Structured Home Versus Supervised Hospital based Exercise Rehabilitation in Patients with Intermittent Claudication: Effects on Functional Capacity and Quality of Life

A Randomized Clinical Trial

Thesis

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List of Abbreviations

Abb.	Full term

ABI .....*Ankle Brachial Index*

ABPI .....*Ankle Brachial Pressure Index*

ALI .....*Acute Limb Ischemia*

AP .....*Ankle Pressure*

BMI .....*Body Mass Index*

CLI .....*Chronic Limb Ischemia*

CLTI .....*Chronic Limb Threatening Ischemia*

COT .....*Claudication Onset Time*

CTA .....*Computed Tomography Angiography*

CVD .....*Cardiovascular Diseases*

DBP .....*Diastolic Blood Pressure*

DFUs .....*Diabetic Foot Ulcers*

DNA .....*Deoxyribonucleic Acid*

DSA .....*Digital Subtraction Angiography*

DUS .....*Duplex Ultrasound*

ECs .....*Endothelial Cells*

ExT .....*Exercise Therapy*

fI .....*Foot Infection*

HbA1c .....*Hemoglobin*

HDL .....*High-Density Lipoprotein*

I .....*Ischaemia*

IC .....*Intermittent Claudication*

IL .....*Interleukin*

LDL .....*Low-Density Lipoprotein*

List of Abbreviations (Cont...)

Abb.	Full term
MDCT	*Multidetector Computed Tomography*
MET	*Metabolic Equivalents*
PWT	*Peak walking Time*
QOLQ	*Quality of Life Questionnaire*
SBP	*Systolic Blood Pressure*
SET	*Supervised Exercise Therapy*
sICAM	*Soluble Intercellular Adhesion Molecule*
SVS	*Society for Vascular Surgery*
TNM	*Tumor, Node, Metastasis*
VCAM	*Vascular Cell Adhesion Molecule*
VEGFA	*Vascular endothelial growth factor A*
vWF	*von Willbrand Factor*
W	*Wound*
WIFI	*Wound, Ischemia and Foot Infection*
WIQ	*Walking Impairment Questionnaire*

Abstract

At the end of the 12 weeks of rehabilitation program per both groups. Primary outcomes measures included Claudication Onset Time (COT) and Peak Walking Time (PWT). Secondary outcomes measures included Walking Impairment Questionnaire (WIQ) & Health related Quality Of Life Questionnaire (QOLQ) & anthropometric measures including Body weight, BMI and laboratory results including Lipid Profile, HBA1C.

Medically supervised exercise programs are efficacious for improving COT and PWT, but more patients could benefit from an exercise program transported to the community setting (ie, home-based walking).

Keywords: Ankle Brachial Index - Ankle Brachial Pressure Index - Chronic Limb Ischemia

INTRODUCTION

Lower Extremity arterial disease (LEAD) is a chronic atherosclerotic cardiovascular disease in which stenosis and/or occlusions of the peripheral arteries limit blood flow to the legs. The age-adjusted prevalence is approximately 10%, increasing to 20% in individuals aged >70 years. The classic symptom of mild-to-moderate LEAD is intermittent claudication (IC), which is lower limb pain or discomfort that is induced by walking and relieved by rest. IC decreases functional capacity and quality of life, and is associated with an increased risk of cardiovascular morbidity and mortality ***(Norgren et al., 2007).***

A primary treatment option for patients with IC is a program of supervised walking exercise, typically delivered as a 3-month program in a hospital or healthcare clinic. Medically-supervised exercise programs have demonstrated clinical efficacy with large improvements noted for pain-free and maximum walking distances/ times. Improvements in patient-reported outcomes and measures of cardiovascular health have also been reported. Despite this evidence and the current recommendations, supervised exercise programs are largely under-utilised, possibly owing to lack of reimbursement from insurance companies, the likelihood that only a small proportion of patients would be able to attend regularly, and concerns regarding long-term cost-effectiveness. As a result, exercise is most commonly promoted in the form of basic

advice to "go home and walk". Patients receiving such "usual care" have often served as the control group in clinical trials, and research suggests this approach is ineffective. This has prompted increased interest in the development of structured interventions that promote self managed walking in the community (home-based exercise programs). However, the role of Home-based exercise programs in the management of LEAD/IC is currently unclear. To inform the development of a coherent evidence-base with which to direct future research and disease-management policy we conducted a randomized clinical Trial of Home-based exercise programs in patients with IC ***(Makris et al. 2012).***

Supervised treadmill exercise significantly improves walking performance in people with lower-extremity artery disease (LEAD). However, 3 times weekly visit to the medical center for supervised exercise is burdensome for people with LEAD and medical insurance does not cover supervised treadmill exercise. Thus, most people with LEAD do not participate in supervised treadmill exercise programs. In addition, whether benefits from supervised treadmill exercise are sustained after LEAD patients complete a supervised exercise program is unclear. Identifying a walking exercise program that does not require 3 times weekly visit to the medical center and achieves sustained improvement in walking performance over long-term follow-up is an important treatment goal for people with LEAD ***(Fakhry et al., 2012).***

AIM OF THE WORK

The aim of the study is to evaluate the effect of 12 weeks of structured home based rehabilitation program on functional capacity and quality of life in comparison to 12 weeks of supervised hospital –based rehabilitation program.