近位PAD患者において監視下運動は歩行能力を向上させる（Abstract＃18642）

CLEVER：末梢動脈疾患患者において監視下運動はステント留置よりも歩行能力をより増加させる

CLEVER: Greater gains seen with supervised exercise than stenting in patients with peripheral artery disease

末梢動脈疾患（PAD）の標準治療を施行されている患者に監視下トレッドミル運動プログラムを加えることによりステントを留置するよりも歩行能力が有意に改善したとのlate-breaking researchの結果が2011年American Heart Association学会で発表され、Circulationに掲載された。間欠性跛行：運動療法と血行再建術の比較研究（CLaudication: Exercise Vs Endoluminal Revascularization Study[CLEVER]）と呼ばれるこのスタディでは、米国29施設の平均年齢64歳（男性61%）のPAD患者111人を組み入れた。半分以上が喫煙者であり4分の1近くが糖尿病を有していた。患者は、自宅でのウォーキングに加えシロスタゾールを内服する群またはこれに他の2つの介入（監視下トレッドミル運動および腸骨動脈内へのステント血行再建術）のいずれかを追加する群に無作為に割り付けられた。スタディ組み入れの6ヵ月後に、監視下運動プログラム群の患者においてはステント留置患者同様トレッドミル歩行時間が有意に増加した。それと比較し、家でのみ運動した患者においてはあまり改善が認められなかった。平均の増加運動時間は監視下運動とシロスタゾールの併用群で5.8分、ステント治療とシロスタゾール併用群で3.7分、家での運動とシロスタゾール併用群で1.2分であった。運動療法は下肢機能および症状は改善したが下肢への血流は改善しなかった。

Full Text

In patients on standard therapy for peripheral artery disease (PAD), adding a supervised treadmill exercise program improved walking ability significantly better than stenting, according to late-breaking research presented at the American Heart Association's Scientific Sessions 2011.

Patients on either additional therapy improved walking ability better than standard therapy alone, which is home walking and cilostazol, a medicine that improves blood flow to the legs.

The study, called CLaudication: Exercise Vs Endoluminal Revascularization Study (CLEVER), is also published in Circulation: Journal of the American Heart Association.

Patients and physicians have treated claudication with either supervised exercise, medications, or angioplasty and stent placement. Until now, however, the relative effectiveness of each type of treatment was unclear. The use of stents has increased, and exercise is not often used.

Investigators randomized patients to home walking plus cilostazol or to the same approach plus one of two other interventions: supervised treadmill exercise or placement of a stent to reduce narrowing in the iliac artery. Stents are most effective for PAD when used at this anatomic site.

Six months after study enrollment, patients in the supervised exercise program significantly increased their treadmill walking time, as did those who received stents. In contrast, patients who only exercised at home showed little improvement.

The average walking time in each group improved by:

- 5.8 minutes — supervised exercise + cilostazol;
- 3.7 minutes — stents + cilostazol;
- 1.2 minutes — home exercise + cilostazol.

"The evidence shows that those who receive the usual medical care do not enjoy a substantial improvement in their symptoms at all," said Timothy Murphy, M.D., study lead author and professor in the diagnostic-imaging department at the Warren Alpert Medical School of Brown University in Providence, R.I.

Patients in both the supervised exercise and stent groups scored better on a variety of quality of life measurements. Surprisingly, however, patients in the stent group described a better quality of life compared to both the supervised- or home-exercise programs. The reasons for the dissociation between treadmill walking and quality of life improvements are not clear.

"It is important to note that both the supervised exercise and stent treatments provided substantially more benefit than usual home-based medical care, and both are proven to be effective treatments," Murphy said. "I think that both of these therapies offer substantial advantages over the usual care."

Exercise treatment improved leg function and symptoms, but not blood flow to the leg.

"Perhaps this should not be surprising at all," said Alan T. Hirsch, M.D., chair of the study and professor of medicine, epidemiology and community health in the Lillehei Heart Institute of the University of Minnesota in Minneapolis. "Leg function can improve tremendously in almost any individual without any increase in blood flow past major artery blockages, as walking efficiency is dependent on much more than one blocked artery. Exercise is known to improve leg function and symptoms in numerous proven ways. Microscopic blood vessels that supply leg muscles and the nerves and muscles themselves all become much more efficient."

The study enrolled 111 PAD patients, average age 64 years, from 29 centers in the United States. Sixty-one percent were male, and 80 percent were Caucasian. More than half smoked and nearly one-fourth had diabetes. Smoking and diabetes are powerful risk factors for PAD.

Researchers began the study in February 2007 and this report described the primary 6-month study outcome. All patients will continue to receive follow-up for a full 18 months to evaluate more long-term outcomes, quality of life and cost-effectiveness. The study will conclude in Jan. 2012.

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