Published in final edited form as:
J Cardiopulm Rehabil Prev. 2011 November ; 31(6): 333–341. doi:10.1097/HCR.0b013e31822f0f79.

Clinical Research in Cardiac Rehabilitation and Secondary Prevention: Looking Back and Moving Forward

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Abstract

Cardiac Rehabilitation/Secondary Prevention (CR/SP) programs are considered standard of care and provide critically important resources for optimizing the care of cardiac patients. The objective of this paper is to briefly review the evolution of CR/SP programs from a singular exercise intervention to its current, more comprehensive multifaceted approach. Additionally, we offer perspective on critical concerns and suggest future research considerations to optimize the effectiveness and utilization of CR/SP program interventions.

Key words or phrases

Cardiac rehabilitation; Secondary prevention; Research considerations

Coronary heart disease (CHD) is the leading cause of death and premature disability in the U.S. and is responsible for 17% of national health expenditures.[1] Both the prevalence and costs of CHD are projected to rise substantially in the future.[2] Coronary heart disease, if left untreated, is a progressive disease and individuals with CHD are at high risk for recurrent events.[1] Cardiac Rehabilitation/Secondary Prevention (CR/SP) programs provide important resources for optimizing the acute and chronic care of patients with CHD.[3] In fact, CR/SP services are considered standard of care and patient participation has been incorporated into numerous major practice guidelines.[4,5]

While the breadth of CR/SP programs are expansive and the benefits are compelling and numerous, challenges and opportunities remain. Historically, the delivery of CR/SP services has evolved, primarily, as results of evidence-based, patient-oriented research. Clinical research has provided the empirical evidence that CR/SP programs are a safe and effective means to improve outcomes in patients with CHD. The objective of this paper is to briefly review the evolution of CR/SP programs from essentially a singular intervention (exercise training) to its current, more comprehensive multi-faceted approach. Furthermore, we offer perspective on critical concerns and suggest future research considerations to optimize the effectiveness and utilization of CR/SP interventions.

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History and Evolution of Cardiac Rehabilitation

The care of patients who experience a cardiac event has evolved dramatically over the last century.[6] In the 1930s, patients with myocardial infarction were advised to observe 6 weeks of bed rest. Physical activities, while sitting in a chair, were introduced in the 1940s. In the 1950s, 5 minutes of daily walking was advocated after 4 weeks of convalescence. Inpatient cardiac rehabilitation programs were first developed in the 1960s when clinicians gradually began to recognize that early ambulation avoided many of the complications of bed rest. At this time, a methodology for a more comprehensive, multidisciplinary approach to the rehabilitation of patients recovering from an acute cardiac event was first proposed.[7]

Contemporary cardiac rehabilitation began in the early 1970s, when exercise programs were extended beyond hospital discharge to highly structured, physician supervised, electrocardiographic-monitored, exercise programs.[8,9] The focus of cardiac rehabilitation programs was almost entirely on exercise training to reverse the physical decline that resulted from extended bed rest. During the 1980s cardiac rehabilitation evolved from a singular exercise intervention to a more comprehensive, multifaceted, medical and lifestyle modification model. In 1994, the American Heart Association (AHA) declared that cardiac rehabilitation should not be limited to an exercise training program but also should include multifaceted strategies aimed at reducing modifiable risk factors for CHD.[8,9] Based on a comprehensive, systematic review of the scientific evidence, the first Clinical Practice Guidelines for Cardiac Rehabilitation, sponsored jointly by the Agency for Health Care Policy and Research and the National Institutes of Health, broadened the scope of cardiac rehabilitation programs to include the assessment and modification of risk factors.[10] This seminal document concluded that cardiac rehabilitation preventive services are an essential component of the management of patients with CHD. The Clinical Practice Guidelines provided the scientific evidence to broaden the scope of cardiac rehabilitation programs to provide a comprehensive approach to assessment and modification of risk factors. Thus, current programs function and are often referred to as secondary prevention centers.[10] As such, the aims of CR/SP programs are to optimize cardiovascular risk reduction, promote adoption and adherence to healthy behaviors, enhance emotional well-being, reduce disability, and promote an active lifestyle for patients with CHD.[11]

Studies have shown that CR/SP programs play a critical role in acute and chronic care of patients with CHD and have demonstrated powerful mortality and morbidity benefits. There is significant evidence confirming that aggressive and comprehensive secondary prevention increases survival, reduces recurrent events and the need for interventional procedures and improves quality of life.[12] Based upon meta-analysis of randomized control trials, the mortality reduction with exercise based rehabilitation is estimated at 27 %,[13] which is comparable to the effects of our most potent pharmacologic agents.[14] The evolution of CR/SP programs has occurred primarily as a result of evidence-based research as our understanding of the atherosclerotic process and the role of risk factors has advanced. Interventions currently employed in CR/SP programs are specifically aimed at slowing or reversing the progression of CHD[15] and reducing cardiac events.[12,16] In fact, it has been demonstrated that CR/SP programs and medical treatments of CHD risk factors are superior to percutaneous coronary interventions in appropriately selected patients in preventing subsequent cardiovascular events and improving exercise tolerance.[17]

Expansion of Services

In the 1970s, participation in outpatient CR/SP programs was essentially limited to males under 65 years of age with a diagnosis of an uncomplicated myocardial infarction or coronary bypass surgery. Irrespective of age or gender, participants in CR/SP programs now include patients with the following heart-related medical conditions: acute myocardial

infarction, coronary artery bypass grafting, chronic stable angina pectoris, percutaneous coronary intervention, chronic heart failure, heart transplant, valvular surgery and arrhythmias.[18] Ideally, for all patients, the care-continuum approach includes comprehensive CR/SP services that begin during hospitalization and transition to the outpatient setting. Present day CR/SP services are multifaceted and multidisciplinary and include, but are not limited to: exercise training, counseling, education, risk factor modification, and psychosocial and nutritional interventions.

Core Components of Care and Measuring Patient Outcomes

The AHA and American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) recognize that all CR/SP programs should contain specific core components that aim to optimize cardiovascular risk reduction, foster and encourage compliance with healthy behaviors, reduce disability, and promote an active lifestyle for patients with CHD. Core components include: (1) patient assessment, (2) nutritional counseling, (3) weight management, (4) blood pressure management, (5) lipid management, (6) diabetes management, (7) tobacco cessation, (8) psychosocial management, (9) physical activity counseling, and (10) exercise training.[11] Within each of these core components, there are specific recommendations relative to that component for evaluation, interventions, and expected outcomes. The intent is to assist CR/SP professionals to design programs with protocols that are inclusive of the comprehensive services that are known to be effective at improving cardiovascular health and reducing the adverse affects of CHD, including morbidity and mortality.

An essential element of developing programs for the optimal treatment of individuals participating in CR/SP programs is the measurement of clinical outcomes. Randomized controlled trials are the gold standard for hypothesis testing but require significant resources and are likely beyond the capacity of most CR/SP programs. Conversely, measurements generated from clinical experience contribute valuable data about program effectiveness and the continuous process of quality improvement. High quality observational data, generated from “real-life” clinical experience, provide important information to help guide the treatment of patients and aid with program development.

On an individual basis, outcome data document patient progress towards achieving cardiovascular risk reduction. Cumulatively, such data provide information on program strengths and weaknesses in delivering services designed to help patients achieve cardiovascular risk-reduction goals. The critical analysis of the data that result from measuring the effectiveness of program interventions is the fundamental component of outcome research. The dissemination of outcome generated results in the form of research provides programs the opportunity to share information about the effectiveness of interventions and pursue quality improvement initiatives when indicated. Increasingly, there are different opportunities available for programs to share the results generated through the outcomes process. Collaborations between programs[19,20] and regional outcome projects[21-23] have demonstrated the ability of programs to collect data, analyze and report results. Furthermore, efforts are underway, spearheaded by AACVPR, to establish a national CR/SP Registry that individual programs will be able to contribute to in the future. Whether individually or collaboratively, gathering and reporting results generated through the outcomes evaluation process will ultimately lead to the development of interventions for the optimal treatment of CR/SP program participants.

Enhancing Referral to and Enrollment in Cardiac Rehabilitation

Despite its proven benefits, CR/SP programs are substantially underutilized. According to data of Medicare beneficiaries from 1997, only 14% and 31% of individuals following a

myocardial infarction and coronary artery bypass surgery, respectively, enrolled in CR/SP programs.[24] This is particularly troubling as attending a singular session was sufficient to have been considered enrolled. A major factor contributing to underutilization of CR/SP services is that many qualifying patients are not referred. In a recent analysis from the AHA's *Get With the Guidelines* (GWTG) program, only 56% of eligible individuals were referred to CR/SP programs prior to hospital discharge.[5] Older individuals and those with most medical comorbidities were less likely to be referred to CR/SP programs.[5] More troubling, the proportion of eligible individuals referred to CR/SP was lower than the proportion receiving other proven therapies such as aspirin use (98%), beta-blocker use (93%), and angiotensin converting enzyme inhibitor or angiotensin receptor blocker use (84%), suggesting that physician awareness of the importance of CR/SP services lags behind that of other proven therapies.[5]

Referral of eligible patients is a necessary first step to enrollment in a CR/SP program. Therefore, researchers have focused on increasing the number of eligible patients who are referred to CR/SP programs prior to hospital discharge. Quality improvement projects that track physician compliance with established treatment recommendations may improve practice habits. Accordingly, recommendations have been put forth that referral to CR/SP services should be a performance measure.[25] Referral to CR/SP programs is currently endorsed as a quality improvement measure by the National Quality Forum, which endorses national consensus standards for measuring and publicly reporting on performance in healthcare delivery.

There is evidence that use of the established clinical pathway associated with GWTG results in improvements in referral to and enrollment in CR/SP programs.[26] Patients on the GWTG clinical pathway had a 2.3 higher odds of obtaining a CR/SP program referral prior to hospital discharge than individuals not on the pathway. Despite increased referral, however, enrollment rates remained low as only 19% of eligible patients ultimately participated in a CR/SP program.[26]

An additional proven method to increase participation is the utilization of an automated computerized referral process of all eligible patients to CR/SP programs prior to hospital discharge. Automatic referral resulted in enrollment rates to as high as 43 to 73%.[27-31] Automatically referring eligible patients is not, in and of itself, an adequately comprehensive intervention. In 1 study, 26% of individuals who were referred to a CR/SP program prior to discharge but did not subsequently enroll reported that they did not recall being referred.[26] Contacting patients with a followup phone call shortly after discharge increased the proportion of individuals who ultimately enrolled in a CR/SP program by 50-80 %.[32,33] In a randomized trial of several referral strategies, the combination of automatic referral followed by a discussion between a health care liaison and the patient about the benefits of CR/SP resulted in the highest enrollment rates.[34]

An emerging challenge for CR/SP providers is to meet the needs of an increasingly diverse society. Currently, over one-third of U.S. residents identify themselves as a racial or ethnic minority and this proportion continues to grow.[35] Unfortunately, minority status predicts lower CR/SP program participation rates. In a study of Medicare patients, Suaya et al[24] described significantly greater participation rates in whites than in non-whites (19.6% vs 7.8%). Similarly, in a nation-wide survey of 500 randomly chosen CR/SP programs, Thomas et al[36] also found significantly higher participation rates in whites compared to minorities. Integration of diverse sociodemographic populations in CR/SP programs is essential not only for ethical considerations but also because cardiovascular disease is more prevalent in blacks and Hispanics[37-39] and persons of low socioeconomic status.[40] Higher

prevalence of cardiac disease in those least likely to utilize CR/SP services underscores the importance of processes to identify, recruit and accommodate underserved populations.

It has been well described that women, ethnic minorities, older individuals, and patients with multiple comorbidities are less likely to be referred to and enroll in CR/SP programs.[5,24,41] While there has been little research investigating methods to increase participation in these traditionally underserved groups, there is some evidence that programmatic changes may enhance CR/SP program utilization among woman. For example, females randomized to women-only CR/SP program attended more sessions[42] and had greater improvements in quality of life scores[43] and depressive symptoms[44] than their counterparts who were randomized to traditional, nongender-tailored programs. Similarly, alternative programmatic changes should be considered to encourage greater participation in other underserved populations.

Future Research Considerations

CR/SP Program Referral, Enrollment and Long-term Adherence

Despite heightened awareness and the employment of interventions such as automatic referral, CR/SP program participation remains underutilized, especially among certain patient populations. Reasons for not attending CR/SP are numerous and involve physical and personal barriers including competing work and family obligations, lack of transportation, suboptimal social support, inadequate insurance coverage and financial concerns.[5] While further research (Table 1) is necessary to determine how to increase overall CR/SP program participation, particular effort needs to be directed toward traditionally underserved populations. Targeting care based on demographic data and outcomes serves to promote research of cultural competency in CR/SP services and allows providers to focus on population-specific strategies to enhance participation and client satisfaction. Once providers identify underserved populations and respective barriers to participation are better understood, interventions to improve culturally-sensitive patient-centered care and their consequences can be measured.

Efforts also need to be directed toward improving patient retention and adherence to treatment. Studies have demonstrated that the benefits derived from CR/SP program participation are dose-related with a greater number of sessions attended resulting in better outcomes.[46,47] Yet, evidence suggests that adherence to preventive strategies is unacceptably low.[48,49] Moreover, as presently constituted, CR/SP services are a relatively short-term intervention and extending services to patients may improve outcomes. For example, the GOSPEL Study[50] demonstrated that the integrated, multifactorial approach of CR/SP services improved cardiovascular outcomes and is effective in promoting the long-term management of CHD risk factors. Moreover, the CR/SP intervention increased compliance with pharmacotherapy and lifestyle habits. Providing patients the opportunity to participate in long-term, maintenance programs may improve adherence with preventive therapies and needs to be investigated further.

Programming for Special Populations and Chronic Disease Management

The demographic characteristics of participants enrolling in CR/SP programs are changing dramatically[51] and studies are needed to determine how best to address the challenges presented by an increasingly diverse patient population. For example, participants in CR/SP programs are increasingly older and less aerobically fit. Alternatives to current interventions that specifically target individuals with diminished strength and cardiovascular fitness need to be considered and tested.

High psychological symptoms and disorders are a prevalent condition among patients with CHD and are negatively impact on prognosis.[52] While CR/SP program participation is associated with reductions in depressive symptoms.[44,52] it remains unclear as to what extent the health benefits of exercise training can be attributed to improving psychosocial stress. Additional study is needed to determine how best to treat CR/SP program participants with high levels of psychosocial distress.

Overweight is a highly prevalent condition in CR/SP programs with nearly half of participants classified as obese.[51] Despite the status as an independent risk factor for CHD, debate persists, about the relative benefits of weight loss. Derived primarily from observational data, the “obesity paradox” suggests a potential survival benefit of overweight in selected populations.[53] Studies of purposeful weight loss in the CR/SP setting, however, report a beneficial effect on CHD risk factors[54] and survival.[55] A prospective, randomized study is needed to clarify the feasibility and impact of weight loss in CR/SP programs.

Meeting the complex needs of patients with chronic illness or impairment presents enormous challenges. Cardiac rehabilitation/SP programs have demonstrated proven results that effective disease management programs can achieve positive patient outcomes. Cardiac rehabilitation/SP professionals have extensive experience in developing exercise training programs for patients with a multitude of chronic diseases. The knowledge and experience gained from developing treatment programs for the most complex individuals provide CR/SP programs with opportunities to expand service beyond the traditional patient population. Medical conditions that may benefit from a comprehensive lifestyle intervention similar to that which has been delivered by CR/SP programs include insulin resistance/metabolic syndrome, diabetes mellitus, chronic kidney disease, breast and colon cancer, cognitive impairment, overweight, sarcopenia, osteoarthritis, osteoporosis, peripheral vascular disease, stroke, and chronic heart failure. Additionally, children and young adults with congenital or other cardiac abnormalities have historically not been considered but would likely benefit from CR/SP services. Measuring and reporting outcomes for these disparate patient populations will be critical in developing optimal treatment programs.

Alternative Models for the Delivery of Services

Multiple models for the delivery of CR/SP services have been employed. These models differ, for example, with regard to the program frequency and duration, on-site versus remote monitoring and supervision, the focus of interventions provided, utilization of kiosk or computer-based coordinated programs, and patient care coordinated through nurse case-management.[15,56-62] The financial cost and expectations of program participants differ significantly between programs. The relative benefits of the different models for delivering services should be compared directly so as to provide patients with the best treatment options available in the most economical fashion.

Developing Exercise Prescription to Target Specific Outcomes

The fundamentals of the exercise prescription commonly used in CR/SP programs, while individualized, is essentially the same for all participants, irrespective of age, gender, body composition, diagnosis or other demographic characteristics. Alternative strategies including exercise performed at a higher intensity[63] or with increased frequency and duration[54] have demonstrated promising results. Studies have also demonstrated the effectiveness of water-based[64] and Tai Chi exercise,[65] along with circuit[66] and resistance training[67,68] in improving physical function, particularly in individuals with diminished functional capacity and the elderly. Further study is indicated to determine the benefits and risks of alternative designs to the traditional exercise prescription.

Education and Technology

Education in the CR/SP setting has traditionally been delivered through individual counseling and group lecture format. There has been very little study of the effectiveness of the education provided in increasing patient knowledge or altering behavior and improving self-efficacy. Educating a diverse patient population will presumably become increasingly challenging if efforts to refer and enroll greater number of patients proves successful. There is a significant need to test the effectiveness of the patient education provided in the CR/SP setting.

Evidence suggests that rural patients and patients living a distance from a CR/SP program are less likely to attend and participate in CR. For example, Bittner et al[69] found that referral was twice as likely if the patient lived in a county where a CR /SP facility was located. Cellular and web-based technology may provide opportunities to expand the reach of programs to offer services to patients who heretofore were unable to access CR/SP services.[70] Monitoring patients remotely appears to be safe[71] and use of activity monitors, accelerometers, and global positioning system devices are related to improved patient outcomes.[70,72] Greater utilization of technology, as part of an overall treatment strategy, needs to be explored.

Conclusion

Cardiac rehabilitation/secondary prevention programs have proven to be instrumental at reducing morbidity and mortality and enhancing the physical and emotional well-being in individuals with CHD. Tremendous progress has been made since the inception of modern cardiac rehabilitation in the 1970s. Despite significant advances in the care of patients with CHD, challenges remain. A substantial percentage of eligible patients are not referred to or do not enroll in CR/SP programs, particularly women, ethnic minorities, and individuals with comorbidities. The changing demographics of cardiovascular disease also present challenges to CR/SP program utilization. Alternatives to current employed CR/SP treatment strategies need to be considered and tested with the goal developing interventions that will result in improved outcomes for program participants. As has been the case historically, it is imperative the delivery of CR/SP services continues to evolve in response to results derived from clinical research.

Acknowledgments

Dr. Brown is supported by grant 5KL2 RR025776-02 from the UAB Center for Clinical and Translational Science with funding from the NIH National Center for Research Resources

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Table 1

Future Research Directions in Cardiac Rehabilitation / Secondary Prevention

Referral, Enrollment and Long-term Adherence with Cardiac rehabilitation / Secondary Prevention (CR/SP)	• Enhance all components of referral and enrollment processes. • Target interventions to traditionally underserved populations including: woman, ethnic minorities and persons of low socio-economic status. • Improve patient retention and long-term adherence to treatment.
Programming for Special Populations and Chronic Disease Management to Optimize Clinical Outcomes	• Optimize programming to meet the clinical profiles of CR/SP program participants including: – Elderly – Psychosocial stress – Overweight/obese – Women – Metabolic syndrome / diabetes mellitus – Chronic disease management (peripheral and cerebrovascular disease, chronic kidney and heart disease, cancer and osteoporosis)
Alternative Models for the Service Delivery	• On-site versus remote, home-based monitoring • Utilization of kiosk or computer-based programs • Varying frequency and duration of program • Patient care coordinated through nurse case-management
Developing Exercise Prescription to Target Specific Outcomes	• Alternatives to the traditional exercise prescription include: – Resistance training – Aerobic interval training – Physical activity counseling – Promoting caloric expenditure for weight loss / weight control – Flexibility, Yoga, Tai Chi
Education and Technology	• Remotely monitoring patients to expand services to underserved populations • Web-based technology to monitor progress and provide interventions such as behavioral weight loss and exercise counseling • Use of devices to monitor physical activity such as accelerometers, pedometers, cellular communication and global positioning devices. • Investigate possible alternatives to “lecture” format to deliver patient education