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When and how to start exercise training after heart failure decompensation? Still more questions than answers

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It is consensual that aerobic exercise programmes are recommended in patients with heart failure as part of a multidimensional and multiprofessional cardiac rehabilitation programme once clinical stability is achieved, having significant benefits over functional capacity and cardiovascular morbidity, irrespective of heart failure aetiology.[1,2] There is a lack of consensus regarding optimal timing for exercise training initiation, with most studies beginning at least one month after the decompensation episode. We compliment Doletsky and colleagues for their effort to add knowledge for the importance and safety of exercise training programmes early after heart failure decompensation.[3] We consider this an interesting and very pertinent study but there are some methodological concerns that need further clarification to assure the validity of their conclusions.

First of all, since it is a randomized controlled trial, authors would be expected to provide information regarding sample size calculation for both groups, including the primary outcome chosen, the minimal clinically relevant difference used for calculations, trial power considered and how the expectedly high attrition and non-compliance was allowed for in the final sample size calculation.[4] Second, randomization is also a crucial aspect of trial design to assure internal validity of study findings and relies on two interrelated aspects: random sequence generation and allocation concealment of the generated sequence until assignment occurs. If carefully performed it minimizes selection bias and allows for hypothesis testing that any difference in outcome between the two groups comes only from chance. We assume the authors used a 1:1 randomization process but cannot verify whether this was a computer-generated allocation sequence and which steps, if any, were made to assure allocation concealment.[4] Third, this a factorial two-group study with measurements performed at three points in time (baseline, three weeks, three months) and with considerable attrition rates in both groups between evaluations. Using the Wilcoxon signed rank test for paired observations (baseline to three weeks; three weeks to three months) ignores the true dependency of the three sequential observations and does not incorporate the effect of missing data, since it evaluates a different number of subjects in each paired observation. These shortcomings would be better dealt with using a mixed-effects model analysis.[5]

Cardiopulmonary exercise testing (CPET) is the gold standard method for functional capacity assessment, prognosis and exercise prescription since it directly measures physiological parameters such as VO_2 peak and VO_2 at the ventilatory thresholds. These parameters are strong predictors of cardiovascular morbidity and mortality amongst heart failure patients, especially those with reduced ejection fraction,[6] and are also widely used to set aerobic exercise intensity for continuous and interval training, most often as per cent VO_2 peak, allowing for standardization and comparability between exercise-based intervention studies.[1] Doletsky and colleagues, despite having a baseline CPET, chose a somewhat unusual approach by setting exercise intensity at 50% of maximal load achieved in a cycle ergometer ramp-test performed at one-week intervals, giving no details or scientific background on the comparability of this approach to standard CPET based methods. Although we understand the feasibility of a ramp-test for periodic reassessment and readjustment of exercise intensity, current recommendations focus on direct methods, when available, or using indirect methods such as maximal heart rate percentage, heart rate reserve percentage and rate of perceived exertion.[1]

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The total attrition rates were considerable at the three-month follow-up visit (intervention group: $7/24 = 29.2\%$ versus control group: $4/22 = 18.2\%$), which raises concerns of losing statistical power by reducing sample size as well as introducing bias due to different disease severity profiles and clinical characteristics between those completing the study and those lost to follow-up.[4] Information on baseline clinical characteristics (disease severity; CPET and echocardiography assessment) for those lost to follow-up would allow for a better interpretation of the study's results and assessment of internal validity.

So, although this is an important study on a current topic within cardiovascular rehabilitation, the aforementioned methodological concerns warrant careful interpretation of study results. Safety and feasibility of exercise-based rehabilitation in early recovery after acutely decompensated heart failure, as well as optimal exercise parameters, remain to be determined.

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