Study Overview

Objective. To compare different diet and exercise interventions for the treatment of dyslipidemia.

Design. Randomized controlled trial.

Setting and participants. The study was conducted at a single Canadian academic medical center with patient recruitment through newspaper, television, and radio announcements. Eligibility criteria included age between 40 and 60 years, no prior history of cardiovascular disease (CVD), a body mass index between 22 and 36 kg/m², and a recent diagnosis of dyslipidemia. For men, dyslipidemia was defined as a total cholesterol/high-density lipoprotein cholesterol (HDL-C) ratio of 4.5 or greater if low-density lipoprotein cholesterol (LDL-C) was greater than 5.0 mmol/L or a total cholesterol/HDL-C ratio of 5.0 or greater if LDL-C was 4.0 to 5.0 mmol/L. For women, it was defined as a total cholesterol/HDL-C ratio of 4.0 or greater if LDL-C was more than 5.0 mmol/L or a total cholesterol/HDL-C ratio of 4.5 or more if LDL-C was from 4.0 to 5.0 mmol/L. Participants were excluded if they were taking lipid-lowering drugs; drugs that could affect their lipid profile; or had a history of psychiatric problems, diabetes, nephrotic syndrome, uncontrolled hypertension, recent weight gain or loss. Current and former smokers were excluded as well as participants currently engaged in regular physical activity.

Intervention. Patients were randomly assigned to receive 1 of 4 interventions: the National Cholesterol Education Program (NCEP) step I diet and printed materials on exercise (standard lifestyle recommendations); the NCEP step I diet with a supervised aerobic exercise-training program; the NCEP step II diet and printed materials on exercise; and the NCEP step II diet and a supervised exercise program. All participants had 1 hour of individual dietary counseling by a registered dietitian, followed by a 15-minute follow-up session. Patients allocated to the step II diet were offered 8 group lectures on dietary lifestyle changes. The exercise-training program was offered 3 times a week for 12 weeks.

Measures were taken at baseline and at the end of the 12-week study.

Main outcome measures. Outcomes included maximum exercise time, body weight and height, blood pressure, and quality-of-life measures. Maximum exercise time was evaluated by exercise stress tests using a Bruce protocol. Quality-of-life measures were assessed using the SF-36 Health Survey, a health status rating scale, and the Standard Gamble Questionnaire. The investigators also calculated the participants' risk using the cardiovascular disease (CVD) Life Expectancy Model.

Main results. Of the 598 people initially responding to the study, 400 (67%) were not eligible to participate. 151/198 eligible participants (76%) refused to participate. 47 patients were randomized, with 41 (87%) completing the study. The authors did not statistically compare the demographic characteristics between the treatment groups. The average attendance was 76% for the step II dietary lectures and 97% for the aerobic exercise classes.

When compared with the standard intervention (average weight loss, 0 kg), patients in the step I diet plus exercise group lost an average of 3.7 kg (95% confidence interval [CI], 1.3–6.1 kg), patients in the step II diet without exercise group lost an average of 1.7 kg (95% CI, 0.2–3.1 kg), and patients in the step II diet with exercise group lost an average of 2.9 kg (95% CI, 0.3–5.5 kg). Improvements in exercise times were seen in both exercise groups, with an average improvement 1.9 and 1.6 minutes for the step I diet group and the step II diet group, respectively. No improvements in exercise times were seen in the groups without structured aerobic exercise. No significant changes in lipid values or blood pressure were seen in the standard lifestyle recommendations group, while the average reductions in the other groups was 4% to 6% for total cholesterol and 6% for LDL-C. When compared with the standard lifestyle recommendations group, the intensive management groups had a 3% to 6% absolute reduction of their 10-year CVD risk. There were no changes seen on the SF-36 Health Survey scores during the study period and no statistically significant changes on the health status rating scale and Standard Gamble.
Conclusion. Standard lifestyle modification recommendations (NCEP step I diet with exercise literature) have little effect on CVD risk factors. While more intensive therapy seems beneficial, in this study population, only a limited number of participants agreed to participate in any intervention.

Commentary
Diet and exercise have been recommended as first-line therapy for dyslipidemia [1], and good evidence supports the use of these interventions at reducing LDL-C, blood pressure, and weight [2,3]. Yet these interventions are not homogenous, and it is unclear if different combinations of interventions might have different influences on patient lipid panels, weight, blood pressure, and quality of life. Lalonde et al’s study compared different combinations of dietary and exercise interventions in order to address this question. The authors also wished to determine the feasibility of implementing these lifestyle interventions in clinical practice.

The authors determined that a standard intervention was not effective. To effect a meaningful change the patients were required to undergo a structured aerobic exercise program, multiple dietary lifestyle didactic sessions, or both. Unfortunately, resource-intense interventions such as these can be difficult to implement in most clinical settings. Furthermore, even when these interventions are available, participation is not guaranteed. In this study, only 24% of eligible participants agreed to participate and of these 13% were lost to follow-up. These conclusions underscore both the challenges of designing lifestyle interventions that are acceptable for patients and the need to critically evaluate these interventions.

However, it is difficult to draw any firm conclusions based on this study. The overall sample size was very small and the follow-up period was short at only 3 months. Compliance with the dietary intervention was assessed by patient self-report, which could introduce recall bias. Finally, the patients who did agree to participate in the study were likely a very motivated group and may not represent the average patient in clinical practice.

Applications for Clinical Practice
Standard lifestyle modification interventions do not seem adequate to reduce CVD risk. Interventions are required that can reduce cardiovascular risk while simultaneously encouraging maximum patient participation.

References

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