Stress Management in Patients Undergoing Carotid Endarterectomy for Carotid Artery Stenosis: A Pilot Randomized Controlled Trial

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Background: Psychological stress is common to patients submitted to cardiovascular operations. The purpose of this pilot, single-center, open-label, randomized controlled trial was to investigate the effects of a stress management program (SMP) on patients undergoing carotid endarterectomy (CEA).

Methods: A sample of 24 patients with significant (>70%) carotid stenosis was finally randomized to SMP (intervention group; $n = 12$) or no-stress management intervention (control group; $n = 12$) before CEA. SMP consisted of 2 relaxation techniques (relaxation-breathing and guided imagery) before and 8 weeks after CEA. Measurements included Perceived Stress Scale (PSS), Hospital Anxiety and Depression Scale (HADS), Health Locus of Control Scale (HLC), and blood pressure and heart rate.

Results: The 2 groups did not differ in terms of demographic characteristics, vascular risk factors, and baseline psychometric measurements. No delay on the time of surgery was caused by the practice of the relaxation techniques. Both perceived stress and anxiety improved within the intervention group at the end of the program ($P = 0.005$ and $P = 0.007$, respectively). No improvement in PSS-14, HLC, and HADS scores were documented in control group at the end of the 8-week follow-up period. The intervention group had lower PSS-14 scores at 8 weeks after CEA (median PSS-14 score, 20 points; range, 10−28) compared with control group (median PSS, 25 points; range, 11−47; $P = 0.026$). No significant effect of SMP was found for blood pressure and heart rate measurements.

Conclusions: Our results indicate that relaxation techniques appear to be beneficial in terms of stress and anxiety reduction in patients undergoing CEA. These findings require independent confirmation in the setting of a larger, double-blind randomized controlled trial.

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INTRODUCTION

The mainstay of treatment options for symptomatic carotid artery stenosis is focused around medical management, carotid endarterectomy (CEA), and carotid artery stenting (CAS). Among these, CEA has demonstrated greater safety and efficacy than best medical treatment in randomized controlled trials (RCTs) in the reduction of risk in ischemic stroke in symptomatic patients with carotid artery atherosclerosis.[1,2] Surgical patients experience high levels of stress, anxiety, and depression and low sense of health control.[3,4] Several recent studies indicated that preoperative stress and anxiety may have an impact on intraoperative cortisol and cardiovascular responses and on postoperative outcomes including frequency of complications, mental functioning, acute pain, use of analgesics, and worsening of preexisting anxiety and depression.[5,6]

Stress management programs have been implemented lately in surgical patients of different fields such as pediatric, general and cardiac surgery, obstetrics, and orthopedics with some promising results in clinical aspects (including sense of pain and analgesia consumption, wound healing, and duration of hospitalization) and in physiological parameters (such as blood pressure, heart rate, and hormonal concentrations of cortisol, oxytocin, and catecholamines).[7,8] Coping with stress may be accomplished by several methods, of which the simplest and most easily administered are relaxation techniques such as relaxation breathing (RB), muscle progressive relaxation, guided imagery (GI), music therapy, and hypnosis.[9] Several relaxation programs have been successfully applied in patients undergoing coronary artery bypass surgery in randomized controlled settings.[10,11] These patients appear to share resemblances with patients undergoing carotid surgery in terms of preoperative and postoperative stress as well as vascular risk factors. However, no relevant study has been performed in patients undergoing CEA. The aim of this pilot, single-center, open-label RCT was to investigate the efficacy of 2 relaxation techniques between CEA patients, concerning reduction of stress, anxiety and depression symptoms, enhancement of self-control feeling, and normalization of physiological stress response.

METHODS

Trial Design

This was a 2-arm, open-label, RCT with a 1:1 allocation ratio of participants to stress-management intervention (intervention group) or no stress-management intervention (control group).

Study Population

The study was conducted at the Vascular Unit of the Third Department of Surgery in University Hospital ''Attikon,'' Athens, Greece. Patients were enrolled in the study between September 2011 and September 2012. Inclusion criteria are outlined in the following points:

(1) Symptomatic or asymptomatic significant ($\geq$70%) carotid artery stenosis scheduled for CEA (recommended first-line treatment) according to American Heart Association (AHA) recommendations[1];
(2) Symptomatic index event defined as nondisabling (modified Rankin Scale score [mRS] of 0–2) acute ischemic stroke or transient ischemic attack (TIA) according to AHA recommendations[2];
(3) Age >40 years;
(4) Ability to read and write in Greek language.

Exclusion criteria included history of previous CEA, history of previous disabling stroke (mRS score of >2), experiencing crescendo TIAs, active mental disease (e.g., dementia, major depression, and post-traumatic stress disorder), use of psychotropic drugs, and practice of other relaxation techniques (e.g., yoga, pilates, meditation, and psychotherapy).

All patients with carotid stenosis were diagnosed using carotid duplex ultrasound according to the Society of Radiologists in Ultrasound Consensus Criteria.[12] All the CEAs were performed by the either of the 2 participating vascular surgeons (S.V. and A.L.) under general anesthesia because of current anesthiosological practice in our hospital. We used eversion and primary closure techniques and no shunt, as previously described.[13] All carotid operations for symptomatic patients were performed within 2 weeks of the index event, and no delay in the time of operation was caused by the application of relaxation techniques. Sociodemographic characteristics (age, gender, marital status, and education level), stroke risk factors including history of smoking, diabetes mellitus, hyperlipidemia, and hypertension, and symptomatic status of carotid stenosis were also recorded. Regular antihypertensive medication was stopped during hospitalization. However, in cases of hypertension, patients were treated with antihypertensive medication occasionally to preserve indicated blood pressure levels below 140/90 mm Hg, according to AHA