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Editorial

Adding Life to Years in Cardiac Rehabilitation: Importance of Measuring Quality of Life

Jack M. Goodman, PhD,[a,b,c] and Susan Marzolini, RKin, PhD[a,c]

[a] Faculty of Kinesiology and Physical Education, University of Toronto, Toronto, Ontario, Canada

[b] Division of Cardiology, University Health Network/Mount Sinai Hospital, Toronto, Ontario, Canada

[c] University Health Network/Toronto Rehabilitation Institute, Cardiovascular Prevention and Rehabilitation Program, Toronto, Ontario, Canada

See article by Francis et al., pages 352–364 of this issue.

Importance of Improving Quality of Life in Cardiac Rehabilitation

Fifty years ago, Herman Hellerstein published the seminal paper entitled "Exercise Therapy in Coronary Disease," originally presented at the New York Heart Association's Conference on Coronary Heart Disease: Preventive and Therapeutic Aspects. He described the effects of exercise therapy on cardiovascular function in patients with coronary heart disease.[1] Their intervention programme included counselling on nutritional and risk factor management and demonstrated that an exercise intervention was well-tolerated, safe, improved fitness, and reduced both blood pressure and ST-segment depression during exertion. These data helped to establish the importance of what became known as cardiac rehabilitation (CR), now catering to a diverse cohort of patients. Long forgotten was his simple description of the study's purpose: "…to determine whether we could add life to years and perhaps add years to life." Although Hellerstein's primary objective was to demonstrate the physical benefits of CR, the implicit desire to improve health-related quality of life (QOL) was both laudable and fortuitous, as the explicit aim to improve health-related QOL is now recognized as a key objective in numerous interventions. Low psychological well-being and feelings of distress may arise years before the clinical manifestation of cardiovascular disease and it is increasingly recognized that cardiac events may provoke psychological reactions that precipitate psychosocial risk factors including depression and anxiety.[2] However, QOL was only considered a contemporary measure or a "modern endpoint" as late as the early 1990s,[3] approximately 30 years after CR had been established. Despite its late acceptance, groundbreakers including Drs Terence Kavanagh and Neil B. Oldridge were among the first to report changes in QOL outcomes in patients with heart failure, heart transplantation surgery, and myocardial infarction undergoing CR.[4-6]

In this issue of the *Canadian Journal of Cardiology*, Francis et al.[7] report findings from a systematic review that included 41 randomized controlled trials of 11,747 patients to assess the effectiveness of providing any core component of CR (nutritional counselling, risk factor management, psychosocial interventions, patient education, and individualized exercise training) on QOL domains. Study outcomes were measured at the time of entry to CR and after a minimum of 6 months of follow-up.

The collected variables included overall, physical, emotional, and social QOL domains. The overarching findings were that patients receiving CR delivering either exercise, nonexercise, or psychological-based interventions demonstrated improved QOL. Furthermore, positive albeit modest improvements in QOL outcomes were observed in either home, community, or hospital settings. Contrary to a recent summary of systematic reviews,[8] the present finding failed to observe a significant effect of exercise-based CR on QOL, yet non-exercise and psychological-based interventions did. This study offered valuable insights by demonstrating improvements in QOL from psychosocial-only and other nonexercise interventions.

The authors are to be commended for conducting a meta-analysis of a challenging topic. However, although the findings offer important evidence that components of CR lead to modest gains in QOL measures in patients with coronary artery disease, a salient question remains unanswered: can an exercise intervention improve QOL in the same patients? Although this question could not be fully answered, their findings also help to unmask the inherent problems in detecting the change in QOL outcomes within disparate CR programme landscapes and contribute to ideas of how future studies in CR might be strengthened to address key issues surrounding QOL outcomes.

Variations in CR Delivery: What Is the Actual Intervention?

CR has been defined variably by numerous organizations around the globe. It is widely accepted to be a comprehensive

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Corresponding author: Dr Jack M. Goodman, Faculty of Kinesiology and Physical Education, University of Toronto, Goldring Centre for High Performance Sport, 100 Devonshire Place, Toronto, Ontario M5S 2C9, Canada. Tel.: +1-416-978-6095; fax: +1-416-971-2118.

E-mail: jack.goodman@utoronto.ca

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programme designed to improve outcomes that target health behaviour change and education, psychological and psychosocial health, cardiovascular risk management, and specific cardioprotective strategies, including counselling on nutrition and tobacco cessation and, of course, exercise.[9] However, there are vast differences in programme delivery models (home, supervised, mixed, exercise modality), many providing all, parts, or only 1 of these components to an equally diverse population. In Canada alone, there are over 200 CR programmes that reflect this diversity, making the assessment of QOL outcomes difficult, particularly when combined with the multitude of instruments used for assessing QOL. It is no wonder why pinpointing the impact of CR on QOL has been challenging and efforts have produced equivocal if not underwhelming results.

Given the collective variability of the studies included in the present meta-analysis, it is not surprising that when some of these studies were included in the same pooled analysis, heterogeneity was extremely high[10] with an I^2 statistic measuring up to 94%, limiting the validity of a fixed-effects model. In the meta-regression, important sources of variability (eg, country where the intervention took place) were not included as covariates. It was this heterogeneity as well as variability in methods of outcome reporting that likely constrained and prevented Anderson et al.[8] from pooling the effects of 20 exercise-based CR studies that measured QOL with a minimum follow-up time of 6 months.

The inherent challenges of assessing QOL outcomes amongst diverse study designs have, with no fault attributed to the authors' efforts, somewhat limited the generalizability of these findings and underscore why the magnitude of change in QOL reported here and elsewhere, may be modest at best. This is particularly true for their pooled analysis, where a significant proportion of studies included were nontraditional interventions developed with the aim to determine if lower resource-dependent CR programmes (compared with control) would result in acceptable outcomes, access, and/or adherence. These interventions by nature may have been less robust and demanding or may have been delivered by less experienced CR professionals compared with others. For example, 1 study included a single telephone call described as including a "low level of advice" by lay persons to patients after hospital discharge.[11] One other study included an intervention comprising an information manual with 1 consultation visit (1 hour);[12] another provided an interventional manual along with two 1-hour home visits,[13] 1 included a telephone-delivered cognitive behaviour therapy and risk-reduction programme for people with low mood,[14] and another intervention included only 8 phone calls by a nurse in the first 6 months after myocardial infarction with QOL measured 1 year later.[15] It is likely that a similarly wide variation existed when exercise intervention was employed, which would introduce an equally weak experimental rigor when seeking to elicit a favourable change. Other "CR" interventions included lay facilitated angina management; trained lay leaders were people with heart disease and carers of people with heart disease,[16] telephone delivered collaborative care for treating depression,[17] and a goal attainment theory-based education programme.[18] This variation is rife across the CR literature and makes programme comparisons difficult at the best of times.

The duration of CR programmes also varies, and increasingly programme length is driven by economics. Large variations exist within and between publically funded or insurer-supported CR programmes. It remains unclear if changes in QOL are time-variant, but there is evidence that improvements occur rapidly with the greatest change occurring in the first 12 weeks, and before physiological adaptations are observed.[19] The present study, as well as the study conducted by Anderson et al.,[8] limited inclusion to those studies with a minimum of 6 months of follow-up. This would exclude many studies, particularly in the United States, where the typical CR intervention lasts 12 weeks, a trend that is likely to continue.[20]

Collectively, these issues serve to undermine the potential effect size one would expect from well-designed and robust interventions, most of which include exercise. It is our contention, although we remain highly supportive of alternative models of CR care delivery and varying primary interventions, that QOL outcomes be studied separately amongst programmes that either include or exclude exercise interventions, with an aim to more carefully isolate the effects of key CR components.

Can You Have a True Control Group in CR?

It is important to carefully dissect the designs of studies that are included in meta-analyses to ensure a faithful adherence to the inclusion criteria, particularly when reference to a control or comparator group is made. In the present study, "…the comparator (usual care) could include standard medical care, such as drug therapy, but patients could not be randomized to receive CR or any of its core components." On careful examination, this assertion might be challenged. In one study, the "control" condition included home-based CR, whereas the intervention included a family-centred empowerment CR model.[21] In another study, 4 groups were examined from a hospital-based CR, a 6-week home-based nurse-supervised intervention, and 2 additional groups who chose their programme CR type,[22] all of which were considered a CR intervention. Finally, another study recruited women after completion of an outpatient CR programme into either a home walking programme or to a control group.[23] In all examples, no "true" comparator group existed and likely mitigated gains in QOL outcomes for the "exercise group." It is noteworthy that another study directed control subjects (considered to be "usual care") to be sedentary,[24] a strategy that would unlikely meet the standard of "usual care" or be considered ethically viable today. Perhaps that is the price of success: the overwhelming evidence of CR improving key outcomes (including mortality and hospital admission rates) has also greatly limited our ability to design studies optimally, precluding the use of a true "control" group.

Conclusions and Future Directions

The current study conducted by Francis et al.[7] has provided important insights of the impact of CR on QOL in patients with coronary heart disease. Their work highlights the complexity of drawing conclusions from pooled QOL data. We are in full agreement with the authors who call for future studies to become more consistent in assessing and reporting

QOL for optimized comparison across trials. We will step slightly further out on the branch and suggest that the development of a harmonized standard assessment QOL battery be implemented in CR studies. In addition, given the well-established benefits of CR, future studies will need to consider creative ways to construct "control" groups, perhaps by contrasting various "doses" of CR. The potential synergistic effects of the various CR components on QOL remain to be investigated and are no less important than examining physiological outcomes, including the potentially variable effects of emerging exercise modalities such as resistance and high-intensity interval training. Finally, just as precision medicine is rapidly gaining traction, a similar individualized approach might be considered when determining the optimal CR intervention that maximizes QOL outcomes and (hopefully) improves long-term compliance.

Disclosures

J.M. Goodman and S. Marzolini have previously co-authored publications with Dr David Alter.

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