



# Feasibility and pilot efficacy of a brief smoking cessation intervention delivered by vascular surgeons in the Vascular Physician Offer and Report (VAPOR) Trial

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## ABSTRACT

**Background:** This study determined the feasibility and potential efficacy of an evidence-based standardized smoking cessation intervention delivered by vascular surgeons to smokers with peripheral arterial disease.

**Methods:** We performed a cluster-randomized trial of current adult smokers referred to eight vascular surgery practices from September 1, 2014, to July 31, 2015. A three-component smoking cessation intervention (physician advice, nicotine replacement therapy, and telephone-based quitline referral) was compared with usual care. The primary outcome was smoking cessation for 7 days, assessed 3 months after the intervention. Secondary outcomes were patients' nicotine dependence and health expectancies of smoking assessed using Patient Reported Outcomes Measurement Information System (PROMIS; RAND Corporation, Santa Monica, Calif).

**Results:** We enrolled 156 patients (65 in four intervention practices, 91 in four control practices), and 141 (90.3%) completed follow-up. Patients in the intervention and control practices were similar in age (mean, 61 years), sex (68% male), cigarettes per day (mean, 14), and prior quit attempts (77%). All three components of the intervention were delivered to 75% of patients in intervention practices vs to 7% of patients at control practices ( $P < .001$ ). At 3 months, 23 of 57 patients (40.3%) in the intervention group quit smoking (23 of 56 patients quit who completed follow-up, plus 1 death included in the analysis in the denominator as a smoker), and 26 of 84 patients (30.9%) in the control group quit smoking (26 patients of 84 who completed follow-up, including 2 deaths included in the denominator as smokers). This difference (40.3% quit rate in intervention, 31% quit rate in control;  $P = .250$ ) was not statistically significant in crude analyses ( $P = .250$ ) or analyses adjusted for clustering ( $P = .470$ ). Multivariable analysis showed factors associated with smoking cessation were receipt of physician advice (odds ratio for cessation, 1.96; 95% confidence interval, 1.28-3.02;  $P < .002$ ) and nicotine replacement therapy (odds ratio, 1.92; 95% confidence interval, 1.43-2.56;  $P < .001$ ).

**Conclusions:** Implementation of a brief, surgeon-delivered smoking cessation intervention is feasible for patients with peripheral arterial disease. A larger trial will be necessary to determine whether this is effective for smoking cessation. (J Vasc Surg 2017;65:1152-60.)

Guidelines endorsed by the Centers for Disease Control and Prevention (CDC) and the United States Preventive Task Force recommend that all health care providers provide smoking cessation counseling at each visit and

patient encounter.<sup>1</sup> This is especially important for patients facing vascular interventions, such as angioplasty or surgical bypass, because smoking cessation has been shown to reduce the risk of major complications,

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improve bypass graft patency, and limit the risk of major limb amputation.<sup>2,3</sup> Current guidelines recommend a three-component approach that incorporates physician advice, nicotine replacement therapy (NRT), and longitudinal counseling from a free, telephone-based quitline.<sup>1,4</sup>

However, successful implementation of evidence-based smoking cessation varies broadly, even for patients facing vascular surgery. For example, a study from the Vascular Study Group of New England demonstrated that smoking cessation in the year after vascular procedures varies nearly threefold, from 28% to 62%.<sup>5</sup> Further, fewer than one in five patients with peripheral arterial disease (PAD) receives evidence-based help with quitting smoking near the time of invasive procedures.<sup>6,7</sup> Surgeons who do not provide smoking cessation often cite time constraints, lack of familiarity with resources for smoking cessation, a perception that smoking cessation is the responsibility of primary care providers, and overall discomfort with smoking cessation counseling as to providing recommended care.<sup>8</sup> The fact that surgeons are less likely to counsel patients on smoking cessation than primary care or medical providers represents a significant lost opportunity to provide cessation at a key “teachable moment.”<sup>6,9</sup>

We hypothesized that implementation of a brief, evidence-based smoking cessation intervention would be feasible for patients facing invasive treatments for PAD. This report describes a pilot, multicenter, cluster-randomized trial called the Vascular Physician Offer and Report (VAPOR) trial in which a standardized, brief smoking cessation intervention was compared with usual care for patients with PAD. Eight vascular surgery practices were randomized to provide usual care for smoking cessation or a standardized protocol consisting of (1) physician “very brief advice” to stop smoking, (2) offering NRT, and (3) referral to a phone-based counseling service.

## METHODS

**Overview.** The Institutional Review Boards at all sites approved the trial. To assess the feasibility and pilot efficacy of a surgeon-delivered, brief smoking cessation intervention, we conducted a multicenter, pilot, cluster-randomized clinical trial that compared the “Offer and Report” protocol to the usual care provided by vascular surgeons in everyday practice. The Offer and Report protocol is an adaptation of the CDC’s recommendations for smoking cessation, designed using physician “very brief advice” designed by the National Centre for Smoking Cessation and Training for use in England’s National Health Service.<sup>10-12</sup> Our primary outcome measure was smoking cessation at 3 months after the intervention.<sup>13-15</sup>

**Study intervention.** The development and testing of our intervention has been described in earlier work.<sup>16,17</sup> The intervention consisted of (1) physician-delivered “very brief advice” about smoking cessation,<sup>12,18,19</sup>

## ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective cluster-randomized multicenter trial
- **Take Home Message:** Implementation of a surgeon-delivered smoking cessation intervention is feasible and holds promise for effective smoking cessation.
- **Recommendation:** The authors suggest that a larger trial be conducted to determine the efficacy of brief, surgeon-delivered smoking cessation intervention.

(2) provision of a prescription for NRT to assist in smoking cessation,<sup>20</sup> and (3) active referral to telephone-based smoking cessation counseling by contacting a state-level quitline for patients using a fax-based referral system. We generated preprinted pocket cards ([Supplementary Fig 1](#), online only) to help study physicians remember each of the three steps and the dosages of commonly used NRT medications. We supplied each practice with copies of their state-level quitline fax referral form. Training for this intervention was administered to all intervention sites using two 2-hour-long Web-based seminars for study site leaders using a study protocol. We reviewed this protocol with site-specific study coordinators at the inception of the study and additionally during biweekly 1-hour-long teleconference protocol review and implementation meetings. These meetings took place for all site coordinators for the entire study period.<sup>17</sup> Finally, surgeons at each site participated in two additional interim Web-based conference calls to review protocol implementation.

**Outcome assessment.** Patients were screened for study enrollment before their clinic visit, and consent was obtained by study nurses before the clinic visit if patients were willing to participate. Study nurses recorded whether each of the three components of the intervention was administered by accompanying the patient throughout the study visit, including during the patient’s interaction with the vascular surgeon. Patients in both arms then completed Patient Reported Outcomes Measurement Information System (PROMIS) Smoking Item Bank Surveys (RAND Corporation, Santa Monica, Calif), which included questions regarding smoking history, quit interest, and assessment of nicotine dependence and smoking-related harms.<sup>15</sup> No financial incentive was provided. Biochemical analysis to assess tobacco use was not performed.

Study nurses also assessed 3-month outcomes using standardized instruments, which included assessment of tobacco use over the last 7 days, as the PROMIS Smoking Item Bank surveys related to Health Expectancies and Nicotine Addiction<sup>15</sup> ([Supplementary Fig 2](#), online only). These outcomes were collected at an in-person visit in the clinic or by phone consultation if in-person

**Table I.** Patient characteristics by control or intervention group status

Variables	Intervention (n = 65)	Control (n = 91)	P value
Patient characteristics			
Age, mean (SD), year	60.2 (7.6)	61.6 (7.8)	.28
Male gender, %	64.9	76.5	.14
Smoking history, mean (SD)			
Pack-years	37.4 (1.5)	41.8 (1.1)	.02
Cigarettes per day	14.9 (1.1)	14.2 (1.0)	.64
Previous quit attempt, %			
Previously used quitline	23.1	14.3	.16
Previous use of medications	61.5	64.8	.67
Previously quit >1 week	78.1	76.9	.86
Education, %			
Less than high school	9.2	15.4	
Finished high School	38.5	47.3	
Some college	29.2	27.5	
College graduate	21.5	9.9	
Previously told by PCP to quit, %	76.9	82.4	.40
Previously told by vascular surgeon to quit, %	76.9	65.9	.14
Procedure (surgical or vascular) was recorded in vascular registry, %	30.8	25.3	.45
Components of evidence-based smoking cessation, %			
Given quit advice by doctor this visit	98.5	76.9	<.0001
NRT offered during office visit	76.9	15.4	<.0001
Quitline referral	93.9	33.0	<.0001
Follow-up, %			
Assessed quit status at 3 months	87.5	92.1	.34
Filled out follow-up survey	35.4	57.1	.01

NRT, Nicotine replacement therapy; PCP, primary care physician; SD, standard deviation.

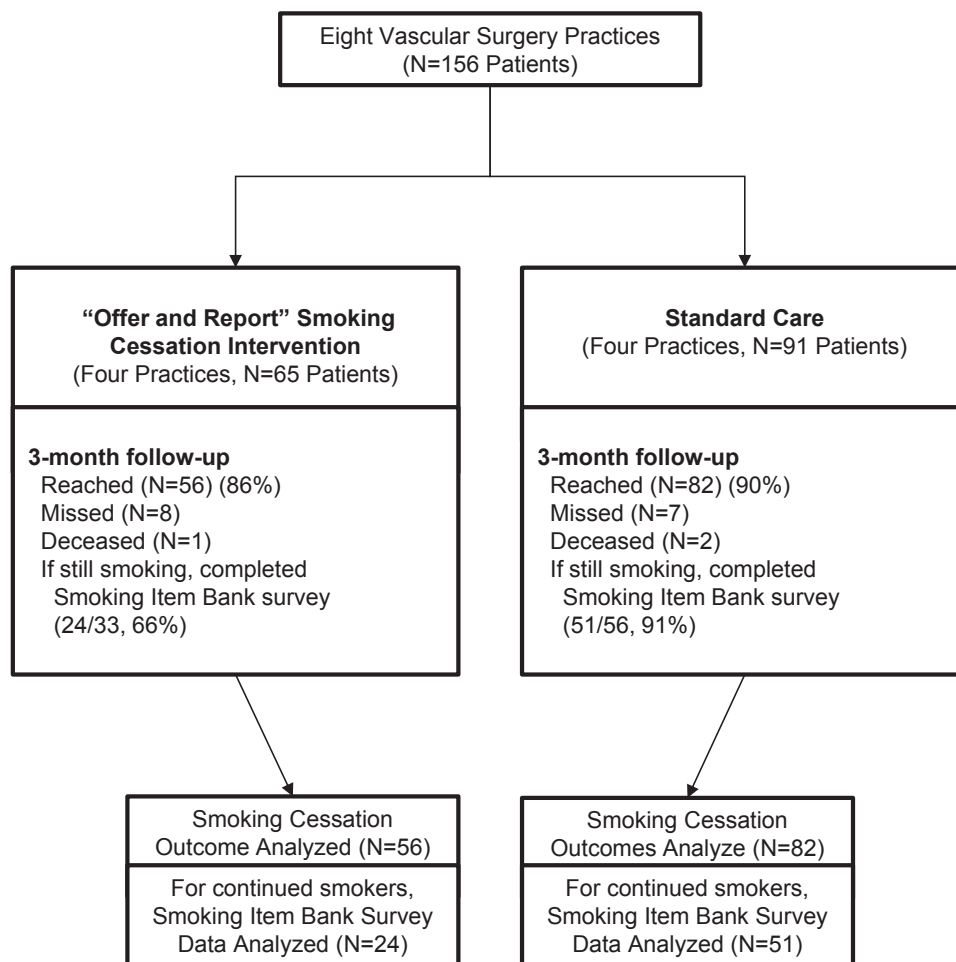
visits were not available. For patients in whom follow-up was missing, systematic attempts to contact patients by phone, letter, office visit, primary care physician contact, or family reference contact were performed. Demographics, patient, and practice characteristics were also collected.

#### Randomization, enrollment goals, and analysis.

Randomization of eight clinical sites occurred in a 1:1 ratio for the intervention or the control protocol. All sites were staffed by vascular surgeons. The eight sites consisted of seven academic practices and one large community-based practice. Before the study was implemented, we estimated the effect size expected from our intervention. Preliminary estimates suggested that 15% to 30% of patients enrolled in smoking cessation programs supplemented by NRT achieve durable smoking cessation at 1 year.<sup>6,21</sup> Further, recent work suggested that patients are more than twice as likely to quit smoking near the time of a vascular surgery procedure compared with patients not treated with invasive procedures.<sup>5</sup>

Our enrollment goal was 25 patients per practice. We estimated that at this study size, our pilot would have 60% power to detect a 30% relative difference (absolute difference, 25% and 17%) in cessation rates between two independent clusters of practices. Given this limited power, the trial was designed to demonstrate the feasibility of implementing the intervention and allow refinement of the potential effect size associated with the intervention for future trials.

In measuring our primary outcome, we calculated crude 3-month smoking cessation rates by site and compared rates between our intervention and control groups. Intraclass correlation coefficients were used to adjust for clustering within sites.<sup>22</sup> This adjustment accounted for within-site clustering of patient characteristics at each of the eight sites in our trial. If patients underwent surgical or endovascular procedures collected within the Vascular Quality Initiative's data registry, information about these procedures was also recorded, and the data were linked to our study files to create a data set that contained smoking data as well as demographic and procedural data, when available.



**Fig 1.** Consolidated Standards of Reporting Trials diagram of patients enrolled at our eight study sites.

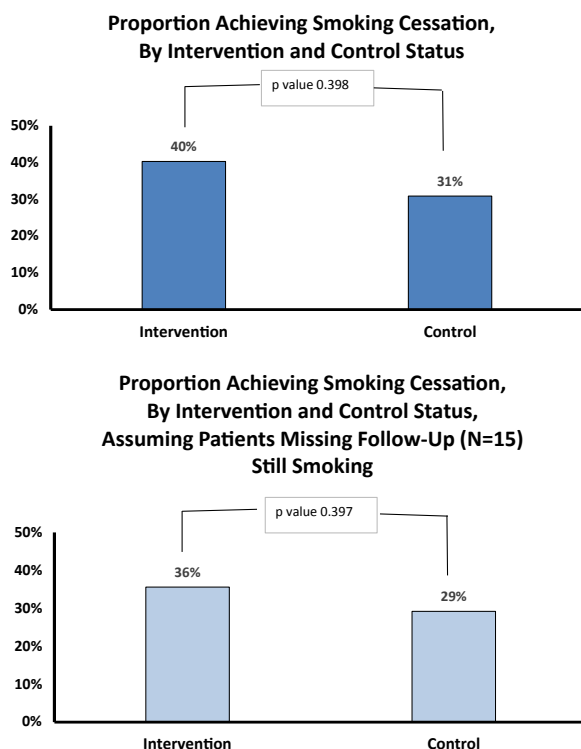
Finally, to ascertain the effects of factors other than our study intervention associated with smoking cessation, we generated logistic models to determine factors that were independently associated with successful smoking cessation at 3 months. These models used smoking cessation as the outcome measure and then used patient demographics, Smoking Item Bank responses, and surgical characteristics to determine factors associated with smoking cessation.

## RESULTS

**Enrollment and characteristics of the sample.** Across the eight vascular surgery practices, we enrolled 156 patients between September 1, 2014, and July 31, 2015. Overall, 65 patients were enrolled in the four intervention practices, and 91 patients were enrolled in the four control practices. Patients in the intervention and control practices were similar in demographics and smoking-related domains (Table I). Patients were predominantly male (65% intervention group, 77% control group;  $P = .14$ ), with an average age of 61 years. Patients had similar PROMIS health expectancy and nicotine dependence scores in the intervention and control practices at the time of the

intervention. Patients smoked ~14 cigarettes per day in both groups (14.9 intervention, 14.2 control;  $P = .644$ ); 78% of intervention patients and 77% of control patients had previously quit ( $P = .861$ ). Although patients in both groups were long-term smokers, those in the intervention group smoked fewer pack-years (37.4 pack-years) than those in the control group (41.7 pack-years;  $P = .02$ ). Overall, 30% (42 of 156) of patients underwent a vascular procedure after the intervention according to data entered in the Vascular Quality Initiative registry.

**Intervention delivery, by study arm.** Each of the three individual components of the smoking cessation intervention was significantly more likely to be provided to patients in the intervention group than in the control group (Table I); for example, 98% of patients in the intervention group and 77% in the control group received smoking cessation advice ( $P < .001$ ). Differences between the intervention and control groups were larger, however, for the other two components of the smoking cessation intervention: NRT was offered in 76% vs 16% ( $P < .001$ ), and quitline referral was made in 98% vs 33%, respectively ( $P < .0001$ ). Overall, receipt of all



**Fig 2.** Smoking cessation rates by intervention and control group status.

three components was confirmed by 75% of patients in the intervention practices but by only 7% of patients in the control practices ( $P < .001$ ). Neither auditing of actual quitline phone discussions nor confirmation of filling of prescriptions for NRT was performed as part of this trial.

**Smoking cessation at 3-month follow-up, by intervention and control groups.** Our main outcome measure was assessed in 90.4% of the cohort at 3 months after the intervention. Of the 156 patients, 15 (9.6% overall, 8 in the intervention practices, and 7 in the control practices) were lost to follow-up (Fig 1). Three of the 141 remaining patients died before the 3-month follow-up (1 in the intervention group, 2 in the control group) and were analyzed as still smoking at the 3-month follow-up. This left 138 patients (56 in the intervention group, 82 in the control group) available for assessment of the outcome measure. Patients who died before completing follow-up were assumed to be smokers at the time of their death, in a conservative assumption.

Of the 138 patients whose smoking status was assessed at 3 months after the intervention, 49 had quit smoking (35.5% overall). At 3 months, 23 of 57 patients (40.3%) in the intervention group quit smoking (23 of 56 patients who completed follow-up, plus 1 death included in the analysis in the denominator as a smoker) and 26 of 84 patients (30.9%) in the control group who completed the follow-up quit smoking (including 2 deaths included in the denominator as smokers). Quit rates were higher

in the intervention group (40.3%) than the control group (30.9%), but this difference did not reach statistical significance (unadjusted  $P = .250$ ; Fig 2). In models adjusting for our cluster randomized design, the odds ratio (OR) for achieving smoking cessation in the intervention group was 1.51 (95% confidence interval [CI], 0.58-3.91; adjusted  $P = .470$ ).

**Factors associated with smoking cessation and power calculations for larger trial.** Results of the multivariable logistic regression model predicting smoking cessation are summarized in Table II. With respect to the specific intervention components (physician advice, NRT prescription, and telephone counseling) participation in a phone-based quitline had the smallest magnitude of association with smoking cessation, whereas physician advice and NRT were associated with a higher likelihood of achieving smoking cessation. Use of a quitline was not associated with smoking cessation. Model results also show that certain health expectancy and nicotine dependence questions were associated with smoking cessation. For example, those patients who reported worrying that cigarettes “were taking years off my life” were threefold more likely to quit. Conversely, those patients who “often” or “always” described “reaching for cigarettes when waking up” were 83% less likely to achieve smoking cessation. Overall, this model had good discrimination (receiver operating characteristic curve = .77) and a goodness-of-fit statistic demonstrating good fit with the actual data seen in the study sample (goodness-of-fit statistic  $P = .342$ ).

Based on the observed effect size of the smoking cessation intervention (OR, 1.51; 95% CI, 0.58-3.91), we examined the sample sizes necessary to conduct a fully powered randomized trial. We determined that to achieve statistical significance in a full-size randomized trial, we would need to enroll >600 patients in each arm (intervention vs control), with site (or cluster) randomization adding to this sample size depending on the number and size of the sites. For example, if a cluster-randomized trial with 20 sites was performed, 34 patients per cluster would be required, resulting in a total sample size of 680 patients per treatment arm, assuming an intracluster correlation of 0.01.

## DISCUSSION

This trial of a brief smoking cessation intervention designed for vascular surgeons treating patients facing decisions about invasive treatments demonstrated the feasibility of our intervention. Across eight vascular surgery practices, we found it was feasible and successful to deliver a systematic, evidence-based smoking cessation intervention. In the intervention practices, 75% of patients received all three components of the intervention compared with 7% in the control practices. And although we found that patients in the intervention



**Table II.** Multivariable logistic regression model for intervention and patient-level factors associated with smoking cessation<sup>a</sup>

Covariate	OR for quitting smoking	95% CI	P value
Components of the intervention			
Physician advice to quit smoking	1.96	1.28-3.02	.002
Provision of NRT	1.92	1.43-2.56	.001
Used a quitline	0.25	0.07-0.86	.027
Health expectancies and nicotine dependence			
Reports "quite a bit" or "very much" that they worry that cigarettes are taking years off his/her life	3.09	1.26-7.57	.013
Reports "often" or "always" thinking about buying cigarettes	3.22	1.07-9.65	.037
Reports "often" or "always" reaches for cigarettes when waking up	0.17	0.06-0.51	.001
Reports "quite a bit" or "very much" that cigarettes makes him/her short of breath	0.24	0.06-0.89	.032
Other physician advice			
Has previously received advice from vascular physician to quit smoking	0.56	0.32-0.96	.037

CI, Confidence interval; NRT, nicotine replacement therapy; OR, odds ratio.  
<sup>a</sup>Adjusted for age, gender, education, occurrence of surgical or procedure, health effects and nicotine dependence, and clustering within sites. Receiver operating characteristic curve = 0.77; goodness of fit = 0.347.

**Table III.** Summary of studies from the Cochrane Database of Systematic Reviews leveraging smoking cessation interventions such as "teachable moments"

Study	Key exposure	Summary of effect
Thomsen et al <sup>10</sup>	Perioperative interventions	Even brief interventions increase cessation by 41%
Stead et al <sup>23</sup>	Physician advice	Intensive interventions are 37% more effective than brief
Civljak et al <sup>24</sup>	Web-based interventions	Variable, but up to 2.05 risk ratio increase in quit rate
Hartmann et al <sup>25</sup>	Multimodality interventions	Up to 57% increase in cessation with multimodality
Lancaster et al <sup>26</sup>	Behavioral counseling	56% increase in quit rate with counseling

group were more likely to achieve smoking cessation, with the limited size of our pilot trial, this finding was not statistically significant.

Delivering evidence-based smoking cessation interventions to patients facing procedural-based subspecialty care has been shown to be a potentially effective treatment paradigm. In several data syntheses compiled in Cochrane Database of Systematic Reviews<sup>10,23-26</sup> (Table III), delivering smoking cessation interventions at a time when the patient is most likely to "hear" smoking cessation advice—the "teachable moment"—has been attempted near the time of cardiac catheterization for coronary artery disease, treatment for lung cancer, and other types of health care interventions.<sup>16,27,28</sup> Smoking cessation interventions at this key time in a patient's health care have been shown to potentially improve smoking cessation rates by 40%.<sup>10,28</sup> The manner in which smoking cessation interventions are delivered may matter just as much as the timing, especially for patients facing invasive treatments. In a study of primary care practices, delivering smoking cessation advice using a standardized empathetic, patient-centered approach increased patients' readiness to quit from 65% to 84%.<sup>9,27</sup> This may represent another avenue to maximize

the potential effect of a smoking cessation intervention—delivering it at the right time, in the best way, to patients who are listening when their surgeon is discussing an invasive treatment.<sup>16</sup>

Potential advantages aside, the goal of this study was to demonstrate feasibility and establish a range of efficacy measures for the planning of a larger, cluster-randomized trial. We identified several successes and challenges during this effort. Despite initial concerns expressed by our surgeons about adhering to an evidence-based smoking cessation protocol, we found that the surgeons at the intervention sites were able to deliver the smoking cessation intervention successfully, including the quitline referral and medication components, with little disruption of their clinical workflow and without substantive changes in existing clinical support staff.

We also learned of the difficulties in performing smoking cessation interventions in populations that include smokers who are not necessarily ready to quit smoking. In our study, nearly 30% reported having no motivation to quit, and many of these patients were difficult to reach in follow-up. For example, 18% of patients who did not quit smoking at 3 months also refused to complete our follow-up survey of smoking

health expectancies and nicotine dependence. An additional 10% of patients were unable to be contacted for 3-month follow-up. These challenges suggest that incentives, such as financial payments, will be needed to ensure optimal follow-up, especially among patients not motivated to quit.

Our findings have several implications. First, we integrated an evidence-based smoking cessation program into everyday clinical practice in vascular surgery clinics across the United States. This integration argues that evidence-based smoking cessation should be considered an achievable goal for routine vascular surgery practice.

Second, our results suggest that the most important parts of smoking cessation interventions for patients facing vascular procedures include input from their surgeon and support for addiction using nicotine replacement; therefore, facilitating the delivery of these components in future studies will be a key priority in future, larger trials.

Finally, our smoking cessation rates, in both the intervention and control arms, are slightly higher than smoking cessation rates obtained in patients not facing surgery, suggesting the potential opportune time for perioperative smoking cessation.

Our study also has several limitations. First, in planning for this trial, we planned to have a 20% to 30% effect size, based on prior studies of smoking cessation interventions for patients facing surgical treatments.<sup>17</sup> Our limited funding necessitated this trial to collect preliminary information, and efforts are underway to secure funding for a larger, definitive study.

Second, our study did not measure expired carbon monoxide or use cotinine testing. Large cross-sectional studies have shown these tests may detect smokers who will report cessation even though they are actively smoking tobacco.<sup>29-31</sup> However, these tests are limited by false-positive results that can be equal in incidence to the proportion of smokers who will falsely report cessation, especially if the patients reside with other smokers such as their spouse or family members.

Third, although CDC guidelines recommend quitline referral and provision of NRT, actually delivering these measures to patients presents logistic and financial challenges to certain patient populations. For example, the cost of varenicline, among the most effective medical therapies for smoking cessation, can be >\$200 monthly. However, the Affordable Care Act, passed in 2010, aimed to enact specific support for smoking cessation during 2013 and 2015 in several states, and future health policy will likely argue to make these supports more broadly available.<sup>32</sup>

Fourth, despite linking our data to procedures as collected in the Vascular Quality Initiative, we found

little interaction with procedure type and quit rates. Of those patients who underwent procedures after the trial, most were carotid endarterectomies (38%), followed by endovascular aneurysm repair (21%) and a variety of lower extremity vascular procedures (~10%). Larger samples in our future work may find associations where our pilot effort was not powered to detect these differences.

Finally, we also learned about the importance of recognizing the different individual characteristics of each practice site. For example, we learned that a practice in the control group had a systematic smoking cessation program in a perioperative clinic outside of the vascular surgery office that closely paralleled the treatments in our intervention arm. This practice had referral requirements in their health center that mandated institution of evidence-based smoking cessation. In other words, even though surgeons at this site behaved like "control" group surgeons, systematic policies across their institution effectively delivered most components of the evidence-based intervention. When we performed an analysis that removed this site from the control group, our findings were nearly significant, even when adjusting for our cluster-randomized study design (smoking cessation rate 40% vs 24%; OR, 2.12; 95% CI, 0.93-4.83;  $P = .06$ ). However, given that this site was randomized to the control arm, we reported it as such in our intention-to-treat analysis.

## CONCLUSIONS

Our pilot study of an evidence-based smoking cessation intervention demonstrated that a brief, standardized, smoking cessation intervention is feasible and can be delivered effectively by vascular surgeons. The most important aspects of this intervention appear to be the advice from the surgeon as well as encouraging the patient facing surgical treatment to use NRT as a tool to help him or her quit smoking. A larger trial testing the implementation of this evidence-based smoking cessation intervention for patients being treated by vascular surgeons is warranted and may help improve the delivery of perioperative smoking cessation for patients with PAD.

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## AUTHOR CONTRIBUTIONS

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Overall responsibility: PG

## REFERENCES

1. Treating tobacco use and dependence: 2008 update from the Centers for Disease Control and Prevention. Available at: <http://www.Ahrq.Gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html#clinic>. Accessed January 1, 2016.
2. Mills E, Eyawo O, Lockhart I, Kelly S, Wu P, Ebbert JO. Smoking cessation reduces postoperative complications: a systematic review and meta-analysis. *Am J Med* 2011;124:144-54.
3. Armstrong EJ, Wu J, Singh GD, Dawson DL, Pevec WC, Amsterdam EA, et al. Smoking cessation is associated with decreased mortality and improved amputation-free survival among patients with symptomatic peripheral artery disease. *J Vasc Surg* 2014;60:1565-71.
4. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FC. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg* 2007;45: S5-67.
5. Hoel AW, Nolan BW, Goodney PP, Zhao Y, Schanzer A, Stanley AC, et al. Variation in smoking cessation after vascular operations. *J Vasc Surg* 2013;57:1338-44. quiz: 1344. e1331-4.
6. Black JH 3rd. Evidence base and strategies for successful smoking cessation. *J Vasc Surg* 2010;51:1529-37.
7. Thorndike AN, Rigotti NA, Stafford RS, Singer DE. National patterns in the treatment of smokers by physicians. *JAMA* 1998;279:604-8.
8. Krupski WC, Nguyen HT, Jones DN, Wallace H, Whitehill TA, Nehler MR. Smoking cessation counseling: a missed opportunity for general surgery trainees. *J Vasc Surg* 2002;36: 257-62; discussion: 262.
9. Flocke SA, Antognoli E, Step MM, Marsh S, Parran T, Mason MJ. A teachable moment communication process for smoking cessation talk: description of a group randomized clinician-focused intervention. *BMC Health Serv Res* 2012;12:109.
10. Thomsen T, Villebro N, Moller AM. Interventions for preoperative smoking cessation. *Cochrane Database Syst Rev* 2010;CD002294.
11. Aveyard P, Begh R, Parsons A, West R. Brief opportunistic smoking cessation interventions: a systematic review and meta-analysis to compare advice to quit and offer of assistance. *Addiction* 2012;107:1066-73.
12. National Centre for Smoking Cessation and Training. Very Brief Advice training module. Available at: [http://www.ncsct.co.uk/publication\\_very-brief-advice.php](http://www.ncsct.co.uk/publication_very-brief-advice.php). Accessed January 1, 2016.
13. Edelen MO. The PROMIS smoking assessment toolkit—background and introduction to supplement. *Nicotine Tob Res* 2014;16(Suppl 3):S170-4.
14. Edelen MO, Stucky BD, Hansen M, Tucker JS, Shadel WG, Cai L. The PROMIS smoking initiative: initial validity evidence for six new smoking item banks. *Nicotine Tob Res* 2014;16(Suppl 3):S250-60.
15. Edelen MO, Tucker JS, Shadel WG, Stucky BD, Cai L. Toward a more systematic assessment of smoking: development of a smoking module for PROMIS(r). *Addict Behav* 2012;37: 1278-84.
16. Newhall K, Burnette M, Brooke BS, Schanzer A, Tan T, Flocke S, et al. Smoking cessation counseling in vascular surgical practice using the results of interviews and focus groups in the vascular surgeon offer and report smoking cessation pilot trial. *J Vasc Surg* 2016;63:1011-7.e2.
17. Spangler EL, Brooke BS, Beck AW, Hoel AW, Farber A, Goodney PP. Design and initial enrollment in the Vascular Physicians Offer and Report (VAPOR) trial. *J Vasc Surg* 2016;63:1121-5.e2.
18. Hjalmarson A, Boethius G. The effectiveness of brief advice and extended smoking cessation counseling programs when implemented routinely in hospitals. *Prev Med* 2007;45: 202-7.
19. Meyer C, Ulbricht S, Baumeister SE, Schumann A, Ruge J, Bischof G, et al. Proactive interventions for smoking cessation in general medical practice: a quasi-randomized controlled trial to examine the efficacy of computer-tailored letters and physician-delivered brief advice. *Addiction* 2008;103:294-304.
20. Critchley JA, Capewell S. Mortality risk reduction associated with smoking cessation in patients with coronary heart disease: a systematic review. *JAMA* 2003;290:86-97.
21. Jorenby DE, Hays JT, Rigotti NA, Azoulay S, Watsky EJ, Williams KE, et al; Varenicline Phase 3 Study Group. Efficacy of varenicline, an alpha4beta2 nicotinic acetylcholine receptor partial agonist, vs placebo or sustained-release bupropion for smoking cessation: a randomized controlled trial. *JAMA* 2006;296:56-63.
22. Perisic I, Rosner B. Comparisons of measures of interclass correlations: the general case of unequal group size. *Stat Med* 1999;18:1451-66.
23. Stead LF, Perera R, Lancaster T. A systematic review of interventions for smokers who contact quitlines. *Tob Control* 2007;16(Suppl 1):i3-8.
24. Civiljak M, Stead LF, Hartmann-Boyce J, Sheikh A, Car J. Internet-based interventions for smoking cessation. *Cochrane Database Syst Rev* 2013;CD007078.
25. Hartmann-Boyce J, Stead LF, Cahill K, Lancaster T. Efficacy of interventions to combat tobacco addiction: Cochrane update of 2013 reviews. *Addiction* 2014;109:1414-25.
26. Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. *Cochrane Database Syst Rev* 2005: CD001292.
27. Flocke SA, Clark E, Antognoli E, Mason MJ, Lawson PJ, Smith S. Teachable moments for health behavior change and intermediate patient outcomes. *Patient Educ Couns* 2014;96:43-9.
28. Flocke SA, Step MM, Antognoli E, Lawson PJ, Smith S, Jackson B. A randomized trial to evaluate primary care clinician training to use the teachable moment communication process for smoking cessation counseling. *Prev Med* 2014;69:267-73.



29. Binnie V, McHugh S, Macpherson L, Borland B, Moir K, Malik K. The validation of self-reported smoking status by analysing cotinine levels in stimulated and unstimulated saliva, serum and urine. *Oral Dis* 2004;10:287-93.
30. Vartiainen E, Seppala T, Lillsunde P, Puska P. Validation of self reported smoking by serum cotinine measurement in a community-based study. *J Epidemiol Community Health* 2002;56:167-70.
31. Rigotti NA, Regan S, Levy DE, Japuntich S, Chang Y, Park ER, et al. Sustained care intervention and postdischarge smoking cessation among hospitalized adults: a randomized clinical trial. *JAMA* 2014;312:719-28.
32. Koh HK, Sebelius KG. Promoting prevention through the affordable care act. *N Engl J Med* 2010;363:1296-9.

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**VAPOR:**  
**The Offer and Report Protocol**

**Step 1: Offer**

Offer "very brief advice" on smoking cessation (<http://www.ncsct-training.co.uk/player/play/VBA>)

**Ask:**

"Are you still smoking?" (if yes, or quit <30 days ago, then proceed as below)

**Advise:**

"Smoking increases the chance that you will have poor results from vascular procedures. Quitting smoking will greatly improve your results."

**Act:**

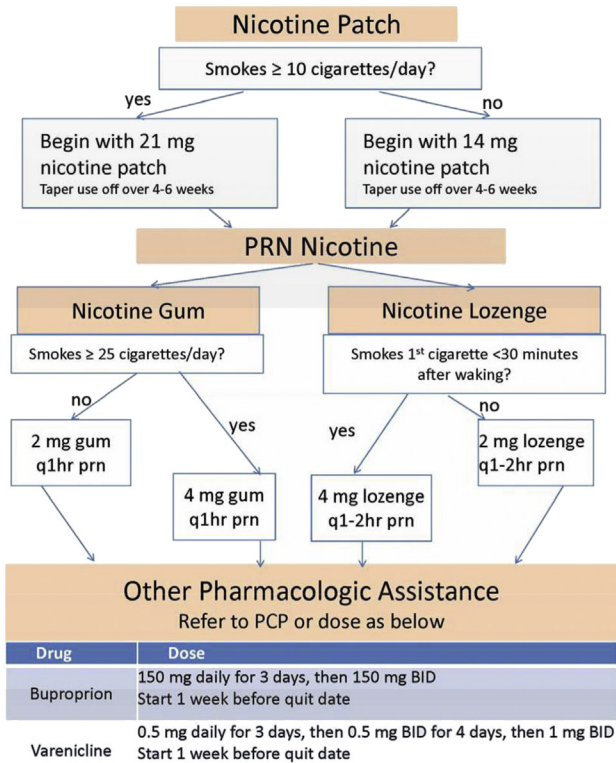
"It is difficult to quit smoking, but I want to help you quit. My approach is two-fold:

First, we are going to connect you to a free, telephone-based program, called 1-800-QUITNOW, that will help you quit. They will contact you by phone to help you do this.

Second, I'll write you a prescription for nicotine replacement therapy, which will consist of a patch for daily use, and gum or lozenges for breakthrough cravings.

**Step 2: Report**

At the end of the surgeon's clinic visit, office staff will assist interested patients in completing a pre-printed fax referral form (in select states the patient must sign the form) and fax completed forms to the quit line. The quit line will contact the patient and assist in smoking cessation.



**Supplementary Fig 1 (online only).** Front and back sides of the preprinted pocket cards for study physicians for each of the three steps in the evidence-based smoking cessation intervention, as well as the dosages of commonly used nicotine replacement medications. *BID*, Twice daily; *PCP*, primary care physician; *PRN*, as needed; *VAPOR*, Vascular Physician Offer and Report.

**VAPOR Trial Initial Visit Questionnaire**  
(White: fill out in VQI. Grey: VQI or paper; Dark Grey: Paper only)

1. During your visit in vascular surgery today, did a doctor, nurse or other health care provider advise you to stop smoking?	<input type="checkbox"/> Yes <i>enter #[VAPORADVICE:1]</i>	<input type="checkbox"/> No <i>enter #[VAPORADVICE:0]</i>
2. Did you receive a prescription today for nicotine replacement (gum, lozenge, or patch)?	<input type="checkbox"/> Yes <i>enter #[VAPORNRT:1]</i>	<input type="checkbox"/> No <i>enter #[VAPORNRT:0]</i>
3. During your visit in vascular surgery today, did a doctor, nurse or other health care provider suggest you use a telephone quitline to help you quit smoking?	<input type="checkbox"/> Yes <i>enter #[VAPORQUITLINE:1]</i>	<input type="checkbox"/> No <i>enter #[VAPORQUITLINE:0]</i>

4. Your highest level of education is:	<input type="checkbox"/> Less than High School	<input type="checkbox"/> High School Graduate	<input type="checkbox"/> Some College	<input type="checkbox"/> College or higher	
5. How interested are you in quitting smoking? <i>enter #[VAPORINTEREST1] #[VAPORINTEREST2] ...</i>	<input type="checkbox"/> A lot (1)	<input type="checkbox"/> Some (2)	<input type="checkbox"/> A little (3)	<input type="checkbox"/> Not at all(4)	
6. How many years have you smoked? <i>enter #[VAPORYEARS:5] IF THEY SMOKED FOR 5 YEARS..</i>				#	
7. How many cigarettes do you smoke each day? <i>enter #[VAPORCIGSQDAY:5] IF THEY SMOKE FOR 5 CIGARETTES PER DAY..</i>				#	
8. Have you ever previously used medication for your tobacco dependence (patch, gum, bupropion, etc)? <i>enter #[VAPORMEDS:0] IF NO MEDS, enter #[VAPORMEDS:1] IF YES</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
9. Have you ever previously participated in a smoking-cessation program of any sort ( group, individual, telephone counseling, etc)? <i>enter #[VAPORPRIORCESS:0] IF NO, enter #[VAPORPRIORCESS:1] IF YES</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
10. Before today, have you ever been counseled to stop smoking by your primary care doctor? <i>enter #[VAPORPRIORMD:0] IF NO, enter #[VAPORPRIORMD:1] IF YES</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
11. Before today, have you ever been counseled to stop smoking by your vascular surgeon? <i>enter #[VAPORPRIORVASC:0] IF NO, enter #[VAPORPRIORVASC:1] IF YES</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
12. Have you been able to quit smoking before for more than 1 week <i>enter #[VAPORPRIOR1WEEK:0] IF NO, enter #[VAPORPRIOR1WEEK:1] IF YES</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
<b>Please indicate how frequently you agree with the following statements:</b>	<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Often</b>	<b>Always</b>
13. I find myself reaching for cigarettes without thinking about it.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
14. I drop everything to go out and buy cigarettes.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
15. I smoke more before going into a situation where smoking is not allowed.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
16. When I haven't been able to smoke for a few hours, the craving gets intolerable.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

<b>Please indicate how much you agree with the following statements:</b>	<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
17. Smoking is taking years off my life.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
18. Smoking makes me worry about getting heart troubles.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
19. Smoking causes me to get tired easily.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
20. Smoking makes me short of breath.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
21. Smoking irritates my mouth and throat.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
22. I worry that smoking will lower my quality of life.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

**Supplementary Fig 2 (online only).** Patient-Reported Outcomes Measurement Information System (PROMIS; RAND Corporation, Santa Monica, Calif) Smoking Item Banks. VAPOR, Vascular Physician Offer and Report; VQI, Vascular Quality Initiative.