Database support for cardiac rehabilitation

RCT evidence for rehabilitation is strengthened by an observational cohort study

THE STUDY BY SUNDARARAJAN et al[1] (*page 268*) is a novel data linkage study and is best described as a cohort study. The study showed 35% lower mortality in patients with cardiovascular disease who had undergone cardiac rehabilitation when compared with patients who had not undergone cardiac rehabilitation. However, even the best cohort studies can give only limited inference on treatment effects. For example, observational studies suggested that women who used hormone replacement therapy (HRT) had a lower incidence of cardiovascular events than did non-users.[2] However, not only did prospective randomised controlled trials (RCTs) fail to confirm the protective effect of HRT,[3] they suggested that such treatment might actually cause cardiovascular disease.[4] The apparent impressive protection of HRT suggested by observational databases may have been accounted for by socioeconomic differences between the users and non-users of HRT. Thus, RCTs have assumed the strongest evidence in suggesting a relationship between treatment and outcome.

So why does the database linkage study by Sundararajan et al[1] appeal at all? Perhaps it is because the evidence base for cardiac rehabilitation programs fails to convince all medical practitioners, despite "level 1" evidence existing from other studies.[5]

Even the best RCTs have intrinsic limitations. The first is that most trials exclude older, sicker patients with multiple comorbidities and those who might not cooperate with the trial protocol. This often results in a clinical trial of low-risk patients, which may miss a beneficial effect of treatment.

The second limitation of RCTs, more common in single-centre studies, is publication bias. It is hard work to prepare a study for publication — even harder for a negative study than for a positive one. As a result, investigators are less likely to submit negative studies and journal editors are less likely to accept them for publication. Publication bias is likely to exist in most, if not all, areas of published research.

So, what are the limitations of the evidence specifically regarding cardiac rehabilitation? The Cochrane Library review of exercise-based rehabilitation for coronary heart disease reviewed 51 RCTs of 8440 patients.[5] Total cardiac mortality was reduced by 31% (random effects model odds ratio [OR], 0.69; 95% CI, 0.51–0.94) and 26% (random effects model OR, 0.74; 95% CI, 0.57–0.96) in the exercise-only and comprehensive cardiac rehabilitation groups, respectively. Neither intervention had any effect on the

occurrence of non-fatal myocardial infarction. In other words, exercise that did not affect cardiac risk factors was as effective in reducing cardiac mortality as a comprehensive program that included exercise and successfully reduced cardiac risk factors. The reasons for this are unclear given the level 1 evidence supporting the proven effects of lowering blood pressure[6] or serum cholesterol[7] in reducing cardiac mortality. Furthermore, one has to be currently active to experience the benefit of physical activity or fitness — loss of activity and fitness means loss of the protection of exercise. So, medical practitioners can have reasonable doubts about the protective effects of a 6- or 8-week cardiac rehabilitation program on cardiac mortality years after the event, despite the Cochrane evidence.

And this is why the data linkage article by Sundararajan et al appeals.[1] The clinical trial data in the Cochrane review were derived from selected patients who had undergone exercise training for periods varying from a few weeks to several years. Sundararajan et al show that Australian patients with coronary heart disease who had undergone cardiac rehabilitation for 6–8 weeks had a better survival rate than did patients not undergoing cardiac rehabilitation. Although the study may be fraught with problems similar to those described for the HRT studies, it is pleasing to note how similar is the magnitude of protection from death associated with cardiac rehabilitation in this Australian series compared with that described in the Cochrane review. This observational study lends strong support to the trial information. Patients surviving an acute coronary syndrome should be referred for cardiac rehabilitation, as the experience may save their life.

There is another nugget in the article by Sundararajan et al.[1] Patients with acute coronary syndromes not undergoing coronary artery bypass surgery are very much less likely to undergo cardiac rehabilitation than patients who have received surgery. Percutaneous cardiac intervention is now performed twice as often as cardiac surgery. Such patients are often younger and fitter and return to work and their usual life within days of their procedures. Alternative models of rehabilitation are required for these patients who have not been physically deconditioned. These were recently discussed in this journal by Scott et al.[8] One such model is the COACH Program, which has been validated by two RCTs.[9,10]

The COACH Program is a training program for patients with coronary heart disease, in which a healthcare professional coach trains patients to aggressively pursue the target levels for their particular coronary risk factors while working in partnership with their own doctors. The COACH Program has been shown to have a favourable effect on many coronary risk factors, including total and low-density lipoprotein cholesterol, arterial blood pressure, dietary saturated fat intake, body weight, and the performance of regular walking.[8,9] If patients do not attend cardiac rehabilitation, then alternative strategies for achieving secondary prevention are required. The COACH Program is one such effective method.

In summary, the evidence supporting cardiac rehabilitation is less than convincing, particularly when the rehabilitation is confined to the period after an acute cardiac illness. The data linkage study by Sundararajan et al adds support to the Australian practice of convalescent-phase cardiac rehabilitation.

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