Original Investigation

Endovascular Revascularization and Supervised Exercise for Peripheral Artery Disease and Intermittent Claudication
A Randomized Clinical Trial

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IMPORTANCE Supervised exercise is recommended as a first-line treatment for intermittent claudication. Combination therapy of endovascular revascularization plus supervised exercise may be more promising but few data comparing the 2 therapies are available.

OBJECTIVE To assess the effectiveness of endovascular revascularization plus supervised exercise for intermittent claudication compared with supervised exercise only.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial of 212 patients allocated to either endovascular revascularization plus supervised exercise or supervised exercise only. Data were collected between May 17, 2010, and February 16, 2013, in the Netherlands at 10 sites. Patients were followed up for 12 months and the data were analyzed according to the intention-to-treat principle.

INTERVENTIONS A combination of endovascular revascularization (selective stenting) plus supervised exercise (n = 106) or supervised exercise only (n = 106).

MAIN OUTCOMES AND MEASURES The primary end point was the difference in maximum treadmill walking distance at 12 months between the groups. Secondary end points included treadmill pain-free walking distance, vascular quality of life (VascuQol) score (1 [worst outcome] to 7 [best outcome]), and 36-item Short-Form Health Survey (SF-36) domain scores for physical functioning, physical role functioning, bodily pain, and general health perceptions (0 [severe limitation] to 100 [no limitation]).

RESULTS Endovascular revascularization plus supervised exercise (combination therapy) was associated with significantly greater improvement in maximum walking distance (from 264 m to 1501 m for an improvement of 1237 m) compared with the supervised exercise only group (from 285 m to 1240 m for improvement of 955 m) (mean difference between groups, 282 m; 99% CI, 60-505 m) and in pain-free walking distance (from 117 m to 1237 m for an improvement of 1120 m vs from 135 m to 847 m for improvement of 712 m, respectively) (mean difference, 408 m; 99% CI, 195-622 m). Similarly, the combination therapy group demonstrated significantly greater improvement in the disease-specific VascuQol score (1.34 [99% CI, 1.04-1.64] in the combination therapy group vs 0.73 [99% CI, 0.43-1.03] in the exercise group; mean difference, 0.62 [99% CI, 0.20-1.03]) and in the score for the SF-36 physical functioning (22.4 [99% CI, 16.3-28.5] vs 12.6 [99% CI, 6.3-18.9], respectively; mean difference, 9.8 [99% CI, 1.4-18.2]). No significant differences were found for the SF-36 domains of physical role functioning, bodily pain, and general health perceptions.

CONCLUSIONS AND RELEVANCE Among patients with intermittent claudication after 1 year of follow-up, a combination therapy of endovascular revascularization followed by supervised exercise resulted in significantly greater improvement in walking distances and health-related quality-of-life scores compared with supervised exercise only.

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