMI category at baseline ($P = .578$, Figure 1). There was not a significant correlation between change in body weight and change in 6MWT distance in either group (ICR: $r = -0.001$, $P = .982$, CR: $r = -0.070$, $P = .492$). Grip strength increased significantly in ICR only (Table 2). All SPPB scores improved; 331 patients increased their sum score (41% of ICR patients, 39% of CR patients, $P = .288$ between groups, Figure 2). The proportion of patients who achieved the highest SPPB sum score of 12 increased from baseline to follow-up in both groups (53 to 71% of ICR patients, 50 to 70% of CR patients, both $P < .001$).

**DIETARY PATTERNS AND HEALTH-RELATED QUALITY OF LIFE**

The Rate Your Plate questionnaire revealed greater improvements in ICR than CR (Table 2). As shown in Figure 3, 46% of ICR patients and 30% of CR patients improved categories, resulting in 73% of ICR patients and 53% of CR patients being in the highest category at follow-up. The Dartmouth COOP General Health Questionnaire revealed significant and comparable improvements in ICR and CR (see the Supplemental Table, available at: http://links.lww.com/JCRP/A389). All SF-36 domains improved in ICR; six of the eight domains improved in CR. The improvements in energy/fatigue and general health subscales were greater in ICR, but all other subscales improved comparably in the two groups. The proportion of patients who achieved the best score of 100 on the subscale “role...
DISCUSSION

This study assessed the benefits of the first 7 yr of the first-ever Pritikin outpatient ICR program. Our major findings are that Pritikin ICR produced favorable improvements in body weight, weight classification, waist circumference, dietary patterns, CRF, physical function, and health-related quality of life. The improvements in weight, BMI, and dietary behaviors were modestly but statistically greater in ICR compared to traditional CR. Evaluation of cardiac outcomes will be important to determine whether ICR has greater long-term clinical benefits than traditional CR.

An encouraging finding of our study was that ICR patients completed more visits, more exercise sessions, and more total sessions than traditional CR patients, despite the additional time and effort required (ie, 2-hr visits composed of exercise plus education sessions for ICR vs 1-hr visits composed of an exercise session for CR). This finding is clinically important because CR participation has been shown to promote favorable health outcomes in a dose-dependent manner.6,30,31 Based on a national sample of 601,099 US Medicare beneficiaries with qualifying cardiac conditions in 1997, Suaya et al30 reported that CR users...
had a 21-34% lower mortality rate compared to nonusers during 5 yr of follow-up, while users who attended ≥25 sessions had 19% lower mortality compared to users who attended ≤24 sessions. An analysis by Hammill et al. of 30,161 Medicare beneficiaries in 2000-2005 highlighted the dose-dependent reductions in all-cause mortality and myocardial infarction for attending 36 CR sessions versus 24, 12, or 1 session. The most striking result was that patients who attended 36 sessions had a 47% lower risk of death and 31% lower risk of myocardial infarction during 4 yr of follow-up compared to patients who attended only one session. Importantly, each additional CR session was associated with a 1% decrease in mortality in a prospective study of 5886 patients who underwent cardiac catheterization in Alberta, Canada, in 1996-2009. The well-documented, unequivocal benefits of CR have spurred national and international initiatives to increase enrollment in and completion of CR programs. The Million Hearts Initiative aims to increase national participation to 70% of qualifying diagnoses by the yr 2022. Nationally, only 24.4% of 366,103 eligible Medicare beneficiaries in 2016 participated in CR; of those, only 26.9% completed 36 sessions. The rationale for ICR is that the additional sessions will confer greater risk reduction than traditional CR.

Important benefits of ICR in our study were reductions in body weight, BMI, and waist circumference, with fewer patients being categorized as obese at follow-up. The potential clinical implications of these results are supported by a recent review by Ades and Savage, which highlights the importance of treating obesity in CR programs. The improvement in BMI in the ICR group was modest (from 29.0 to 28.5 kg/m²) after ~9.6 wk. In comparison, Katzenberg et al. reported a change from 26 to 25 kg/m² in 104 participants after a 12-wk community-based ICR program. Mirman et al. reported a BMI change from 27.8 to 26.6 kg/m² among 199 participants in a 9-wk ICR program, and Silverman et al. reported a BMI decrease from 33.3 to 31.2 kg/m² among 2633 patients at 24 sites after 12 wk of a comprehensive CR program. Of clinical importance, 51 ICR patients in our study transitioned from obese to overweight or from overweight to healthy weight.

As highlighted in a recent review, intensive nutrition interventions in CR programs have important benefits on dietary patterns, weight, BMI, CVD, and mortality. Consistent with the Pritikin ICR program, recommended components of intensive nutrition interventions include individualization, additional nutrition sessions, cooking demonstrations, and a cardioprotective diet composed of wholesome, natural, predominantly plant-based foods. The educational videos, nutrition classes, and lifestyle strategies that comprise Pritikin ICR likely contributed to the beneficial dietary changes and decreases in weight and BMI observed in our study. Similarly, the Ornish Heart Disease Reversing Program resulted in significantly greater improvements in dietary patterns, weight, BMI, and several other CVD risk factors compared with traditional CR.

Most physical function measures improved comparably in our ICR and CR groups, which is not surprising because the exercise prescriptions, modes, and staff were the same across groups. Consistent with the increases in 6MWT distance in our study, the multisite study of comprehensive CR programs demonstrated a significant improvement in functional capacity, from 8.5 to 10.4 METs (metabolic equivalents) on a treadmill test, after 12 wk. These improvements are clinically meaningful because higher CRF is associated with lower risk for major adverse CVD events and mortality.

A strength of our pragmatic study is the relatively large sample of patients enrolled in ICR during the first 7 yr at the first Pritikin outpatient ICR program. Limitations include the nonrandomized, retrospective design, attrition from both ICR and traditional CR, lack of follow-up data on patients who did not complete the program, and lack of long-term outcome data. Additionally, performing follow-up assessments at visit 24 may have blunted the beneficial effects observed (ie, more favorable changes may have been observed after 36 visits) and/or skewed the completion statistics (ie, patients who left the program between visits 24 and 36 were categorized as completers in our analysis).

In summary, we observed that the Pritikin outpatient intensive CR program resulted in improvements in anthropometric measures, dietary patterns, CRF, physical function, and health-related quality of life. These results support the value of the Pritikin ICR program for individual patients and potentially for the health care system. The longer-term benefits of Pritikin ICR on CVD events and mortality will be important to explore in future studies.

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