

Relationship between Risk Factor Control and Compliance with a Lifestyle Modification Program in the Stenting Aggressive Medical Management for Prevention of Recurrent Stroke in Intracranial Stenosis Trial

Tanya N. Turan, MD, MS,* Sami Al Kasab, MD,* Azhar Nizam, MS,†
Michael J. Lynn, MS,‡ Jamie Harrell, BS,* Colin P. Derdeyn, MD,‡
David Fiorella, MD, PhD,§ L. Scott Janis, PhD,|| Bethany F. Lane, MSN,†
Jean Montgomery, RN,† and Marc I. Chimowitz, MBChB* for the SAMMPRIS
Investigators

Background: Lifestyle modification programs have improved the achievement of risk factor targets in a variety of clinical settings, including patients who have previously suffered a stroke or transient ischemic attack and those with multiple risk factors. Stenting Aggressive Medical Management for Prevention of Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) was the first vascular disease prevention trial to provide a commercially available lifestyle modification program to enhance risk factor control. We sought to determine the relationship between compliance with this program and risk factor control in SAMMPRIS. *Methods:* SAMMPRIS aggressive medical management included a telephonic lifestyle modification program provided free of charge to all subjects (n = 451) during their participation in the study. Subjects with fewer than 3 expected lifestyle-coaching calls were excluded from these analyses. Compliant subjects (n = 201) had greater than or equal to 78.5% of calls (median % of completed/expected calls). Non-compliant subjects (n = 200) had less than 78.5% of calls or refused to participate. Mean risk factor values or % in-target for each risk factor was compared between compliant versus noncompliant subjects, using *t* tests and chi-square tests. Risk factor changes from baseline to follow-up were compared between the groups to account for baseline differences. *Results:* Compliant subjects had better risk factor control throughout follow-up for low-density lipoprotein, systolic blood pressure (SBP), hemoglobin A1c (HgA1c), non-high-density lipoprotein, nonsmoking, and

From the *Department of Neurology, Medical University of South Carolina, Charleston, South Carolina; †Department of Public Health, Emory University, Atlanta, Georgia; ‡Department of Radiology, University of Iowa, Iowa City, Iowa; §Department of Neurosurgery, State University of New York at Stony Brook, Stony Brook, New York; and ||Division of Clinical Research, National Institute of Neurological Disorders and Stroke, Bethesda, Maryland.

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Address correspondence to Sami Al Kasab, MD, Department of Neurology, Medical University of South Carolina, 96 Jonathan Lucas St, Charleston, SC 29425. E-mail: alkasab@musc.edu.

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exercise than noncompliant subjects, but there was no difference for body mass index. After adjusting for baseline differences between the groups, compliant subjects had a greater change from baseline than noncompliant subjects for SBP did at 24 months and HgA1c at 6 months. *Conclusion:* SAMMPRIS subjects who were compliant with the lifestyle modification program had better risk factor control during the study for almost all risk factors. **Key Words:** Stroke—intracranial atherosclerosis—medical management—compliance—lifestyle modification program. Published by Elsevier Inc. on behalf of National Stroke Association.

Introduction

The Stenting Aggressive Medical Management for Prevention of Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) Trial was the first stroke prevention trial to employ protocol-driven multimodal aggressive management of multiple vascular risk factors, including elevated blood pressure, cholesterol, diabetes mellitus (DM), smoking, weight, and exercise. The results of the trial showed that aggressive medical management was superior to stenting for stroke prevention in patients with recently symptomatic severe intracranial stenosis¹⁻³ and that good risk factor control was associated with better outcomes.⁴ The SAMMPRIS Trial was also the first vascular disease prevention trial to incorporate a commercially available telephonic lifestyle modification program for study participants to enhance risk factor control. Although lifestyle modification programs have improved the achievement of risk factor targets in a variety of clinical settings, including patients who have previously suffered a stroke or transient ischemic attack,⁵⁻⁷ to our knowledge, such programs have not been evaluated in the setting of a vascular prevention clinical trial. In the present study, we sought to determine if utilization of a lifestyle modification program improved risk factor control in the setting of a clinical trial.

Methods

The overall design of SAMMPRIS and its aggressive medical management protocols have been described previously.^{1,8} Funded by the National Institutes of Health, SAMMPRIS was an investigator-initiated and designed phase III randomized multicenter trial in which 451 patients were randomized at 50 sites in the United States. Institutional review boards at all 50 participating sites approved the study protocol. Aggressive medical therapy alone versus percutaneous transluminal angioplasty and stenting with the wingspan stent system plus aggressive medical therapy versus stenting plus aggressive medical therapy. Aggressive risk factor management primarily targeted systolic blood pressure (SBP) less than 140 mm Hg and low-density lipoprotein (LDL) less than 70 mg/dL. Secondary risk factors targeted included diabetes mellitus, physical inactivity, weight, and smoking. Using a commercially available lifestyle mod-

ification program (INTERVENT), all subjects received coaching on healthy lifestyle behaviors at regularly scheduled times throughout the study at no charge. Lifestyle coaches provided individualized risk factor counseling (by telephone or Internet) twice a month for 6 months and monthly thereafter. For this analysis, subjects with fewer than 3 expected lifestyle-coaching calls (e.g., those who left the study early due to end point, or withdrew consent) were excluded. There was no prespecified definition of compliance. Therefore, subjects were considered "compliant" if they completed more than the mean percentage of expected calls or more. Subjects were considered "noncompliant" if they completed less than the mean percentage of expected calls or refused to participate in INTERVENT at all.

Risk factor values for each subject during follow-up were recorded at baseline, 30 days, 4 months, and every 4 months thereafter. Mean risk factor values (SBP, LDL, non-high-density lipoprotein [HDL], hemoglobin A1c [HbA1c], body mass index [BMI]) or percent in-target (physical activity and smoking cessation) were compared between compliant and noncompliant subjects, using *t* tests and chi-square tests. To account for baseline differences between groups, risk factor changes from baseline to follow-up were also compared between the groups using *t* tests, Fisher's exact tests, and chi-square tests.

Results

The median percentage of expected calls that were completed by the subjects was 78.5%. Therefore, "compliant" subjects (*n* = 201) were defined as those who completed 78.5% or more expected calls from lifestyle coaches and "noncompliant" subjects (*n* = 200) completed less than 78.5% of calls or refused to participate at all. Baseline characteristics are summarized in Table 1. African-Americans were found to be less compliant with INTERVENT (9% compliant vs. 15% noncompliant) when compared to whites (38% compliant vs. 32% noncompliant) (*P* = .04). There was no significant difference with regard to compliance among assigned treatment groups (*P* = .29).

As shown in Figure 1, compliant subjects had better control than noncompliant subjects of LDL, non-HDL, and HgA1c at baseline (*P* < .05). At several time points in the study follow-up period, compliant subjects also had better risk factor control than noncompliant subjects for

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