The Lowering of Vascular Atherosclerotic Risk (LOVAR) program: an approach to modifying cerebral, cardiac, and peripheral vascular disease.

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Published In/Presented At

Castaldo, J. E., & Reed, J. F., 3rd (2008). The Lowering of Vascular Atherosclerotic Risk (LOVAR) program: an approach to modifying cerebral, cardiac, and peripheral vascular disease. *Journal of stroke and cerebrovascular diseases : the official journal of National Stroke Association*, *17*(1), 9–15. https://doi.org/10.1016/j.jstrokecerebrovasdis.2007.09.002

The Lowering of Vascular Atherosclerotic Risk (LOVAR) Program: An Approach to Modifying Cerebral, Cardiac, and Peripheral Vascular Disease

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More than 1 million US citizens die of cerebral, cardiac, and peripheral vascular disease (collectively, CVD) each year. Basic science and clinical outcome research aimed at reducing the burden of this illness is widespread, but the knowledge gleaned from controlled trials has not fully translated into everyday clinical practice and care of patients with CVD and their inherent risk factors. The Lowering of Vascular Atherosclerotic Risk (LOVAR) program was a 5-year observational study that evaluated the feasibility of a high-intensity multidisciplinary program of risk factor reduction in a population with known symptoms of CVD. The population comprised patients with documented clinically symptomatic cerebral, cardiac, or peripheral vascular disease and at least two modifiable risk factors for stroke, myocardial infarction, or peripheral vascular occlusive disease. Final outcomes were evaluated by comparing primary and secondary end points and quality of life. A total of 271 patients were enrolled in the intervention group, and 242 were enrolled in the standard care group (control). At 3 years, significant improvements in several risk factors were seen in the intervention group, with no significant improvements for the control group. The rate of patient retention was 95% at 3 years, and overall rates of physician and patient satisfaction were high. We believe that the Lowering of Vascular Atherosclerotic Risk program is generalizable to a sufficiently motivated population targeted as high risk for vascular disease. **Key Words:** Atherosclerotic disease—lifestyle intervention—outcome—risk factor modification.

Cerebral, cardiac, and peripheral vascular disease (collectively, CVD) remains the leading cause of death and disability in the United States, currently accounting for more than 40% of all deaths annually.[1,2] More than 1 million US citizens die of CVD each year. Out of the current US population of about 258 million, more than 60 million people have some form of CVD, entailing national health care costs of nearly $300 billion annually.[3,4]

Basic science and clinical outcome research aimed at reducing the burden of this illness is widespread, but the knowledge gleaned from controlled trials has not fully translated into everyday clinical practice and care of patients with CVD and their inherent risk factors; for example, 23% of men and 31% of women will experience recurrent myocardial infarction (MI), and approximately 700,000 people have new or recurrent stroke each year, resulting in 280,000 deaths annually. Approximately one third of these strokes occur in persons younger than 65 years.[4]

Although there is a large evidence base for prevention, there is widespread documentation of under use in both primary and secondary prevention settings.[5-7] For example, fewer than 10% of eligible patients in a national survey were referred to formal secondary prevention

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Received June 25, 2007; accepted September 12, 2007.

Supported by the Dorothy Rider Pool Health Care Trust.

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1052-3057/$—see front matter

doi:10.1016/j.jstrokecerebrovasdis.2007.09.002

programs, an intervention that has been shown to increase survival by 25%, even after an acute coronary event or revascularization procedure.[8] Only 25% of the US hypertensive population is adequately treated for the condition despite the ease of screening, detection, and treatment.[7,9-11] Smoking is increasing among US teenagers, and a sedentary lifestyle is becoming increasingly accepted in children and adolescents.[12,13] Hyperlipidemia is a major contributor to increased risk for coronary heart disease in the national population, yet less than one third of patients who need treatment receive it, and less than half of patients who start therapy remain compliant after 1 year of therapy.[14] Approximately 7 million people in the United States have been given the diagnosis of diabetes mellitus, making it one of the most prevalent and treatable chronic conditions among US citizens. Another 7 million may unknowingly have the disease, making it the seventh-leading cause of death in the nation. Disability, death, and long-term complications of diabetes remain unacceptably high, in large part because of poor success with early detection, prevention, monitoring, and treatment through current community standard practice.[7,15]

In 2002, the American Heart Association (AHA), in its Report from the Task Force on Strategic Research Direction, identified 5 priority areas of research to achieve the Healthy People 2010 objectives and to support the association's long-term goals and mission. These 5 areas are: (1) methods to improve use and quality of preventive service and health care; (2) disparities in cardiovascular risk in subpopulations; (3) lifestyle and metabolic risk factors; (4) psychosocial risk factors; and (5) population genetics/pharmacogenetics related to prevention.[8]

There is no doubt that modifying risk factors is an effective strategy for preventing CVD. Based on these findings, a series of national recommendations have been made with regard to the physician's role in evaluating and treating smoking, hyperlipidemia, and other risk factors.[16,17] Because change at the individual physician level lags behind the evidence base, systems of prevention that are cost-effective and increase adherence to prevention guidelines in diverse clinical and community settings need to be developed and tested. Population-wide strategies, including policy and environmental changes, are also in need of further development, evaluation, and dissemination so that research can be translated into effective practice.[7,8]

Risk factors for CVD (eg, obesity, diabetes, sedentary living, smoking, hypertension, and hyperlipidemia) remain highly prevalent in the Lehigh Valley region of Pennsylvania, many above statewide and nationwide levels.[18-20] LOVAR provides one of the most aggressive and practical models of vascular disease prevention currently available. Its cornerstone is lifestyle and risk factor intervention, combined with detailed clinical, physiologic, and cost-effective outcome measurements.

Methods

LOVAR was a 5-year prospective cohort controlled trial to evaluate patients in terms of subsequent development and progression of atherosclerosis. This was accomplished by comparing primary and secondary end points and quality-of-life indicators in a group of patients undergoing a comprehensive lifestyle modification program with another group of patients treated following community standards of care for an average of 3 years. Because the study was designed to test the hypothesis that intensive preventive strategies will result in fewer vascular events, hospitalizations, and vascular procedures, we proposed to confine the study to the evaluation of patients at high risk who were most likely to experience measurable end points during the 3-year observation period. The study design was approved by our institutional review board.

Study Population

The study population comprised patients aged 39 to 79 years from the Lehigh Valley region of Pennsylvania with documented clinically symptomatic cerebral, cardiac, or peripheral vascular disease. Patients were recruited within 6 months of a vascular event of nondisabling MI, coronary artery disease, peripheral vascular disease, retinal artery occlusion, transient ischemic attack, or stroke and presented with at least two modifiable risk factors for MI, stroke, or peripheral vascular disease.

Patient Recruitment and Consent

Patients were identified from inpatients at Lehigh Valley Hospital and Health Network ([LVHHN]; Allentown, PA) and outpatients during routine office follow-up and care. Primary care physicians, including internal medicine, family practice, and other specialists, participated in the LOVAR program by referring eligible patients for study. Recruitment was done during a 3-year period. Participants were followed up for a minimum of 3 years.

All patients admitted to LVHHN with the diagnosis of a qualifying event as described earlier were screened for the study as soon as appropriate after the qualifying event occurred. Patients entering the hospital for a vascular procedure were screened before discharge or at the next elective follow-up appointment with the attending physician. For potentially eligible patients, the primary care physician was contacted about the study. Physician permission and cooperation were sought before a patient was approached about entering into the trial. After risk factors were explained and informed consent was obtained, the patient was allowed to choose either the intervention or control arm of the study, based on the patient's judgment as to which program would better control his or her risk factors. Prospective control patients were obtained from the same physician offices. Some of the patients were recruited after being referred

for a comprehensive program but on interview expressed feeling unready to make the physical and emotional commitment necessary for the intervention arm. A patient was considered enrolled in the study if he or she agreed to participate after the first 3 visits (nurse screening, history review, physician examination, and outline of the program).

Clinical evaluation determined each patient's eligibility for the study through personal interview, physical evaluation, and diagnostic testing and medical record review. The team of physicians on the LOVAR Executive Committee, in conjunction with the nurse research coordinators, was responsible for verifying that patients met all eligibility criteria for study entry.

A total of 1931 patients were referred and screened. Of these, 906 (47%) were deemed ineligible based on inclusion/exclusion criteria, and 1025 (53%) were considered eligible candidates. Of the 1025 eligible patients, 443 (43%) were not interested or not able to participate after the first visit, and 582 (57%) ultimately entered the study. After the third visit, another 69 patients were not interested, leaving a total of 513 patients enrolled (271 in treatment group, 242 in control group) (Fig 1). There were 11 crossovers (7 from the treatment group to the control group and 4 from the control group to the treatment group) and 25 dropouts (23 from the treatment group and 2 from the control group).

Baseline/Follow-up Test and Procedures

Clinic Visits

At 1 month and 6 months after entry, and every 6 months thereafter, each participant was seen for a comprehensive evaluation including interview, physical and neurologic examination, risk factor modification and compliance assessment, and medical and psychologic follow-up questionnaires. Each control patient was seen and examined on a yearly basis by the LOVAR team, and at least quarterly by his or her primary care provider.

Telephone Contacts and Group Support

At 3-month intervals, all patients were contacted to determine whether any hospitalizations or medical events occurred since the last visit. The patients in the intervention arm participated in a monthly support group that focused on social support and further education on vascular prevention.

Unscheduled Visits

Whenever a potential end point was identified, the participants were interviewed and examined immediately or within 1 week of the event. End point diagnoses and forms were collected and patient records reviewed by the end point verification committee. Mortality classification forms were completed on all participants who died during the course of the study.

Program Implementation

An executive committee of 14 physicians collaborated to determine and administer the standards of care for the vascular preventive medicine program. Support services at the executive committee level included the center for health promotion and disease prevention, Helwig diabetes center, cardiac rehabilitation, vascular clinical nurse specialists, food and nutrition services, neurosciences research, pharmacy, vascular laboratory, community health and health studies, and the Dorothy Rider Pool Healthcare Trust. Cardiology, neurology, and internal medicine physicians provided onsite support and education for patients and the LOVAR team. A multidisciplinary team of a nurse practitioner; cardiovascular and cerebrovascular clinical nurse specialists; a dietitian; an exercise physiologist; and certified tobacco cessation, stress management, and diabetes educators provided the core preventive medicine intervention program and case management.

Interventions

Assessment (including research data collection from patients) included the following aspects:

- Initial patient examinations involving history, physical, review of diagnostics, and data collection.
- Discussions between LOVAR physicians and the patient's primary care physician.

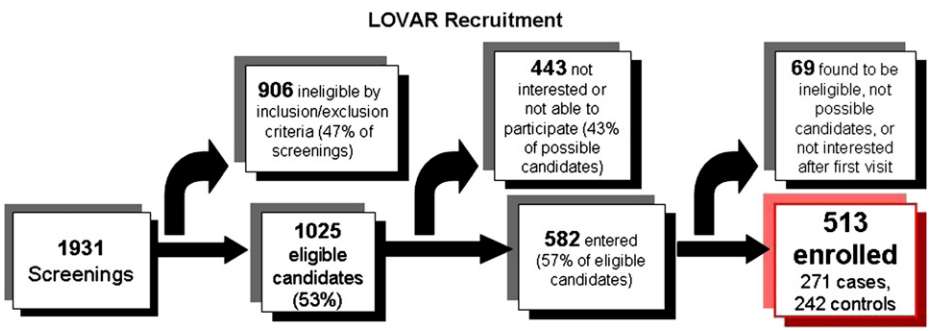

Figure 1. *LOVAR recruitment.*

- Telephone contact by the nurse case manager at least every 3 months and more often if necessary to ensure compliance (6 months for control patients).
- Office follow-up visits every 6 months (1 year for control patients) with the nurse practitioner or LOVAR physician.
- Quality of life (QOL) assessed using the MOS Short Form-36 (SF-36) every 6 months (1 year for control patients).

The multidisciplinary risk factor reduction/lifestyle behavior modification program included the following individual sessions (minimum of 3 hours total):

- Food diary/nutrition assessment/recommendations with a registered dietitian, with instructions to follow a low-fat, low-calorie Mediterranean diet high in fresh fruit, vegetables, and fish.
- Individual exercise prescription with a master's-level trained exercise physiologist involving aerobic and weight training instruction, with the patient encouraged to exercise 5 to 7 days per week for 30 to 40 minutes per session.

Small group education (a minimum of 17.5-25.5 hours for the core vascular preventive medicine education program taught by the multidisciplinary team) included the following:

- Four stress management sessions, covering implications of stress, rational emotive thinking, and relaxation exercises (10 hours).
- One session on managing atherosclerosis risk factors and symptoms of disease, including vascular foot care (2.5 hours).
- Two nutrition education sessions beyond the individual session (3 hours).
- Two exercise education sessions beyond the individual session (2 hours).
- Two diabetes education sessions and 3 tobacco use cessation sessions, if needed (8 hours).

Case Management

Each patient in the intervention group was contacted on a regular basis by a nurse case manager to evaluate the patient's progression with risk factor modification, lifestyle changes, medication compliance, and other strategies to prevent disease exacerbation through discussion and education. Each patient was given a personalized instructional booklet outlining his or her risk factors for CVD and goals for smoking cessation, diabetes management, diet, weight control, and exercise, as appropriate.

Maintenance Activities

The patients in the intervention group were provided access to an optional 2-hour monthly support group featuring educational and social opportunities. Quarterly newsletters were sent to the patients to provide additional information on the study and on vascular prevention strategies. Newsletters were also sent to all participating physicians (n = 460) in the study.

Results

A total of 271 patients were enrolled in the intervention group, and 242 patients were enrolled in the control group. The patients were matched for age, sex, and vascular burden. Risk factor comparison data at baseline are given in Table 1. A significantly higher percentage of patients with hypertension and MI entered the control arm; this was balanced by a higher percentage of patients with stroke and diabetes mellitus entering the intervention arm. The groups were equally matched for risk factors of smoking, hyperlipidemia, age, and sex. Despite the differences in historical risk factors, uncontrolled risk factors clinically present at baseline such as hypertension, hyperlipidemia, body mass index (BMI), and diabetes were equally matched for both groups (Table 2). The intervention group participated in the comprehensive program of lifestyle changes and risk factor education and received ongoing coordinated case management, whereas the control group received community standard care.

The patients in the intervention group demonstrated significant 1- to 3-year improvements in 4 out of 8 SF-36 quality-of-life indicators: general health ($P = .049$), physical role ($P < .001$), emotional role ($P < .001$), and social functioning ($P = .004$) (Fig 2). During the same period, the control patients exhibited deterioration in almost all SF-36 quality-of-life indicators with no significance for improvement. There was significant improvement in control of diabetes, hypertension, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and total cholesterol. No significant improvement was seen in the community control patients in any area (Tables 3 and 4).

Table 1. *Comparison of baseline risk factors and demographics in the intervention and control groups*

	Intervention (n = 271)	Control (n = 242)	*P* value
Gender, n (%)			
Male	194 (71.6%)	175 (72.3%)	
Female	77 (28.4%)	67 (27.7%)	.855
Age, years ± standard deviation	60.4 ± 9.8	62.8 ± 9.8	.007
History, n (%)			
Diabetes	70 (26.8%)	65 (28.0%)	.766
Smoking	172 (63.5%)	171 (70.7%)	.084
Current smoker	33 (12.3%)	29 (12.0%)	.922
Hypertension	196 (72.3%)	163 (67.4%)	.220
Stroke	84 (31.1%)	58 (24.1%)	.076
Myocardial infarction	131 (48.3%)	161 (66.5%)	.001

Table 2. *Baseline risk factors for at-risk patients in the intervention and control groups*

Risk factor	Intervention	n	Control	n	*P* value
SBP > 130 mmHg	144 ± 12	121	146 ± 14	117	.213
DBP > 90 mmHg	95 ± 6	8	93 ± 2	9	.371
>120/80 mmHg					
Systolic	151 ± 16	41	153 ± 16	37	.560
Diastolic	86 ± 6		86 ± 5		.892
>130/90 mmHg					
Systolic	164 ± 12	8	166 ± 20	9	.841
Diastolic	95 ± 6		93 ± 2		.371
Total cholesterol	228 ± 21	79	238 ± 39	49	.065
HDL cholesterol	35 ± 6	172	34 ± 6	145	.083
LDL cholesterol	131 ± 24	139	129 ± 28	108	.384
BMI	31.3 ± 5.1	222	31.4 ± 5.2	185	.893
Fasting glucose	189 ± 48	32	190 ± 48	35	.898
HbA1c	9.0 ± 1.3	29	9.6 ± 1.5	25	.161

Discussion

LOVAR was designed to determine whether a program of comprehensive cardiovascular risk factor reduction could help achieve the AHA's Healthy People 2010 goals in a rapid fashion with good patient acceptance and compliance to protocol while at the same time increasing quality-of-life measures. In addition, we hoped to be able to determine the long-term cost efficacy of the program by evaluating the cost of the program in terms of clinical

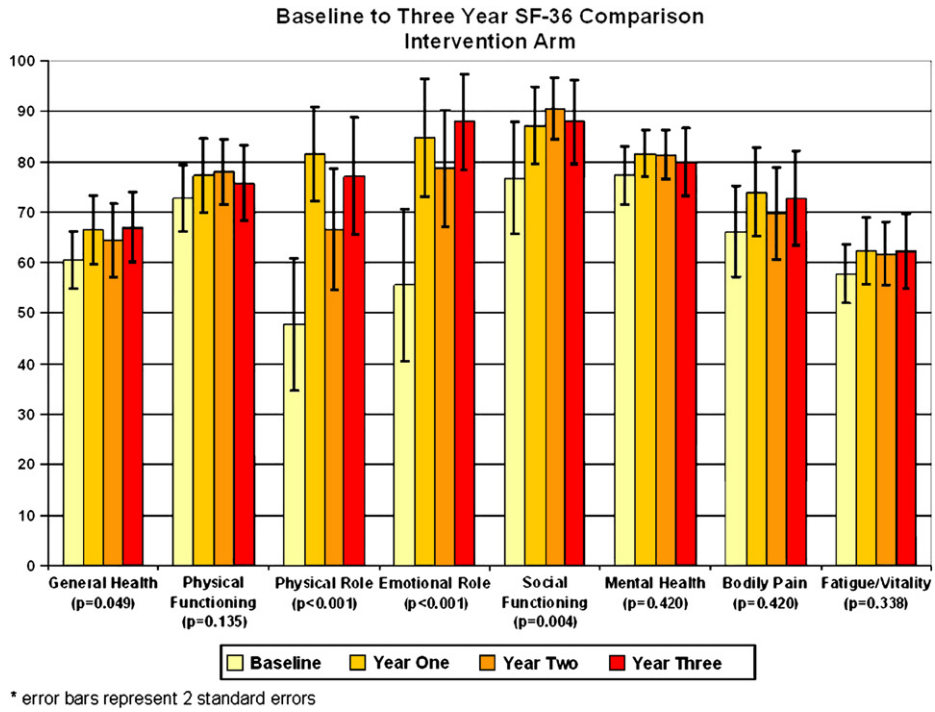

Figure 2. *Baseline to 3-year SF-36 comparison, intervention arm. Category definitions are as follows:*

- *General health: Person evaluates health in range from "poor, likely to get worse" to "excellent."*
- *Physical functioning: Person rates performance of physical activities including bathing or dressing in a range from "limited a lot" to "without limitations."*
- *Physical role: Person is able to do work or other daily activities in a range from "problems as a result of physical health" to "no problems."*
- *Emotional role: Person is able to do work or other daily activities in a range from "problems as a result of emotional problems" to "no problems."*
- *Social functioning: Person is able to perform social activities in a range from "extreme and frequent interference due to physical or emotional problems" to "perform without interference."*
- *Mental health: Person has feelings in a range from "nervousness and depression all of the time" to "peaceful, happy, and calm all of the time."*
- *Bodily pain: Ranges from "very severe and extremely limiting pain" to "no pain or limitations due to pain."*
- *Fatigue-vitality: Person feels in a range from "tired and worn out all of the time" to "full of pep and energy all of the time."*

From Ware JE. SF-36 health survey: Manual and interpretation guide. Boston: The Health Institute, New England Medical Center Hospitals.

Table 3. *Changes in the intervention group over time (baseline, year 1, and year 2)*

Risk factor	n	Baseline	Year 1	Year 2	*P* value
SBP > 130 mmHg*	78	142 ± 12	141 ± 18	136 ± 15	.011
DBP > 90 mmHg*	5	93 ± 3	80 ± 6	79 ± 8	.089
>120/80 mmHg					
Systolic	27	148 ± 18	138 ± 17	134 ± 14	.001
Diastolic	27	85 ± 5	77 ± 9	76 ± 8	.001
>130/90 mmHg					
Systolic	5	161 ± 13	145 ± 9	144 ± 16	.346
Diastolic	5	93 ± 3	80 ± 6	79 ± 8	.089
Total cholesterol	139	181 ± 37	172 ± 34	169 ± 31	.001
HDL cholesterol	137	41 ± 12	44 ± 12	45 ± 12	.001
LDL cholesterol	133	109 ± 32	97 ± 28	94 ± 25	.001
BMI	170	30.1 ± 5.5	30.3 ± 5.5	30.4 ± 5.5	.164

*Blood pressure readings are the average of right and left sitting pressures.

outcomes achieved. We will address this latter question in a future report.

Ornish et al[21] has demonstrated the efficacy of diet and lifestyle changes on subsequent progression of cardiovascular disease. This study involved enrolling small groups of highly selected, motivated individuals in a ritualized and costly program of heart disease prevention using a vegetarian diet. For most physicians in clinical medicine, these results, although interesting, cannot be generalized to the vast majority of patients at risk of death or disability from CVD. LOVAR has proven that a comprehensive program of lifestyle behavior change can be successfully implemented. The LOVAR study group was a much larger, comprehensive population of patients with CVD who took advantage of new, effective antihypertensive, antilipidemia, and antidiabetic medication treatments.

Although randomized clinical trials (RCTs) are considered the gold standard of clinical testing,[22] we believe that an RCT of lifestyle changes is not feasible for a number of reasons, based on a pilot study:

1. Randomizing patients at high risk to 1 of 2 forms of treatment is ethical if both treatments are believed to be of equal efficacy. Our study was designed not only on the principle that more attention to prevention will result in better outcomes, but also to address the issue of whether the improvement seen is durable and cost-effective over time.
2. For patients already failing with community standard care and referred to LOVAR for aggressive case management in an attempt to stay the relentless progression of their disease, randomization to the community standard of care proved problematic.
3. For patients interested in more aggressive treatment of their condition, randomization to community standard care led to some either dropping out of that arm or for all intents and purposes crossing over to obtain aggressive treatment. Similarly, some patients who entered the study at their physician's request but who had insufficient self-motivation

Table 4. *Changes in the control group over time (baseline, year 1, and year 2)*

Risk factor	n	Baseline	Year 1	Year 2	*P* value
SBP > 130 mmHg*	69	147 ± 15	145 ± 22	140 ± 19	.079
DBP > 90 mmHg*	5	94 ± 2	85 ± 13	78 ± 19	.223
>120/80 mmHg					
Systolic	31	150 ± 18	142 ± 19	136 ± 23	.002
Diastolic	31	85 ± 5	78 ± 10	77 ± 12	.001
>130/90 mmHg					
Systolic	5	170 ± 19	155 ± 24	143 ± 38	.418
Diastolic	5	94 ± 2	85 ± 13	78 ± 19	.223
Total cholesterol	138	175 ± 40	174 ± 38	169 ± 38	.183
HDL cholesterol	137	41 ± 12	46 ± 13	46 ± 13	.001
LDL cholesterol	130	101 ± 35	97 ± 26	92 ± 25	.015
BMI	153	29.4 ± 5.1	29.6 ± 5.2	29.7 ± 5.1	.126

*Blood pressure readings are the average of right and left sitting pressures.

and were randomized into the intervention arm later crossed over to the community standard (control) arm for their own convenience.

4. An RCT does not address the question of whether motivated patients willing to make lifestyle changes can accomplish this better than current proven or integrated physician programs.

In summary, the patients in the LOVAR program demonstrated improved risk factor modification, which translated into greater life expectancy, with a decrease in vascular events predicted for the subsequent 10 years and improved quality of life, with decreased depression and higher energy levels; moreover, the referring physicians expressed greater satisfaction with respect to patient treatment.[23] This observational study of prevention strategies provides insight into important strategies for community risk factor modification for the masses of citizens who remain untreated, or undertreated, in what appears to be an ongoing epidemic of preventable vascular disease in the United States. We believe that the LOVAR program is generalizable to a sufficiently motivated population targeted as high risk for vascular disease.

Acknowledgment: We thank the LOVAR Executive Committee for their support and assistance: John Fitzgibbons, MD, Donald Belmont, MD, Nelson Kopyt, DO, William Gee, MD, Anthony Matejicka, DO, Michael Kaufmann, MD, J. Sanford Schwartz, MD, PhD, Kim Sterk, RN, and Patricia Parker, RN.

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