Brief Physician-Initiated Quit-Smoking Strategies for Clinical Oncology Settings: A Trial Coordinated by the Eastern Cooperative Oncology Group

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Purpose: **Although tobacco use by cancer patients increases the risk of relapse, diminishes treatment efficacy, and worsens quality of life, about one third of patients who smoked before their diagnosis continue to smoke. Because patients have regular contact with oncologists, the efficacy of a physician-based smoking cessation treatment was evaluated.**

Methods: **Cancer patients (n = 432) were randomly assigned to either usual care or a National Institutes of Health (NIH) physician-based smoking intervention. The primary outcome was 7-day point prevalence abstinence at 6 and 12 months after study entry.**

Results: **At the 6-month follow-up, there was no significant difference in quit rates between the usual care (11.9%) and intervention (14.4%) groups, and there was no significant difference between the usual care (13.6%) and intervention (13.3%) groups at the 12-month follow-up. Patients were more likely to have quit smoking at 6 months if they had head and neck or lung cancer, began smoking after the age of 16, reported at baseline using a cessation self-help guide or treatment in the last 6 months, and showed greater baseline desire to quit. Patients were more likely to have quit smoking at 12 months if they smoked 15 or fewer cigarettes per day, had head and neck or lung cancer, tried a group cessation program, and showed greater baseline desire to quit. Finally, there was greater adherence among physicians to the NIH model for physician smoking treatment for patients in the intervention versus the usual care group.**

Conclusion: **While training physicians to provide smoking cessation treatment to cancer patients can enhance physician adherence to clinical practice guidelines, physician smoking cessation interventions fail to yield significant gains in long-term quit rates among cancer patients.**

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THE RANGE of adverse health consequences of tobacco use are well documented and widely acknowledged. However, there is generally less awareness of the important ways that continued tobacco use by cancer patients can further compromise the patients' health. Studies with cancer patients show that continued smoking after diagnosis and treatment reduces survival time,[1-3] increases the risk of a recurrence or a second primary tumor,[4-6] reduces treatment efficacy,[7] and exacerbates and prolongs treatment-induced complications such as mucositis, dry mouth, loss of taste and voice, impaired pulmonary function and wound healing, and tissue and bone necrosis.[8-12] Despite the significant increase in risk for these negative health effects, upwards of one quarter to one third of cancer patients who smoked before their diagnosis continue to do so after diagnosis.[13-19] Such findings lend strong support for the need to integrate formal smoking cessation clinical services within Comprehensive Cancer Centers.

Over the last 20 years, there has been a steady accumulation of research on the efficacy of smoking cessation interventions provided in a medical context.[20,21] One treatment approach that has received a sizable amount of research attention is physician-based intervention.[22] This approach, whereby the physician is trained to deliver cessation advice and assistance, yields abstinence rates of 10% to 11%.[22-24] The effectiveness of this intervention approach may be attributable to the fact that hospitalizations or visits to physicians represent a "window of opportunity" during which patients are particularly motivated to quit smoking and are especially receptive to smoking cessation treatments.[20,21,25] Indeed, patients highly respect physicians' opinions and recommendations, and they enter a medical encounter with a focus on their health and a readiness to engage in actions relevant to improving their well-being, such as quitting smoking.[26] The growth of physician-based smoking interventions has been spurred by a number of additional factors as well, including the finding that more than 90% of smokers who are able to achieve abstinence have not used formal clinical programs to do so[27] and the observation that this approach to treating nicotine addiction can reach a substantial number of smokers, because more than 80% of smokers visit a physician at least once each year.[28] When considering the recent emphasis on assessing the effectiveness of smoking treatments in terms of their impact value (ie, the abstinence rate yielded by the intervention multiplied by the participation rate),[29,30] physician-based smoking interventions represent a relatively potent way to address the epidemic of tobacco use in the United States.

In light of accumulated data supporting the effectiveness of physician-based smoking interventions, public health agencies have urged physicians to implement smoking interventions by providing treatment guidelines and training manuals.[31] One model for physician-based smoking treatments, referred to as the "5 A's," was devised by the Agency for Healthcare Research and Quality:[32] Ask (screen for tobacco use), Advise (provide a

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personalized and strong quit message), Assess (evaluate the smoker's readiness to quit), Assist (provide cessation counseling, pharmacotherapy, and self-help guides), and Arrange (appraise cessation progress). Because use of this model can yield a 10% to 11% quit rate and upwards of 80% of smokers could be reached by this treatment approach, physician-based smoking treatments have the potential to yield sizable reductions in the overall population rate of tobacco use. To date, however, the potential effectiveness of this model for reducing continued tobacco use by cancer patients has yet to be explored. A review of the literature[33] uncovered only five studies of smoking treatments with cancer patients.[34-38] Further, the studies that have been conducted have used small samples and/or have failed to maintain sufficient internal validity.[33] As such, despite the need to provide cancer patients with formal cessation assistance,[39] cancer patients who smoke remain a group of smokers for whom smoking interventions have yet to be adequately evaluated.

Thus, in this study, we examined the effectiveness of a 5 A's, physician-based smoking cessation intervention for promoting long-term abstinence among cancer patients. We expected that patients who smoke and who are randomly chosen to receive a physician-based smoking intervention would show higher quit rates at 6-month and 12-month follow-up time points, versus patients who smoke who receive usual care. In addition, we explored whether sociodemographic (eg, age, sex), medical (eg, cancer site or stage), and behavioral (ie, desire to quit, expectations about quitting) factors, along with smoking history (eg, level of nicotine addiction, number of years smoked), predict long-term abstinence. With few exceptions,[13,40] there has not been sufficient assessment of factors predictive of long-term tobacco use among cancer patients, although such analyses can provide important information for the design of smoking cessation interventions with this population.[33] Finally, we explored the degree to which the physician-based intervention enhanced physician adherence to the 5 A's model (eg, improved the rate at which physicians assessed smoking behavior) to provide a possible explanation for an effect of the physician-based intervention on patient quit rates.

METHODS

Participants

This study was originally conducted by Fox Chase Cancer Center (Philadelphia, PA) outside a cooperative. From December 1990 to May 1991, institutions that were members of the Eastern Cooperative Oncology Group (ECOG), the Southwestern Oncology Group, and the Cancer and Leukemia Group B participated in the study (see Table 1), although not through cooperatives. ECOG assumed direction of the study from June 1992 until it was closed in June 1999. Participants were 19 years of age or older; were diagnosed with stage I-II cancer (of any type) or stage III-IV breast, prostate, or testicular cancer or lymphoma; and had an ECOG performance status score of 0 or 1. To be eligible, patients must have given informed consent, have been scheduled to return to the treatment site, and have reported smoking one or more cigarettes in the past 30 days or have self-identified as a smoker. Four hundred thirty-five patients were randomly assigned; three patients were dropped (two because they were ineligible and one because of a duplicate registration), leaving the final sample at 432.

Table 1. Accrual by Institution

Institution Name	No. of Patients	
	n	%
Pre-ECOG oversight		
Mayo/Carle Clinic (CCOP)	1	1.0
VA Medical Center (Syracuse)	4	3.9
Medical Center of Delaware	5	4.8
Metro-Minnesota CCOP	14	13.5
Columbia River CCOP	62	59.6
Marshfield Clinic	18	17.3
Total	104	23.9
ECOG oversight		
Albany Medical College	6	1.8
Johns Hopkins University	14	4.2
Mayo Clinic	96	29.0
University of Pennsylvania	6	1.8
University of Wisconsin	9	2.7
Vermont Regional Cancer Center	12	3.6
University of Florida (Gainesville)	21	6.3
Vanderbilt University	7	2.1
Metro-Minnesota CCOP: Abbott-NW	155	46.8
Lankenau Hospital	4	1.2
Washington Medical Center	1	0.3
Total	331	76.1

Abbreviations: CCOP, Community Clinical Oncology Program; NW, Northwest.

Procedure

Participating physicians at the recruitment sites identified potentially eligible patients, using standard intake evaluation forms. Eligible patients had the study objectives explained to them, and they were presented with an informed consent form. Consenting patients then completed a baseline assessment, which included an evaluation of their smoking history and certain behavioral factors that are strongly related to the ability to quit smoking (eg, desire to quit). Sociodemographic and medical data were recorded from medical charts or self-report. Random assignment to the usual care condition or the physician-based intervention was conducted using permuted blocks with dynamic balancing within the recruitment sites.

Patients randomly assigned to the usual care arm (n = 218) received standard care after recruitment. Because physicians, from an ethical standpoint, could not withhold quit advice and prevent the patient from seeking cessation treatment outside the study, patients in the usual care arm might have been provided with physician quit advice and/or may have sought assistance with quitting. At the end of the study, patients in this arm who were smoking were instructed to call 1–800-4-CANCER for assistance and/or referral to a cessation program.

Patients randomly assigned to the physician-based intervention (n = 217) received quit advice and assistance during a physician visit in accordance with the National Institutes of Health guidelines for physician-based smoking interventions;[31] all patients, regardless of the site of their tumor, received the same intervention. For the intervention, the physician provided brief (< 5 minutes) quit advice, which emphasized the overall benefits of quitting (eg, improved general health) and the specific health benefits for cancer patients (eg, lower chance for recurrence); tried to convince the patient to set a quit date and worked with the patient to identify the quit date; discussed nicotine replacement therapy (NRT) with the patient and provided a prescription if indicated (ie, for patients who exhibited high nicotine dependence); provided the patient with a self-help smoking cessation guide (ie, *Freedom from Smoking for You and Your Family*)[41] and the 1–800-4-CANCER telephone number for additional assistance and/or referral to a cessation program; and assessed cessation progress during subsequent medical visits. ECOG-trained data coordinators assisted physicians with standardizing intervention components at each site.

All patients were contacted by telephone to complete a 6-month and a 12-month assessment, which contained the same information as the baseline assessment and questions (at the 6-month assessment only) to assess physician adherence to the smoking cessation treatment model (eg, whether or not the physician discussed the patient's smoking habits).

Measures

Sociodemographic data. The following sociodemographic data absent from medical charts were collected from the patient: age, sex, race, level of education, and marital status.

Medical data. Data on the patient's diagnosis and health were collected from the medical chart or from the patient. These included cancer site, time since diagnosis (ie, the duration from diagnosis to baseline assessment), cancer stage, ECOG performance status, and physical symptoms (eg, trouble breathing, pain or tightness in chest) and diseases or conditions (ie, diabetes, high blood pressure, heart trouble/attack, emphysema, chronic bronchitis, or asthma).

Smoking history. Participants indicated age of smoking initiation; average number of cigarettes smoked per day in the past 7 days; how soon they smoke after they wake (to assess level of nicotine addiction); whether others in the household smoke; number of lifetime 24-hour quit attempts; whether or not they had tried to quit in the past year; whether they had been advised to quit by a health care worker; whether they had ever tried individual counseling, group counseling, or NRT to quit smoking; whether, in the past 6 months, they had tried to reduce the amount they smoked, tried to quit, or used a quit-smoking guide; whether they used other forms of tobacco besides cigarettes (eg, cigars); and whether they are seriously contemplating quitting smoking in the next 6 months.

Behavioral data. Two attitudinal variables were assessed as potential predictors of quitting, because in previous studies these have been linked to the ability to quit smoking.[40] First, using six Likert-type questions, which ranged from 0 (not at all) to 4 (very much), desire to quit smoking was assessed (eg, "How much, if at all, do you want to quit smoking?"). Second, using six Likert-type questions, ranging from 0 (not at all) to 4 (very much), negative expectations about quitting were assessed (eg, "How much of a problem do you think being irritable, angry, or tense might be for you when you quit smoking?"). For each of these, a sum score was formed and used as a predictor variable in the analyses; higher scores on each composite variable represent, respectively, greater desire to quit or greater negative expectations about quitting.

Smoking status. This variable, which served as the primary outcome measure, was assessed using 7-day point prevalence abstinence, as has been done in previous studies.[14] The patient was considered abstinent if he or she reported not smoking for at least 1 week before the interview (ie, 7-day point prevalence abstinence). This measure of smoking status is as reliable and valid as other common measures of smoking status, such as 24-hour point prevalence, 30-day prolonged abstinence, and 6-month prolonged abstinence.[42] All nondeceased nonrespondents were considered to be smokers at the follow-up assessments.

Physician adherence to the 5 A's model. At the 6-month follow-up, patients reported physician adherence to the physician-based smoking cessation clinical guidelines (ie, the 5 A's). A yes or no format was used to assess whether physicians discussed smoking with the patient, suggested that the patient quit smoking, reviewed with the patient the benefits of quitting, helped the patient to set a quit date, sent a follow-up letter about the patient's quitting plans, provided the patient with quit-smoking materials, and provided a prescription for NRT.

Statistical Analyses

At the outset, we used Fisher's exact test and the Jonckheere-Terpstra test for categorical and ordered categorical variables, respectively, and the Wilcoxon rank sum statistic for continuous variables to assess baseline differences between the study arms with regard to sociodemographic, medical, behavioral, and smoking history data. Next, we addressed the study objectives in three stages. First, we compared the proportion of patients that quit smoking across the study arms, using a one-sided Fisher's exact test. Deceased patients were not included in these analyses; however, we considered participants who were not deceased but did not complete the follow-up assessments as smokers. Using the one-sided Fisher's exact test, we also assessed possible differences in long-term quit rates between study arms if the results were stratified by sex.

Second, a Bayesian model was used to assess baseline predictors of long-term abstinence at the follow-up, including all participants regardless of missing data in the covariates. A Bayesian approach was used because this would allow for including all the subjects in the model, even those that have missing data in the covariates. There was a fairly high level of missing data (see Table 2, Table 3, and Table 6, where "unknown" represents missing data, and Table 4 and Table 5, where missing data are indicated). A more standard approach, such as multiple logistic regression, would have used only the complete case data, and therefore, the parameter estimates would have been biased and less precise than the ones obtained using all the available information. Again, deceased patients were not included in the analyses, but we considered participants who were nondeceased and nonresponsive to be smokers. A univariate logistic regression analysis was used to select the baseline variables to be included in the Bayesian model. The following baseline variables were used as potential predictors: sociodemographic variables (ie, age, sex, marital status, education), medical variables (ie, cancer site, time since diagnosis, and stage), smoking history variables (ie, the 11 variables listed earlier), behavioral variables (ie, desire to quit smoking, negative expectations about quitting), and treatment arm (ie, usual care versus physician-based intervention). Noninformative priors were assigned to the regression coefficients $\beta \sim N(0,10^6)$. To allow proper imputation of missing values, prior distributions for the covariates were assumed to be Bernoulli (P), with P distributed as Uniform (0,1). The BUGS program (Bayesian inference using the Gibbs sampling algorithm) was used to estimate the coefficients and 95% credible intervals.[43] Parameter estimates are the mean and the SD of the 10,000 Gibbs samples; 95% credible intervals are computed as the lower and upper 2.5th percentiles of the 10,000 Gibbs samples. To build the final model, we included the variables with two-sided P values $\leq .25$ in the univariate analysis, one at a time. Variables were eliminated if their 95% credible intervals included the null value and their odds ratios (ORs) were lower than 1.5; variables with ORs above 1.5, even if their 95% credible intervals include the null, likely have clinical significance. To check the assumption that the sampling and nonresponse mechanisms are jointly ignorable, we compared the distribution of the response variable according to the presence or absence of missing data in the covariates, and we found no indication of nonignorable missing data; P values are two-sided unless stated otherwise.

Finally, to explore the degree to which the intervention affected physician adherence to the 5 A's model, we calculated the proportions across the study arms of patients who indicated that the physician assisted them with quitting smoking. Because this aim was primarily exploratory in nature, we restrict these analyses to descriptive analysis.

RESULTS

Descriptive sociodemographic, medical, and smoking history data for the sample are shown in Tables 2 and 3. (Behavioral data are not shown in a table because there were no differences across conditions.) There were only two significant differences in patient characteristics across the study arms ($P < .05$): there were more males in the usual care arm than in the physician-based intervention (39% *v* 29%, respectively); and a lower proportion of patients in the usual care arm reported experiencing heart trouble or a heart attack in the past year than did patients in the physician-based intervention (3.7% *v* 11.6%, respectively). Because neither of these variables was related to long-term quit rates, they were not included as covariates in subsequent analyses.

The Effect of Physician-Based Smoking Intervention on Long-Term Quit Rates

Table 4 (top) shows the quit rates at 6 months for the study arms; 14 patients (3.2%) were deceased at this follow-up and were not included in the analysis. In addition, 55 patients (12.7%) were lost to follow-up and were considered to be smokers. There was no significant difference between the study arms in attrition caused by death or refusal to complete the assessment. Overall, at 6 months, 13.2% of patients reported

Table 2. Patient Characteristics by Treatment Arm: Sociodemographic and Medical Data

Patient Characteristic	Usual Care		Physician-Based Intervention		Overall	
	n	%	n	%	n	%
Number of patients	217		215		432	
Age						
Median	55		55		55	
Range	24-77		20-81		20-81	
Sex						
Male	85	39.2	63	29.3	148	34.3
Female	132	60.8	152	70.7	284	65.7
Race*						
White	155	71.4	158	73.5	313	72.5
Hispanic	1	0.5	0	0.0	1	0.2
Black	5	2.3	5	2.3	10	2.3
Native American	2	0.9	1	0.5	3	0.7
Other	0	0.0	1	0.5	1	0.2
Unknown	54	24.9	50	23.3	104	24.1
Level of education						
Grade school/some high school	30	13.8	27	12.5	57	13.1
High school graduate/GED	82	37.8	77	35.8	159	36.8
Some college/technical school	68	31.3	79	36.7	147	34.0
College grad or beyond	30	13.8	30	14.0	60	13.9
Unknown	7	3.2	2	0.9	9	2.1
Marital status						
Never married	15	6.9	13	6.0	28	6.5
Widowed	19	8.8	28	13.0	47	10.9
Married	138	63.6	140	65.1	278	64.4
Divorced or separated	43	19.8	33	15.3	76	17.6
Unknown	2	0.9	1	0.5	3	0.7
Primary site of cancer						
Bladder	3	1.4	1	0.5	4	0.9
Head and neck	9	4.1	7	3.3	16	3.7
Lung	17	7.8	12	5.6	29	6.7
Other	188	86.6	195	90.7	383	88.7
Time since diagnosis						
≤ 6 months	118	54.4	118	54.9	236	54.6
> 6 months	99	45.6	97	45.1	196	45.4
Stage						
I-II	172	79.3	171	79.5	343	79.4
III-IV	45	20.7	44	20.5	89	20.6
Physical symptoms, diseases, conditions						
Trouble breathing or shortness of breath						
Yes	94	43.3	88	40.9	182	42.1
No	112	51.6	115	53.5	227	52.6
Unknown	11	5.1	12	5.6	23	5.3
Frequent coughing or heavy chest colds						
Yes	94	43.3	79	36.7	173	40.1
No	110	50.7	119	55.4	229	53.0
Unknown	13	6.0	17	7.9	30	6.9
Getting very tired in a short time						
Yes	93	42.9	92	42.8	185	42.8
No	108	49.8	109	50.7	217	50.2
Unknown	16	7.3	14	6.5	30	6.9
Pain or tightness in the chest						
Yes	42	19.4	49	22.8	91	21.1
No	158	72.8	152	70.7	310	71.7
Unknown	17	7.8	14	6.5	31	7.2
Diabetes						
Yes	7	3.2	12	5.6	19	4.4
No	188	86.7	188	87.4	376	87.0
Unknown	22	10.1	15	7.0	37	8.6
High blood pressure						
Yes	44	20.3	42	19.5	86	19.9
No	155	71.4	159	74.0	314	72.7
Unknown	18	8.3	14	6.5	32	7.4
Heart trouble or heart attack						
Yes	8	3.7	25	11.6	33	7.6
No	187	86.2	172	80.0	359	83.1
Unknown	22	10.1	18	8.4	40	9.3
Emphysema, chronic bronchitis, asthma						
Yes	40	18.4	43	20.0	83	19.2
No	157	72.4	156	72.6	313	72.5
Unknown	20	9.2	16	7.4	36	8.3

*Incomplete data; unknown is equivalent to missing data.

Table 3. Patient Characteristics by Treatment Arm: Smoking History Data

Patient Characteristic	Usual Care		Physician-Based Intervention		Overall	
	n	%	n	%	n	%
How old were you when you started smoking regularly (at least one cigarette per day)?						
Median	17		17		17	
Range	7-40		5-43		5-43	
Unknown	3		0		3	
During the past 7 days, how many cigarettes did you smoke on a typical day?						
Median	20		20		20	
Range	0-60		0-70		0-70	
Unknown	18		25		43	
How soon after you wake do you smoke your first cigarette?						
Within 15 minutes	112	51.6	110	51.2	222	51.4
16-30 minutes	57	26.3	53	24.7	110	25.5
More than 30 minutes	44	20.3	49	22.8	93	21.5
Unknown	4	1.8	3	1.4	7	1.6
How many people in your household smoke?						
I am the only smoker	120	55.3	107	49.8	227	52.5
At least one smoker besides me	96	44.2	105	48.8	201	46.5
Unknown	1	0.5	3	1.4	4	0.9
How many times have you tried to quit smoking and stayed off for 24 hours or more?						
Never	27	12.4	21	9.8	48	11.1
1-3 times	136	62.7	133	61.9	269	62.3
4-6 times	31	14.3	38	17.7	69	16.0
7 or more times	20	9.2	23	10.7	43	10.0
Unknown	3	1.4	0	0.0	3	0.7
Have you tried to quit and stayed off for 24 hours or more in the past year?						
Yes	116	53.5	122	56.7	238	55.1
No	99	45.6	91	42.3	190	44.0
Unknown	2	0.9	2	0.9	4	0.9
Has a health worker recommended that you stop smoking in the past year?						
Yes	152	70.0	168	78.1	320	74.1
No	60	27.6	45	20.9	105	24.3
Unknown	5	2.3	2	0.9	7	1.6
Have you ever tried . . . to quit smoking?						
A one-on-one counseling program						
Yes	11	5.1	13	6.0	24	5.6
No	155	71.4	157	73.0	312	72.2
Unknown	51	23.5	45	20.9	96	22.2
A group program or clinic						
Yes	25	11.5	37	17.2	62	14.4
No	144	66.4	141	65.6	285	66.0
Unknown	48	22.1	37	17.2	85	19.7
Nicotine gum or nicotine skin patches						
Yes	68	31.3	91	42.3	159	36.8
No	108	49.8	101	47.0	209	48.4
Unknown	41	18.9	23	10.7	64	14.8
In the past 6 months, have you. . .						
Cut back on the number of cigarettes						
Yes	148	68.2	166	77.2	314	72.7
No	36	16.6	34	15.8	70	16.2
Unknown	33	15.2	15	7.0	48	11.1
Tried to quit						
Yes	97	44.7	103	47.9	200	46.3
No	76	35.0	69	32.1	145	33.6
Unknown	44	20.3	43	20.0	87	20.1
Used a quit-smoking guide or treatment						
Yes	23	10.6	34	15.8	57	13.2
No	132	60.8	124	57.7	256	59.3
Unknown	62	28.6	57	26.5	119	27.5
How often in the past month did you use a form of tobacco besides cigarettes (eg, pipes)?						
Never	203	93.5	205	95.3	408	94.4
Sometimes	7	3.2	6	2.8	13	3.0
Daily	5	2.3	3	1.4	8	1.9
Unknown	2	0.9	1	0.5	3	0.7
Thinking about quitting in the next 6 months						
Yes	182	83.9	181	84.2	363	84.0
No	27	12.4	29	13.5	56	13.0
Unknown	8	3.7	5	2.3	13	3.0

Table 4. Quit-Smoking Percentages at 6 Months and 12 Months by Arm

Patient Quit-Smoking Status	Usual Care n	Usual Care %	Physician-Based Intervention n	Physician-Based Intervention %	Overall n	Overall %	1-Sided *P*
Number of patients	217		215		432		
6-month follow-up							
Deceased	7	3.2	7	3.3	14	3.2	
Lost/refused to be interviewed	28	12.9	27	12.6	55	12.7	
Quit smoking							.27
Yes	25	11.9	30	14.4	55	13.2	
No	185	88.1	178	85.6	363	86.8	
12-month follow-up							
Deceased	11	5.1	12	5.6	23	5.3	
Lost/refused to be interviewed	37	17.1	41	19.1	78	18.1	
Quit smoking							.52
Yes	28	13.6	27	13.3	55	13.4	
No	178	86.4	176	86.7	354	86.6	

having quit smoking. There was no significant difference, however, between the study arms, with 11.9% of usual care patients reporting abstinence, versus 14.4% of patients in the physician-based intervention reporting abstinence ($P = .27$).

The quit rates at 12 months are shown in the bottom of Table 4; 23 patients (5.3%) were deceased at this follow-up and were not included in the analysis. In addition, 78 patients (18.1%) were lost to follow-up and were considered to be smokers. There was no significant difference between the study arms in attrition caused by death or refusal to complete the assessment. Overall, at 6 months, 13.4% of patients reported that they had quit smoking. There was no significant difference, however, between the study arms, with 13.6% of usual care patients reporting abstinence, versus 13.3% of patients in the physician-based intervention reporting abstinence ($P = .52$).

Finally, there were no significant differences in quit rates at 6 months and at 12 months when the results were stratified by sex. At 6 months, the quit rates for males were 12.5% in the usual care arm and 15.0% in the physician-based intervention arm ($P = .34$); at 12 months, the quit rates for males were 13.6% in the usual care arm and 14.8% in the physician-based intervention arm ($P = .46$). For females, the 6-month quit rates were 11.0% in the usual care arm and 13.1% in the physician-based intervention arm ($P = .45$); the 12-month quit rates were 13.6% in the usual care arm and 9.8% in the physician-based intervention arm ($P = .34$).

Examination of Predictors of Long-Term Smoking Cessation

Variables with P values $\leq .25$ in the univariate analysis at the 6-month follow-up were cancer site (head and neck or lung *v* other), age at starting smoking ($>$ 16 years), number of cigarettes smoked per day ($\leq$ 15), having been advised to quit by a health care worker, having tried individual cessation counseling, having tried group cessation counseling, having tried NRT, having tried to quit in the past 6 months, having used a quit-smoking guide, exhibiting a high level of desire to quit (above the median of 18), and reporting contemplation of quitting in the next 6 months. Variables with $P \leq .25$ in the univariate analysis at the 12-month follow-up were cancer site (head and neck or lung versus other), cancer stage (I-II *v* III-IV), time since diagnosis ($\leq$ 6 months *v* $>$ 6 months), marital status (married), number of cigarettes smoked per day ($\leq$ 15), nicotine addiction (time from wake-up to smoking), having tried group cessation counseling, having tried NRT, reducing the amount smoked in the past 6 months, having used a quit-smoking guide or treatment in the past 6 months, and exhibiting a strong desire to quit (above the median of 18). These variables were selected for the Bayesian models.

Table 5 (top) shows the results of the Bayesian multiple regression for quitting smoking at 6 months for the 418 nondeceased patients. Four variables were significantly associated with 6-month cessation: age of smoking initiation ($>$ 16 years; OR =

Table 5. Bayesian Multiple Regression Model for Quitting Smoking at 6-Month and 12-Month Follow-Ups

Variables	β	SE(β)	OR	95% CI
6-month follow-up (n = 418)				
Constant	−3.475	0.383		
Age started smoking ($>$16 years *v* $\leq$ 16 years)	0.910	0.337	2.48	1.30 to 4.88
Used quit-smoking guide (yes *v* no)	0.817	0.391	2.26	1.04 to 4.75
Desire to quit smoking ($>$18 *v* $\leq$ 18)	1.065	0.339	2.90	1.54 to 5.71
Cancer site (head/neck or lung *v* other)	1.219	0.398	3.38	1.55 to 7.33
12-month follow-up (n = 409)				
Constant	−3.487	0.403		
Number of cigarettes smoked/d ($\leq$ 15 *v* 15)	0.939	0.328	2.56	1.35 to 4.86
Tried group cessation program (yes *v* no)	1.246	0.363	3.48	1.66 to 6.98
Desire to quit smoking ($>$18 *v* $\leq$ 18)	0.566	0.317	1.76	0.94 to 3.30
Cancer site (head/neck or lung *v* other)	0.644	0.440	1.90	0.77 to 4.42
Time since diagnosis ($\leq$ 6 *v* $>$ 6 months)	0.681	0.338	1.98	1.03 to 3.85

Table 6. Adherence and Helpfulness of the Intervention at 6 Months of Follow-Up

Physician Practices	Usual Care		Physician-Based Intervention	
	n	%	n	%
Did your doctor discuss your smoking habits with you at any of your visits?				
Yes	78	37.1	133	63.9
No	100	47.6	44	21.2
Unknown	32	15.2	31	14.9
Did your doctor at the clinic recommend that you stop smoking?				
Yes	118	56.2	157	75.5
No	60	28.6	25	12.0
Unknown	32	15.2	26	12.5
Did your doctor talk to you about the benefits of quitting?				
Yes	74	35.2	137	65.9
No	63	30.0	33	15.9
Unknown	73	34.8	38	18.2
Did your doctor or his/her staff help you set a quit date?				
Yes	11	5.2	77	37.0
No	130	61.9	99	47.6
Unknown	69	32.9	32	15.4
Did your doctor send you a follow-up letter about your quitting plans?				
Yes	6	2.9	104	50.0
No	129	61.4	46	22.1
Unknown	75	35.7	58	27.9
Did your doctor give you any materials to help you quit smoking?				
Yes	36	17.1	164	78.8
No	144	68.6	15	7.2
Unknown	30	14.3	29	13.9
Did your doctor give you a prescription for nicotine gum or nicotine patches?				
Yes	40	19.1	70	33.6
No	141	67.1	111	53.4
Unknown	29	13.8	27	13.0

NOTE. Unknown is equivalent to missing data.

2.48; 95% confidence interval [CI], 1.30 to 4.88), having used a quit-smoking guide or treatment in the past 6 months (OR = 2.26; 95% CI, 1.04 to 4.75), exhibiting a strong desire to quit smoking (> median of 18; OR = 2.90; 95% CI, 1.54 to 5.71), and cancer site (head and neck or lung versus other; OR = 3.38; 95% CI, 1.55 to 7.33).

The Bayesian multiple regression model of 12-month quitting is shown in Table 5 (bottom). Five variables were retained as predictors of quitting at 12 months. These were number of cigarettes smoked per day (≤ 15; OR = 2.56; 95% CI, 1.35 to 4.86), having tried a group counseling cessation program (OR = 3.48; 95% CI, 1.66 to 6.98), exhibiting a strong desire to quit smoking (> median of 18; OR = 1.76; 95% CI, 0.94 to 3.30), cancer site (head and neck or lung versus other; OR = 1.90; 95% CI, 0.77 to 4.42), and time since diagnosis of the present cancer (≤ 6 months *v* > 6 months; OR = 1.98, 95% CI, 1.03 to 3.85).

Physician Adherence to Smoking Cessation Treatment Guidelines

Table 6 shows the proportion of physicians in each study condition that adhered (on the basis of patient reports) to aspects of the 5 A's model. As seen in this table, a greater proportion of physicians in the physician-based intervention discussed smoking behavior with patients (Ask), provided quit advice to patients and discussed the benefits of quitting (Advise), and assisted the patient with establishing a quit date, provided a follow-up letter summarizing a quit plan, provided quit-smoking materials, and provided a prescription for NRT (Assist), compared with the proportion of physicians in the usual care condition.

DISCUSSION

When taken together, our analyses yield several important findings. First, contrary to our hypothesis, we did not find that the provision of a physician-based smoking intervention increased long-term quit rates among cancer patients. This finding is consistent with a study by Gritz et al,[36] which reported no significant difference in the rates of quitting between patients provided with a physician-based cessation treatment and patients randomly assigned to a control comparison group. However, our finding contradicts the general literature concerning the effect of physician-based smoking interventions, which indicates that brief physician-based interventions yield upwards of a 10% to 11% increase in quit rates (versus usual care).[22]

There are several possible explanations for our null finding. First, our finding may be the result of methodological confounding that was caused by the inability to use a "true" control group for this study (ie, an arm that received no active treatment). Although our findings indicated greater adherence to the 5 A's model among the physicians in the intervention condition (Table 6), a substantial proportion of patients in the usual care condition received several potent aspects of the cessation intervention. Indeed, 56% of patients in the usual care condition received quit advice from the physician; 35% of usual care patients had the benefits of quitting discussed with them; and 19% of usual care patients received NRT. In addition, because the usual care condition was not standardized (and because there is great variability among oncologists in their approach to dealing with tobacco use among their patients), it is possible that a number of

physicians in the usual care condition provided continual quit advice and assistance over the follow-up duration. Although it appears that the study conditions were divergent in terms of the proportion of patients in each that received cessation counseling and assistance (Table 6), future studies in this area may need to use research designs that can better control for the confounding influence of physician behavior, such as the evaluation of physician-based interventions that differ in intensity or content rather than a focus on testing a treatment to a control group.

A second possible explanation for our null finding is that the brief, relatively low-intensity, physician-based intervention evaluated here was not sufficient to increase long-term quit rates among cancer patients, who may be considered "hard-core" smokers because they continue to smoke despite their diagnosis. The relatively low overall rate of long-term quitting across both conditions (13.2% and 13.4% at the 6-month and 12-month follow-ups, respectively), when compared with previous intervention studies with cancer patients, lends support for this explanation. For example, in a study that evaluated the benefits of a nurse-managed, 5 A's model–based smoking intervention for lung cancer patients, Browning et al[34] found that 10 of 14 (71%) patients in the intervention condition were abstinent at a 6-month follow-up, versus six of 11 (55%) patients in the usual care group. Compared with the quit advice and self-help literature provided in the usual care condition, the intervention condition in the study by Browning et al[34] consisted of eight structured clinical sessions involving quit advice, guidance in the establishment of a quit date, teaching of behavioral and cognitive strategies to manage stress, provision of support and encouragement, use of self-help guides, recommendation to use NRT and bupropion, and follow-up telephone booster contacts. That the regression models in the present study found that patients who used more-intensive forms of smoking treatment (ie, group counseling, NRT) were more likely to have quit smoking in the long term supports this explanation as well. Thus, future studies in this area may need to assess higher-intensity interventions (ie, physician-based intervention plus adjunctive behavioral and pharmacologic treatment), with the understanding that the brief, low-impact, physician-based intervention that may be sufficient for initiating quitting among healthy smokers (even in a medical context) is not adequate for smokers diagnosed with cancer.

A third possible explanation for a lack of statistical impact of the intervention relates to the inclusion of patients whose primary cancer was not linked to tobacco use (eg, breast or testicular cancer, lymphoma), because the intervention, in large part, relies on the high level of quit motivation among the individuals diagnosed with a tobacco-related illness. The inclusion of such patients, who may have lower levels of desire to quit because they do not necessarily perceive their current health problem as linked to their tobacco use, may have contributed to the low cessation rates across the two conditions and created a scenario from the beginning of the study that was to make a treatment effect unlikely. Supporting this explanation is the higher cessation rate demonstrated in prior smoking intervention studies that used either head and neck or lung cancer patients.[34,36,37] In addition, the present analyses found that cancer site was a strong predictor of long-term quit rates, with patients who have head and neck or lung tumors (whose etiology is strongly linked to tobacco use) exhibiting significantly higher quit rates than patients diagnosed with other forms of cancer. Thus, it may be the case that physician-based interventions such as the one tested here are effective only with patients manifesting a tobacco-related illness.

A final possible explanation for the null findings concerns the outcome measure selected. In this study, we did not assess immediate quit rates after cessation advice but, rather, focused on long-term abstinence. It may be that the physician intervention yielded a significant increase in initial quitting after the provision of cessation advice but was not effective at promoting long-term maintenance of abstinence. (However, we did not assess immediate quit rates after quit advice.) This distinction between initial quitting and long-term abstinence is important to consider, because if a physician-based treatment can motivate initial cessation but fail to promote long-term abstinence, low-cost relapse prevention techniques, rather than incorporating more intensive interventions at the outset, may be a useful adjunct to a physician's quit advice.

A second important finding from this study concerns the results from the prediction models of long-term quitting. These models identified several medical, smoking, and behavioral factors (assessed at baseline) that are linked to the patient's ability to quit smoking in the long term. As mentioned, the tumor site has an effect on the likelihood of quitting; patients diagnosed with head and neck or lung cancer were substantially more likely to be abstinent at the 6-month and 12-month follow-up, versus patients with tumors at other sites. This finding may be attributable to the awareness among patients that the etiology of head and neck and lung tumors is strongly linked to tobacco use. This recognition, in turn, may spark greater quit motivation. Indeed, a study with head and neck cancer patients found that attributing the cause of the disease to tobacco use predicted the ability to quit smoking after diagnosis.[44] Alternatively, smoking rates may be lower among head and neck cancer patients because of the greater likelihood of physical disability from treatments for this cancer type, which makes it impossible to smoke. Regardless, to boost quit motivation and eventual cessation, more-intensive interventions may need to be targeted toward patients with tumors that are not traditionally linked with tobacco use. In addition, interventions may need to be targeted to patients with a longer time since diagnosis, because these patients were less likely to have been abstinent at the 12-month follow-up, as reported previously.[38,40] After the diagnosis, risk of smoking may increase over time because, initially, debilitating medical treatments or symptoms make it impossible for patients to smoke. Alternatively, once sufficient time has elapsed, and treatments have been completed, patients may minimize the seriousness of their diagnosis, and they might be, thus, less committed to maintaining abstinence from tobacco use. Finally, smoking rates may be lower at the outset as a result of a strong message from a physician requiring that the patient abstain from smoking during treatment, but as time elapses, the effect of this message fades. Regardless of the explanation, this finding highlights the need for relapse prevention for patients.

Four variables, assessed at baseline, related to the patient's smoking history predicted long-term quitting in the regression models. Patients who started smoking before the age of 16 (ie,

smoked for a greater number of years) and patients who smoked 15 cigarettes per day or more (ie, heavier smokers) were less likely to quit at follow-up. The link between smoking duration and the amount smoked, on the one hand, and the ability to quit smoking, on the other hand, has been shown in large prospective studies with noncancer populations.[45,46] In addition, patients who reported using a quit-smoking guide or treatment in the past 6 months or who tried a group cessation program were more likely to have quit smoking in the long term. This finding is also supported by literature that has demonstrated the benefits of such treatments.[32,47] These results replicate those previously found concerning smoking history and the ability to quit, and they indicate that patients who start smoking at a younger age or patients that are heavy smokers require more intensive cessation treatments and that methods for promoting use of cessation interventions should be explored to increase the likelihood that patients will abstain from tobacco use in the long term.

Finally, patients who showed a strong desire to quit smoking at baseline were more likely to be abstinent in the long term. Prospective studies show that the desire to quit smoking (often referred to as quit motivation, readiness to change, or stage of change) is a consistent predictor of smoking cessation.[36,48] Further, treatment studies show that initial motivation to quit smoking predicts success in a smoking intervention.[49] Quit motivation predicted a better outcome in treatment studies with cancer patients, as well.[36,38] Such data sparked the development of behavior change theories, such as the Transtheoretical model,[50] and clinical approaches, such as motivational interviewing.[51] One important contribution of this research has been the matching of clinical techniques to the individual's level of quit motivation.[52] For instance, although action-oriented techniques (eg, NRT, behavioral counseling) can promote quitting among those motivated to quit, such methods may be met with resistance by those with low quit motivation. Instead, unmotivated smokers require a unique set of techniques designed to boost motivation and prepare the person for engaging in action-oriented strategies.[52] Thus, as seen in the general population of smokers, interventions for cancer patients who smoke may also need to be tailored to the person's level of readiness to quit to maximize the impact of treatment.

A third important finding concerns the effect of the intervention on physician adherence to the 5 A's model. Despite the potential benefits of physician-based smoking interventions, only 20% to 25% of U.S. smokers receive smoking cessation counseling from their physician.[53] One explanation for the low rate of physician adherence to the 5 A's model is the lack of training in smoking cessation counseling for physicians. Ferry et al[54] surveyed 120 U.S. undergraduate medical programs and found that only 2.4% of those schools require students to complete a course in tobacco education. Because our study found that physicians in the intervention condition showed greater adherence to the 5 A's model, providing physicians with basic training in conducting smoking interventions may improve physician practice. One caveat to highlight is sources of bias in patient recall of physician practices, which may yield unreliable measures of physician behavior. First, because these measures were taken 6 months after physician intervention, patients may have forgotten that physicians had provided such treatment, thereby artificially lowering the rate of adherence. Second, patients' recall may have been influenced by whether they had made a quit attempt and failed; these patients may be reluctant to report physician attempts to encourage their cessation because they want to provide a rationale for their inability to maintain abstinence.

Our findings should be viewed in the context of additional limitations. First, because the use of self-reporting, versus biochemical verification, to determine smoking status can be unreliable,[55] a certain number of patients may have been incorrectly classified at the follow-ups. It is important to note that large studies have shown false reporting rates to be about 3% to 5%,[56,57] which indicates that, if deception occurred in this study, the rate was small. Nevertheless, future studies that evaluate smoking interventions with cancer patients should use biochemical verification of smoking status. Second, the external validity of this study is limited by the sample's lack of ethnic diversity. Even though patient ethnicity has not been found to be associated with the patient's ability to quit smoking after diagnosis, future studies in this area should use samples that better approximate the ethnic distribution of U.S. cancer patients. Third, as mentioned, a "true" control group was not used. Thus, confounding the content of from exposure to smoking cessation treatment among patients in the usual care arm may have undermined the study's internal validity. Fourth, practical constraints required that patients be randomly assigned, rather than physicians. Thus, the same physicians implemented the usual care as well as the physician-based intervention. If this methodological approach affected the data, it would be expected to yield a type I error (ie, declaring the physician-based intervention to be effective when it is not), because physicians' knowledge of which treatment condition the patients are in could influence their treatment approach in favor of the study hypothesis. With a null finding for treatment condition, this cannot be the case (indeed, only a type II error is plausible). Thus, although we acknowledge the methodological shortcoming of having the same physician provide both treatments, we do not believe that this would explain the null findings. Finally, the eligibility criteria used allowed recent quitters to be included in the study. This procedure can artificially increase quit rates. However, as a product of the random assignment procedures, the proportion of these individuals in each condition could be reasonably expected to be equivalent.

With these limitations acknowledged, this study makes an important contribution to the literature on smoking treatments for cancer patients, because only one previous study[36] tested a physician-based smoking cessation with cancer patients. As the recognition for the need to address tobacco use among cancer patients grows, studies such as this can help guide the implementation of clinical initiatives. It is important that this study suggests the need for more intensive smoking interventions for this population than basic physician-based treatments, as well as the need for the development of relapse prevention strategies. Although the provision of physician advice and basic assistance (eg, self-help guides, referral for NRT) should be seen as the standard of care (and likely to be effective in a primary care setting), a substantial proportion of cancer patients (especially those with non-tobacco-related neoplasms and those in latter

stages of recovery) are likely to need more intensive cessation treatment, which could include the use of antidepressants and formal behavioral counseling tailored to the patient's quit motivation,[33] or long-term relapse prevention in the form of quit lines or support groups. The seamless integration of more intensive smoking interventions or relapse prevention approaches within the oncologic context represents an important priority for Comprehensive Cancer Centers and potentially a promising approach to assisting patients to achieve a better quality of life.

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