

Increasing awareness about venous disease: The American Venous Forum expands the National Venous Screening Program

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Objective: To evaluate the results of the expanded National Venous Screening Program (NVSP) as administered by the American Venous Forum.

Methods: Eighty-three physicians across 40 states participated in screening Americans for venous disease. The NVSP instrument included demographics, venous thromboembolism (VTE) risk assessment, quality-of-life (QOL) assessment, duplex ultrasound scan for reflux and obstruction, and clinical inspection. Participants received educational materials and a report card to give their physician.

Results: A total of 2234 individuals underwent screening (mean, 26 people/site; range, 4-42). Demographic data observed included mean age of 60 years (range, 17-93 years); 77% female; 80% Caucasian; mean BMI of 29 (range, 11-68); 40% current or previous smoker; and 24% taking antiplatelet therapy and 4% taking warfarin. If placed in a situation conducive for VTE, 40% of participants were low risk, 22% were moderate risk, 21% were high risk, and 17% were very high risk. On a venous QOL assessment, 17% had a combined total score for all 11 questions of "very limited" or "impossible to do." Reflux or obstruction was noted in 37% and 5% of participants, respectively. CEAP class 0 to 6 was 29%, 29%, 23%, 10%, 9%, 1.5%, 0.5%, respectively.

Discussion: Despite a dramatic expansion in the second annual NVSP (from 17 to 83 centers), the presence of venous disease observed in a larger screened population continues to be high. The NVSP represents one pathway to increasing public awareness about venous disease. (J Vasc Surg 2008;48:394-9.)

The sequelae of venous thromboembolism (VTE) and chronic venous disease (CVD) continue to cause major mortality and significant morbidity in millions of Americans. Despite a considerable wealth of knowledge that has been acquired over the past 25 years about the basic science, natural history, risk factor delineation, prevention, and treatments of these two common manifestations of venous disease, a significant proportion of physicians, allied health personnel, health care administrators, and, most importantly, the lay public continue to be conspicuously unaware of these advances.¹⁻⁴ Bridging this gap by involving the aforementioned groups in screening of Americans for venous disease represents a major goal of the American

Venous Forum (AVF) to increase awareness of venous disease.

Findings from the pilot launch of the National Venous Screening Program (NVSP) during 2005 and 2006, which involved 17 centers, were profound.⁵ Important observations included 77% of participants were at high or very high risk of developing VTE if put in a high-risk situation; 40% and 6% had evidence of venous reflux or obstruction, respectively; and, according to the CEAP criteria,⁶ 20% had a clinical classification of 3 or greater. Additionally, the screening instrument demonstrated correlation between risk stratification, duplex ultrasound findings, and severity of CVD by inspection. Data and analysis presented herein reflect the findings of a broad expansion of the NVSP 1 year after the pilot program.

METHODS

Oversight for the expansion of the NVSP was provided by the NVSP committee of the AVF (co-chairs, R.M., M.P.). Michele F. Lentz (NVSP Coordinator, RF Associates, Baltimore, Md) in concert with Administrare, Inc (Salem, Mass) assisted in executing the expansion as prescribed by the NVSP Committee.

Physicians targeted for participation in the NVSP were members of one of three medical societies: the American Venous Forum, the Society for Vascular Surgery, and the American College of Phlebology. Membership mailing lists were given to the NVSP committee for the sole purpose of

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Competition of interest: none.

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inviting physicians to participate. Mailings for invitations to participate and "save the dates" were distributed by electronic mail in August 2006. National Venous Screening Week was designated from November 6-11, 2006. Physicians desiring to participate in the NVSP were not limited to only that time; they could perform a screening during the following 4 months. Instructional and educational materials needed to perform the NVSP were provided to physicians and the public for free. Funding for the NVSP was through grants from Juzo Corporation (Cleveland, Ohio) and Sanofi-Aventis (Bridgewater, NJ). Materials given to physicians and the public had no associated industry labeling or advertising.

The process of the NVSP screening has been previously described in detail.⁵ Briefly, participants who attended a free screening completed a self-administered demographic questionnaire and VTE risk assessment, underwent an abbreviated duplex ultrasound examination for venous reflux and obstruction, and had their lower extremities inspected and graded according to CEAP classification.⁶ Briefly, the abbreviated duplex ultrasound testing examined the common femoral vein, saphenofemoral junction, and the above-knee popliteal vein. Participants were put in the supine position with the head of the bed elevated to 30 degrees; then a Valsalva maneuver was performed at each vein location to evaluate for reversal of flow greater than 0.5 seconds. Manual compression of the same segments using B-mode was performed to evaluate for obstruction. Obstruction was defined as the inability to completely oppose the walls because of an acute or chronic deep venous thrombosis (DVT).

In a new feature of the expanded NVSP, participants also completed an abbreviated form of the previously validated Chronic Venous Insufficiency Quality of Life questionnaire (CIVIQ).^{7,8} The abbreviated CIVIQ questionnaire ranked symptoms experienced during the last 4 weeks before the screening according to a Likert scale of 1 to 5 (1 = no pain/not bothered at all; 5 = intense pain/impossible to do). Of the 11 questions used, four addressed pain repercussions, four addressed physical functioning, and three addressed social activities.

After completion of the aforementioned steps, an exit interview was completed by the physician who then discussed with the participant the screening findings. Participants received a venous report card and were encouraged to share the report with their primary care physician. Participants also received free educational brochures on common venous afflictions as well as a monograph explaining the meaning of their VTE risk assessment if they were placed in a high-risk situation.

Data from each screening site were sent to Michele F. Lentz who coordinated entry into the NSVP database (Access; Microsoft Corp, Seattle, Wash). Statistical analyses were performed with SAS v9.1 (SAS Institute Inc, Cary, NC) with the assistance of the Division of Statistics and Research Consulting at Southern Illinois University (S.M.). Relationships between participant demographics, VTE risk factors, presence/absence of venous reflux and

obstruction, CEAP classification, and CIVIQ quality-of-life scores were examined. Independent group *t* tests were used to compare the presence/absence of reflux or obstruction with variables that included age, body mass index (BMI), and VTE risk score. The relationship of the presence/absence of reflux or obstruction to categorical demographic variables was examined with χ^2 tests of independence. These tests were also used to examine the relationship of VTE risk category with similar variables. Wilcoxon rank sum tests were performed to compare dichotomous CEAP classification on demographic, VTE risk, reflux/obstruction, and CIVIQ variables. Spearman correlation coefficients were used to examine the relationships between CIVIQ variables and VTE risk score and CEAP classification. For purposes of comparison, current and past smokers were grouped together as smokers. In comparisons between VTE risk groups, low and moderate risk were combined as was high and very high risk. Multivariate analysis was not performed because of low numbers of significant findings in the univariate analyses for each major group comparison. *P* values less than .05 were considered statistically significant.

RESULTS

After distribution of invitations to participate to members of the three aforementioned societies, 164 physicians indicated a desire to participate and received materials to conduct the NVSP. Eighty-three (51%) physicians completed a screening and returned data for entry into the database (Fig 1). To ensure maximum return of data, the NVSP coordinator oversaw follow-up with participating physicians who received materials. A total of 2234 individuals were screened in 40 states with a mean of 26 participants screened per site (range, 4-42). General demographics for the entire population screened are listed in Table I. Most participants (82%) indicated their primary physician was either in family practice (48%) or internal medicine (34%). Reasons cited for attending the screening included 60% desiring a free screening, 42% having varicose veins, 35% having leg pain, 18% having a swollen leg, 7% having a "blood clot", and 6% having a cosmetic problem.

Table II outlines the each participant's answers to the questions about risk factors for VTE. Fig 2 illustrates the distribution of the total point score across the population screened. On the basis of affirmative answers and cumulative score,^{5,6} VTE risk assessment for participants if they were placed in a high-risk situation was as follows: 17% of people screened were at very high risk (≥ 5 points); 21% were at high risk (3-4 points); 22% were at moderate risk (2 points); and 40% were at low risk (0-1 point). Table III shows the distribution of reflux and obstruction discovered in the common femoral vein, saphenofemoral vein junction, and popliteal vein for each leg for the entire group. Thirty-seven percent of participants had one or more segments of reflux, and 5% had one or more segments of obstruction. Table IV lists the distribution of clinical class (CEAP) for CVD. Varicose veins were present in 23% of people, edema without skin changes in 10%, skin changes

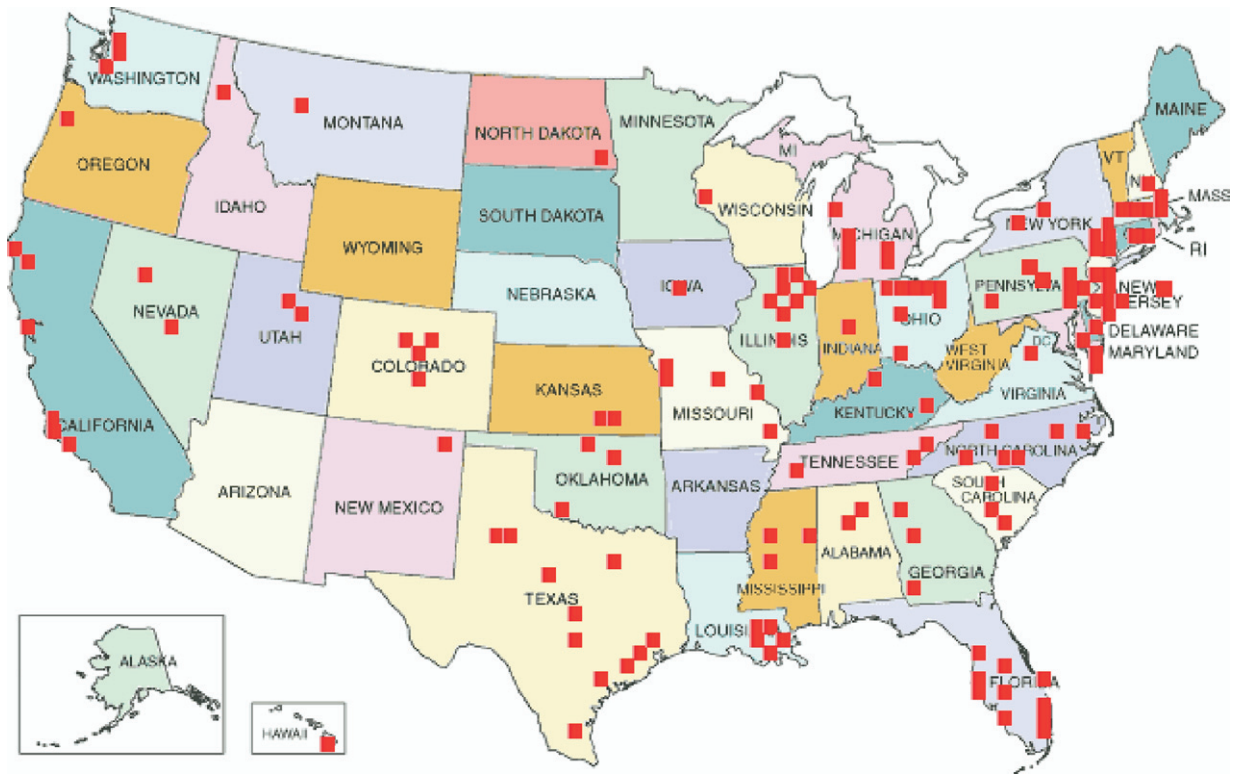


Fig 1. Map of the United States showing the location of the each site (n = 83) for the National Venous Screening Program.

Table I. General demographics and medical information for 2234 individuals participating in the National Venous Screening Program

<i>Variable</i>	<i>Mean; median (range)</i>
Age (y)	60; 62 (17-93)
Body mass index	29; 25 (11-68)
	<i>Number (percent)</i>
Gender	
Female	1720 (77)
Male	514 (23)
Race	
Caucasian	1787 (80)
African American	134 (6)
Hispanic	67 (3)
Asian	67 (3)
Pre-existing conditions	
Diabetes mellitus	223 (10)
Hypertension	760 (34)
Congestive heart failure	45 (2)
Smoking status	
Non-smoker	1340 (60)
Smoker	156 (7)
Past smoker	737 (33)
Current treatment	
Aspirin	491 (22)
Clopidogrel	45 (2)
Warfarin	89 (4)

attributable to venous disease in 7%, and healed or active venous stasis ulcer in 2.0%. **Table V** shows the results of distribution of answers for the abbreviated CIVIQ questionnaire. In the four questions addressing pain, 29% of participants had a score ≥ 3 (moderately to intensely bothered or limited). Similarly, a score ≥ 3 for the four physical functioning questions and the three social activity questions was observed in 25% and 20%, respectively.

Age of participants with reflux (mean, 59 years; SD = 12.9 years) compared with those without reflux (mean, 60 years; SD = 12.9 years) reached a statistically significant difference ($P = .01$). The VTE risk score in those with reflux (mean, 2.0; SD = 2.0) was significantly higher ($P < .0001$) than in those without reflux (mean, 1.4; SD = 1.9). Age of participants with obstruction (mean, 63 years; SD = 13.9 years) compared with those without obstruction (mean, 60 years; SD = 13.0 years) reached a statistically significant difference ($P = .02$). The VTE risk score in those with obstruction (mean, 2.4; SD = 2.2) was significantly higher ($P < .0001$) than in those without obstruction (mean, 1.6; SD = 2.0). Caucasians had significantly less obstruction compared with non-Caucasians (4% vs 9%; $P < .001$). Participants with diabetes mellitus had significantly more obstruction than participants without obstruction (9% vs 4.5%; $P = .005$). Participants with hypertension

Table II. Number (percent) of people (n = 2234) who gave affirmative answers to questions that assess their risk for venous thromboembolism if placed in a high-risk situation

	Number (percent)	
1. Have you ever had a blood clot in your legs or lungs?	(3)	168 (8)
2. Do you have a family history of blood clots in the veins?	(3)	292 (13)
3. Do you currently or have you ever had swollen legs?	(1)	438 (20)
4. Do you have visible varicose veins other than spider veins?	(1)	1146 (51)
5. Do you have ileitis, Crohn disease, or inflammatory bowel disease?	(1)	105 (5)
6. Do you have serious lung disease or emphysema?	(1)	59 (3)
7. Within the last month, have you had more than 3 days of continuous bed rest attributable to injury or illness?	(1)	48 (2)
8. Within the last month, have you had a pelvic fracture or a plaster leg cast?	(1)	12 (1)
9. Have you had a stroke, heart attack, or heart failure?	(1)	105 (5)
10. Have you had major surgery lasting over an hour in the last month?	(1)	17 (1)
11. Do you have or have you had a malignant disease (cancer)?	(2)	157 (7)
12. Do you weigh over 250 pounds?	(1)	110 (5)
13. Age between 40-59 years?	(1)	631 (28)
14. Age between 60-69 years?	(2)	368 (16)
15. Age equal to or greater than 70 years?	(3)	399 (18)
Women only		
16. Do you take birth control pills or estrogen (hormone) replacement therapy?	(1)	164 (7)
17. Are you pregnant or have you given birth within the last month?	(1)	3 (0.1)

Number in parentheses after each question represents the number of points assigned if an affirmative answer is given. Points are added to calculate the risk score.

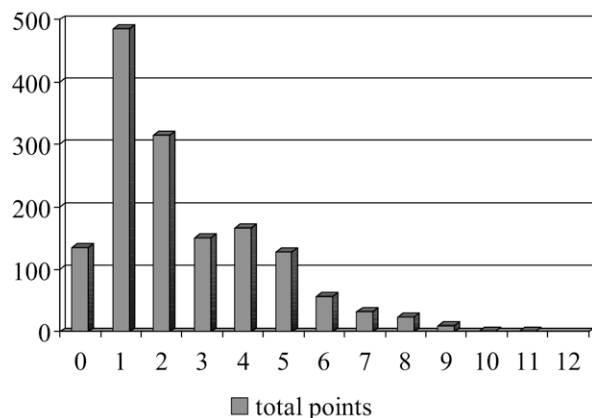


Fig 2. The bar graph depicts the distribution across the screened population (n = 2234) of the total number of points (indicative of increasing number of risk factors) for developing venous thromboembolism if placed in a high-risk situation.

had significantly more obstruction versus those without hypertension (7.5% vs 3.7%; $P < .0001$). Participants with obstruction were significantly more likely to be taking warfarin compared with those without obstruction (12% vs 4.6%; $P = .001$). The BMI did not differ in those with and without reflux ($P = .26$) or obstruction ($P = .06$). Smoking status did not differ in those with and without reflux ($P = .09$) or obstruction ($P = .58$).

Significantly higher CEAP classification scores were observed in participants with reflux ($P < .001$) or hypertension ($P = .01$) and in participants having a VTE risk in the combined high/very high categories ($P < .001$). Increasing CIVIQ scores (decreasing QOL) also correlated with higher CEAP classification ($r = 0.08$; $P = .01$). Further analyses revealed that CIVIQ scores were signifi-

cantly higher (decreasing QOL) in participants with the following variables: African American ($P = .006$); female ($P = .001$); smoking ($P = .006$); heart failure ($P = .007$); hypertension ($P < .001$); diabetes mellitus ($P = .0003$); VTE risk in high/very high category ($P = .001$).

DISCUSSION

Expansion of the NVSP in the United States has led to further knowledge of the risk and presence of venous disease in a screened population. Although the screening is not a randomized sample of the public, valuable information has been acquired about the population who responded to the offer of a free screening. Demographics of those individuals across 40 US states were similar to those of the smaller NVSP pilot in 17 centers performed 1 year earlier.⁵ The population reported herein was largely older (mean age, 60 years), Caucasian (80%), female (77%), and obese (mean BMI, 29).

Several inferences can be made regarding these data. First, older Americans are more prone to venous disease, which may increase their interest in obtaining more information. Additionally, retired Americans may have a schedule conducive to participating in screenings. Information is lacking as to the demographics of minorities who lived in the vicinity of each site and participated in the NVSP. This important and complex issue requires efforts by the AVF to increase the opportunities for screening in minorities. Nevertheless, expansion of the NVSP did show significantly more obstruction in minorities (as a whole) than in Caucasians (9% vs 4%; $P < .001$) as determined by an abbreviated duplex ultrasound examination. African Americans were also observed to have significantly worse CIVIQ QOL scores. The predominance of women desiring to participate could be due to the higher incidence of varicose veins in this population as well as their increased attention to use of

Table III. Percent of vein segments that were positive by duplex ultrasound examination for the presence of venous valve reflux or obstruction in each lower extremity of the population screened (n = 2234)

	<i>Reflux right leg</i>	<i>Reflux left leg</i>	<i>Obstruction right leg</i>	<i>Obstruction left leg</i>
Common femoral vein	15%	16%	3%	3%
Saphenofemoral vein junction	21%	21%	3%	3%
Popliteal vein	8%	9%	4%	4%

Table IV. Percent distribution of participants (n = 2234) with the highest CEAP classification for chronic venous disease (CVD)

<i>Classification</i>	<i>Distribution</i>
C0 (no CVD)	29%
C1 (telangiectasias)	29%
C2 (varicose veins)	23%
C3 (edema)	10%
C4 (skin changes)	7%
C5 (healed ulcer)	1.5%
C6 (ulcer)	0.5%

health care services.^{9,10} More attention should be given to attracting men, particularly with regard to education about the risk of VTE and more severe forms of CVD. Obesity continues to plague Americans as exemplified in those individuals participating in the NVSP. Indeed, even with a dramatic expansion in the number of participants compared with the previous year (476 vs 2234 individuals), the mean screening BMI increased by one point to 29, which is still in the overweight category but borders on the obese category (BMI \geq 30).

Risk factor delineation, abbreviated duplex ultrasound examination, and classification of CVD showed similarities to findings in the smaller pilot NVSP report (Tables II-IV). These data underscore the importance of increasing efforts to provide more education about venous disease in the public arena. Important to the next phase of the NVSP is to determine what course individuals follow after obtaining information from the screening and, more importantly, if they retain information about identification and risk of the disease process. Do those screened individuals actually give the report card to their physician? Do participants seek further information and find potential treatments? Will they alert their physician as to their risk of DVT if put in a high-risk situation? The AVF will seek to answer these important questions, because this screened population was the first to sign a release form allowing NVSP representatives to contact them at a later date for further follow-up.

Statistical analyses continue to illustrate the strength of the NVSP as a valid process. Significantly higher CEAP classification scores were observed in participants with reflux and those having a VTE risk in the combined high/very high categories. Moreover, VTE risk scores were significantly higher in those individuals with reflux or obstruction. Interestingly, varying BMI and smoking did not show any differences with regard to the presence of venous reflux or obstruction.

Table V. Percent distribution (**in bold**) of findings for participants who completed the abbreviated Chronic Venous Insufficiency Quality of Life questionnaire (CIVIQ)

1. What is the intensity of the pain?	None	Light	Moderate	Strong	Intense
	1 (23)	2 (29)	3 (29)	4 (14)	5 (5)
2. Bothered/limited in your work or other daily activities?	None	A little	Moderately	Very	Extremely
	1 (36)	2 (31)	3 (21)	4 (9)	5 (3)
3. How often do you sleep badly?	Never	Seldom	Fairly	Very	Every night
	1 (34)	2 (32)	3 (20)	4 (10)	5 (4)
4. Bothered/limited by standing for a long time?	None	A little	Moderately	Very	Extremely
	1 (25)	2 (32)	3 (23)	4 (18)	5 (2)
5. Bothered/limited by climbing stairs?	None	A little	Moderately	Very	Extremely
	1 (36)	2 (29)	3 (18)	4 (15)	5 (2)
6. Bothered/limited by crouching/kneeling?	None	A little	Moderately	Very	Extremely
	1 (31)	2 (26)	3 (18)	4 (17)	5 (8)
7. Bothered/limited by walking briskly?	None	A little	Moderately	Very	Extremely
	1 (40)	2 (28)	3 (16)	4 (11)	5 (5)
8. Bothered/limited by travel by car, bus, plane?	None	A little	Moderately	Very	Extremely
	1 (39)	2 (31)	3 (20)	4 (9)	5 (1)
9. Bothered/limited in performing housework such as working in kitchen, carrying child, cleaning floors, doing handy work?	None	A little	Moderately	Very	Extremely
	1 (40)	2 (29)	3 (19)	4 (10)	5 (2)
10. Bothered/limited in going to discos, weddings, parties, cocktails?	None	A little	Moderately	Very	Extremely
	1 (61)	2 (20)	3 (9)	4 (6)	5 (4)
11. Bothered/limited in strenuous sporting activities?	None	A little	Moderately	Very	Extremely
	1 (44)	2 (24)	3 (13)	4 (9)	5 (10)

Symptoms/activities asked about in the questionnaire pertained to or were caused by the ankles/legs during the last 4 weeks prior to the screening. (For purposes of reporting, the questions and answers are shortened versions of those in the original CIVIQ.)

Added to the expansion of NVSP was the administration of an abbreviated form of the CIVIQ. Because of the need for brevity in the screening process, questions in the full questionnaire pertinent to the effect on morale (questions 12-20) were not used. The first 11 questions of the full CIVIQ are more specific for vein symptoms that affect the legs and were deemed more appropriate for use in the screening process. These data also illustrate increasing CIVIQ scores (decreasing QOL) in participants with higher CEAP classification and in those with VTE risk in

the combined high/very high category. Although previous validation of the CIVIQ used 20 questions,^{7,8} the abbreviated version also shows correlation with individuals with increasing severity of CVD and those at increasing risk of developing acute VTE if put in a high-risk situation. Of note, the finding that African Americans were significantly more likely to have a higher CIVIQ score (lower QOL with respect to venous disease) should be viewed in the context that this specific QOL questionnaire was not previously validated in this ethnic group.

The pilot NVSP performed a year earlier provided valuable guidance to appropriately expand the program. One important step to improvement was providing more educational information to the participants about the VTE risk assessment and the meaning of being placed in a high-risk situation conducive to increasing the risk of VTE. A specific monograph developed to more fully explain these concepts in lay terms was given to participants. This monograph further assisted physicians in assuring participants that, although their VTE risk may be very high if placed in a high-risk situation such as undergoing major abdominal surgery, the risk at the time of the screening would be considerably lower given that they are not in that high-risk situation. The AVF will continue its mission to educate, identify, and empower Americans about and with all types of venous disease, acute and chronic. Certainly the scope and presence of venous disease necessitate continued action in the public and health professional sectors. More work is needed, particularly in the area of physician awareness about proper DVT prophylaxis and new opportunities for treatment. New opportunities assimilated from this expansion include the possible addition of the venous clinical severity score as well as looking for opportunities to work with hospital systems to foster more screening and physician education. As with education about other important preventive health measures, such as the use of seat belts or the ill effects of smoking, we should also provide education about how to prevent the devastating effects of venous disease. This enormous socioeconomic burden deserves more attention.

AUTHOR CONTRIBUTIONS

Conception and design: RM, MP, JC, TR, JL, MM, BE, TW, MD

Analysis and interpretation: RM, MP, JC, TW, SM

Data collection: RM, MP, JC, TR, JL, TW, MD

Writing the article: RM

Critical revision of the article: RM, MP, JC, TR, TW, MD

Final approval of the article: RM, MP, JC, TR, SM, JL, MM, BE, TW, MD

Statistical analysis: RM, SM

Obtained funding: RM, MP, JC

Overall responsibility: RM

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