COMPARING CANCER PATIENTS WHO ENROLL IN A SMOKING CESSATION PROGRAM AT A COMPREHENSIVE CANCER CENTER WITH THOSE WHO DECLINE ENROLLMENT

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Abstract: Background. Despite the availability of smoking interventions for cancer patients, many eligible patients decline enrollment into such programs. We examined reasons patients provide for declining smoking treatment and compared treatment decliners to enrollees.

Methods. Eligible cancer patients (N = 231) were offered smoking cessation treatment. During recruitment, demographic, medical (eg, cancer stage), and smoking-related behavioral (eg, readiness to quit) data were collected, and decliners stated a reason for refusal. Patients who enrolled in the cessation program (N = 109) were compared with those who declined (N = 122) in terms of recruitment data, and reasons for declining were compiled.

Results. Decliners were significantly more likely to: (1) have head and neck cancer (vs lung cancer), (2) exhibit fewer physical symptoms (eg, shortness of breath), (3) report a lower readiness to quit smoking, (4) indicate no intention to quit smoking, and (5) smoke fewer cigarettes. A preference to quit without professional assistance was the most common reason for declining treatment.

Conclusions. Our findings highlight important differences between patients who enroll in a smoking cessation program and those who decline and underscore the need for motivational interventions to facilitate enrollment into smoking interventions for cancer patients. © 2004 Wiley Periodicals, Inc. Head Neck 26: 278–286, 2004

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Continued smoking after a cancer diagnosis reduces survival time, increases the risk of a recurrence or a second primary tumor, reduces treatment efficacy, and exacerbates and prolongs treatment-induced complications such as mucositis, dry mouth, loss of taste and voice, and impaired pulmonary function and wound healing. Yet, 23% to 35% of head and neck cancer patients and 13% to 20% of lung cancer patients continue to smoke after diagnosis. Consequently, the availability of smoking cessa-
tion treatments at comprehensive cancer centers has grown in the past several years. Integrating cessation treatment within cancer centers might be especially effective for reducing smoking rates, because cancer patients may show increased motivation to quit and receptivity to cessation assistance once diagnosed.19,26

Four randomized intervention studies with cancer patients have been completed21–24; a fifth used a repeated-measures design without a comparison group.25 These studies have provided limited results because, with one exception,23 small samples were used, which limited statistical power. An additional limitation of these studies, which warrants attention as research continues in this area, is selection bias caused by a high rate of refusal to enter the study among eligible patients. Whereas four studies failed to provide adequate data to determine the rate of participant accrual, one study indicated that 40% of eligible patients declined enrollment.22 This rate generally parallels those reported outside of the oncologic context. In a study that offered a smoking cessation program to those attending Planned Parenthood, 26% of smokers declined enrollment.26 Likewise, of 279 pregnant smokers eligible for a smoking intervention trial, 28% declined enrollment.27 In another study,28 78% of low-income smokers attending a primary-care facility opted not to enroll in a smoking cessation program. Worksite smoking cessation programs show even higher rates of refusal, with 83% to 93% of eligible smokers declining cessation programs.29–31 Studies of hospital-based smoking cessation programs have reported participant refusal rates of 9% to 52%.32–37 A high rate of participant refusal can allow for a selection bias because there may be systematic differences between enrollees and decliners (eg, enrollees are more motivated to quit or are physically healthier).

Furthermore, the intervention studies with cancer patients do not present data describing reasons for treatment refusal or comparing patients who enrolled with those who declined. Outside of the oncologic context, smoking cessation studies have provided some data about why smokers decline enrollment in a cessation program and have described characteristics that may differentiate between enrollees and decliners. First, data suggest that decliners either do not want to quit or believe that they can quit on their own. Valbo et al27 reported that 56% of pregnant women who declined a cessation study had an interest in cessation but did not want assistance, and 44% did not want to quit smoking. Likewise, among hospitalized patients who declined a cessation program, 47% wanted to quit without formal help, and 53% did not want to quit smoking.35 Second, a range of factors, including the use of financial incentives, demographic factors (eg, ethnicity, age), and smoking-related behavioral characteristics (eg, readiness to quit, amount smoked), distinguish between those who enroll in smoking cessation programs and those who decline. Bains et al38 and Hennrikus et al30 reported that monetary incentives increased enrollment among eligible smokers in a cessation program. Woods et al39 found that, among African-American smokers eligible for a smoking cessation study, decliners were more likely to be men, younger, less educated, and unemployed. Men were also less likely to enroll in a school-based cessation program than women, as were African-American smokers, as opposed to Latinos.40 Although younger smokers approached for a pharmacologic cessation study were more likely to decline than older smokers were,41 a study of a nurse-managed inpatient cessation program found that decliners were more likely to be older than enrollees.35 Furthermore, smokers who declined cessation programs, versus those who enroll, exhibited lower levels of motivation39,41,42 and confidence39 to quit. Last, compared with enrollees, smokers who declined cessation programs were lighter smokers.43

Identifying a selection bias in smoking cessation studies with cancer patients could address methodologic shortcomings within this literature and help place intervention study findings into a more accurate context; it may also assist with designing treatments and initiatives to increase recruitment into smoking intervention programs. Currently, because smoking cessation research with cancer patients has focused on characteristics of enrollees (eg, predictors of smoking44,45), there is a gap in the literature regarding cancer patients who decline cessation assistance despite their tobacco-related illness and ongoing tobacco use. Thus, in this study, we examined the rate of enrollment among head and neck and lung cancer patients to a smoking cessation clinical trial and compared patients who enrolled in the trial with those who declined in terms of demographic, medical, and smoking-related behavioral data. We also examined the reasons for refusal to enroll in the cessation program among decliners. We expected our findings to mirror those from non-cancer populations, with decliners more likely to
be men, less educated, and less motivated to quit smoking. Furthermore, we expected that “wanting to quit without formal assistance” would be the most common reason for declining. Because past intervention studies with cancer patients have not reported differences between enrollees and decliners, we had little basis for hypotheses concerning medical variables, such as disease stage. Gritz et al \(^{23}\) found that patients with a more advanced disease stage were more likely to withdraw from a cessation program, so we predicted that decliners would be more likely to have advanced disease and manifest more physical symptoms than enrollees.

**PATIENTS AND METHODS**

**Participants.** A health educator (HE) reviewed intake forms for head and neck or lung cancer patients at a comprehensive cancer center to identify eligibility (ie, smoked within the past 6 months and reachable by phone). If eligible, the HE contacted the patient to assess interest in a free smoking cessation program (ie, an individual 2-hour counseling session consisting of education about the harmful effects of tobacco, skills-training to quit and avoid relapse, and nicotine patches). The intervention also included: (1) three “booster” calls to reinforce cessation, (2) the completion of brief follow-up surveys, and (3) a $40 incentive. Over 22 months, 584 patients were screened, and 231 eligible patients were identified (40% of those screened). Ineligibility was due to self-reported abstinence for 6 months or more. Patient characteristics are shown in Table 1.

**Procedure.** Each week, the HE reviewed intake forms for head and neck and lung cancer patients. Patients were recruited at any point in time (ie, at diagnosis, during treatment, or during recovery). Eligible patients indicated their interest in the cessation program that involved nicotine replacement therapy (NRT) and counseling. Intake forms documented demographic (eg, age), medical (eg, disease stage), and smoking-related behavioral (eg, readiness to quit smoking) information. Interested patients were recruited for the program; decliners were given a program brochure and instructed to contact the research team should they decide to enroll. No additional clinic visits were required for counseling sessions or follow-up assessments and, if patients had just quit, NRT was not provided and counseling focused on relapse prevention. Decliners were asked to provide a reason for refusal. With physician and institutional review board approval, the data collected to assess eligibility were used to compare enrollees (\(n = 109\)) to decliners (\(n = 122\)).

**Measures.** The intake forms, devised by the authors, asked patients to provide: (1) demographic data (sex, education, marital status, and age); (2) medical data (tumor site [if confirmed], tumor stage [if aware], previous cancer diagnoses [yes or no], and number of symptoms [ie, difficulty breathing, mucositis, difficulty swallowing or dry mouth, and pain in chest or mouth]); and (3) smoking-related behavioral data (readiness to quit smoking, classified as precontemplation [not considering quitting], contemplation [considering quitting], and preparation [considering quitting and making attempts to quit\(^{16}\); intention to quit smoking in the next 30 days [yes or no]; average number of cigarettes smoked per day in the past 30 days; and number of 24-hour quit attempts in the past 3 months). Tumor site and stage were confirmed by chart review, and a total score for number of symptoms was calculated (ie, \(0 = \text{no symptoms and } 4 = \text{all symptoms}\)).

**Statistical Analyses.** First, we examined differences between enrollees and decliners using the analysis of variance (ANOVA) procedure for ratio or interval data (ie, age, number of symptoms, average number of cigarettes smoked per day in the past 30 days, and number of 24-hour quit attempts in the past 3 months) and the chi-square test for nominal or ordinal data (ie, sex, education, marital status, tumor site, tumor stage, whether the patient previously had a cancer diagnosis, readiness to quit, and intention to quit smoking in the next 30 days). A difference with a probability value of .05 or less (two-sided) was declared significant. Next, variables found in the univariate analyses to be significantly related to enrollment status were entered into a binary logistic regression analysis to assess a prediction model of enrollment status. Wald chi-square tests, beta-weights, and odds ratios were computed. Last, a frequency distribution was constructed for the reasons given by decliners for not entering the smoking cessation program. Recent quitters were excluded from the univariate analyses of smoking variables, in the multivariate analysis, and in the assessment of reasons for quitting, because there is a conceptual reason for doing so. We did not exclude recent quitters from the assessment of demographic or medical variables because sex,
education, marital status, age, first diagnosis versus recurrence, and tumor stage remained nonsignificant and tumor site and symptoms remained significant when the recent quitters were excluded and because there was not a good conceptual reason for doing so.

RESULTS

Univariate Differences Between Decliners and Enrollees. With regard to medical variables, tumor site \((\chi^2[1] = 7.86, p < .05)\) was associated with enrollment status, with decliners more likely to have head and neck cancer (53%) versus lung cancer (47%). Decliners \((M = .55)\) also exhibited significantly fewer symptoms than enrollees did \((M = 1.48; F[1216] = 53.79, p < .05)\). On the other hand, cancer stage \((\chi^2[3] = 1.6, p > .05)\) and whether the patient had received a diagnosis of cancer previously \((\chi^2[1] = .577, p > .05)\) were not associated with enrollment status. With regard to smoking-related behavioral data, decliners \((M = 13.2)\) reported smoking significantly fewer cigarettes than enrollees did \((M = 18; F[1215] = 8.18, p < .05)\). Also, significantly fewer decliners (69.9%)...
reported an intention to quit smoking in the next 30 days compared with enrollees (95.3%; \( \chi^2 [1] = 23.52, p < .05 \)); and a significantly greater percentage of decliners (30.8%) were characterized as being in the precontemplation stage of readiness to quit smoking compared with enrollees (5.7%; \( \chi^2 [2] = 23.22, p < .05 \)). In contrast, decliners (\( M = 2.4 \)) reported similar levels of 24-hour quit attempts compared with enrollees (\( M = 2.0; F[1, 178] = .225, p > .05 \)). Last, with regard to demographic variables, sex (\( \chi^2 [1] = 1.3, p > .05 \)), education (\( \chi^2 [3] = .53, p > .05 \)), marital status (\( \chi^2 [3] = 3.19, p > .05 \)), and age (\( F[1,228] = .71, p > .05 \)) were not associated with enrollment status.

Multivariate Analysis of Predictors of Enrollment Status. As seen in Table 2, the multivariate regression analysis, in which the variables found to be related to enrollment status in univariate analyses were entered into the model, indicated that tumor site (Wald [1] = 8.13, \( p < .01 \)), number of symptoms (Wald [1] = 23.47, \( p < .01 \)), and intention to quit smoking in the next 30 days (Wald [1] = 7.51, \( p < .01 \)) remained predictors of enrollment status; in addition, average number of cigarettes smoked per day in the past 30 days approached significance (Wald [1] = 3.37, \( p = .06 \)). In particular, decliners were more likely to have head and neck cancer (vs lung cancer), reported fewer symptoms, exhibited less intention to quit smoking in the next 30 days, and smoked fewer cigarettes.

Reasons for Declining the Smoking Cessation Program. As seen in Table 3, the most common reason given by decliners for not enrolling in the cessation program was that they wished to quit on their own without formal assistance from a cessation program (42 of 91; 46.2%); the second most frequent reason was that they were not interested in quitting (20 of 91; 22%). A sizable proportion of decliners (15 of 91; 16.5%) also indicated that they did not wish to partake in the cessation program because it would be too inconvenient to attend a counseling session, and 13 (14.3%) of 121 eligible patients were unreachable for enrollment, despite telephone contact and the mailing of program brochures. (The 15 patients who were unreachable may not be “decliners.” Our classification of these patients as such may be considered a conservative approach to determining the rate of enrollment into the cessation program.)

DISCUSSION

In this study, about 50% of eligible patients declined the cessation program. This refusal rate parallels those reported with cancer patients,\(^{22}\) cardiac patients,\(^{37}\) and with a heterogeneous group of medical patients\(^{35}\) and indicates that refusal of cancer patients to partake in available smoking-cessation programs remains an important problem. High refusal rates may create bias in clinical trials of smoking cessation programs for cancer patients and limit the external validity when differences exist between enrollees and decliners.

Indeed, enrollees and decliners differed on factors that may be relevant to treatment outcomes. First, decliners have less intention to quit and a lower readiness to quit, although the latter emerged only in univariate analyses. This is consistent with past reports with medical patients\(^{39–43}\) and suggests that cancer patients

| Table 2. Summary of multivariate logistic regression analysis predicting enrollment status. |
|-----------------------------------------------|----------------|----------------|---------|-------|---------|----------------|
| Predictor variable                          | Wald \( \chi^2 \) | df  | \( p \)  | \( \beta \) | SE    | Odds ratio   |
| Tumor site                                  | 8.13            | 1   | < .01  | 1.03  | .36    | 2.81         |
| Number of symptoms                          | 23.47           | 1   | < .01  | 1.15  | .24    | 3.14         |
| Transtheoretical model stage                | .013            | 1   | .91    | .04   | .35    | 1.04         |
| Intention to quit in next 30 days            | 7.51            | 1   | < .01  | 2.21  | .81    | 9.15         |
| Average number of cigarettes/day in past 30 days | 3.37            | 1   | .06    | .03   | .02    | 1.03         |

Enrollee status as the dependent variable classified participants as decliner (0) versus enrollee (1); for tumor site, participants were head and neck (0) vs lung (1); recent quitters were excluded from this analysis.

<table>
<thead>
<tr>
<th>Table 3. Reasons given by decliners for not entering the smoking cessation program (( N = 91 )).</th>
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<tbody>
<tr>
<td>Reason</td>
</tr>
<tr>
<td>Wants to quit on own without formal help</td>
</tr>
<tr>
<td>Not interested in quitting smoking</td>
</tr>
<tr>
<td>Inconvenient now or unable to attend</td>
</tr>
<tr>
<td>Unreachable for enrollment</td>
</tr>
<tr>
<td>Does not speak English or cannot hear</td>
</tr>
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</table>

Recent quitters were excluded from this analysis.
may benefit from brief motivational interventions to persuade enrollment in a cessation program. One proven motivational treatment for patients with drug or alcohol addictions, referred to as motivational interviewing (MI), encourages the patient to articulate ambivalence about change and formulate a method for resolution and may be useful with the present population. Manfredi et al compared the quit rates of women attending public health clinics that used MI to promote smoking cessation with rates among women attending clinics that gave standard care; 15% of 1064 women receiving MI were abstinent versus 8% of 683 women in the standard care group (see also Ref 54). Indeed, there has been a growing recognition for the need to integrate MI within medical settings to urge patients who smoke to capitalize on available cessation treatments.

Second, consistent with research among non-cancer patients, lighter smokers were more likely to decline enrollment. Although we do not have data to unequivocally support this interpretation, this result may suggest that beliefs among decliners serve as barriers to enrolling in a cessation program. In particular, because decliners smoke fewer cigarettes, they may believe that they can quit on their own at any time or that their habit does not pose a serious health threat. This interpretation is, in part, supported by a study with vascular disease patients which found that patients who declined a cessation program exhibited both a lower rate of tobacco use and lower perceived risk for adverse health problems from smoking. Thus, decliners may benefit from motivational messages that emphasize that even light smokers require formal assistance to quit smoking and that smoking even a few cigarettes can be harmful (eg, increase risk for recurrence). In addition, lighter smokers may have been more likely to be decliners because they were less likely to have a physician encourage them to enroll. Okuyemi et al found that light smokers are less likely to have physicians assess smoking status or provide cessation counseling than are heavier smokers. Thus, it may be necessary to ensure that physicians provide quit messages to all patients, even those who are light smokers.

Third, head and neck versus lung cancer patients were more likely to decline the quit program (although the effect might be small). This result converges with a previous study that showed that head and neck cancer patients are less likely to quit smoking than lung cancer patients are. Again, although we cannot empirically support this interpretation directly, beliefs about health risks may underlie this phenomenon. Head and neck cancer patients may resist enrollment because they believe that only lung cancer is etiologically linked to smoking; anecdotally, we have seen head and neck cancer patients report that smoking is unrelated to their disease. Also, because head and neck cancer can have a favorable prognosis, patients who smoke may minimize the seriousness of the diagnosis and are, thus, less committed to quitting. In fact, there is some evidence that disease stage, which may serve as a proxy for beliefs about health risks, is linked to smoking behavior in that patients with a lower disease stage (and, presumably, more lower perceived health risks) show higher rates of tobacco use compared with patients with a higher disease stage. Either alternately or in addition, head and neck cancer patients may manifest certain smoking-related factors (eg, low quit motivation) or personality characteristics (eg, heavy alcohol use) that have been shown to be barriers to quitting smoking (see Refs 12 and 15). However, systematic differences between head and neck versus lung cancer patients on these variables have yet to be shown. Thus, messages that emphasize the link between smoking and their disease and stress the gravity of their illness may be needed for head and neck cancer patients (although lung cancer patients should still be targeted for enrollment into smoking cessation programs).

Fourth, our finding of the link between fewer physical symptoms and a greater likelihood of declining the cessation program (contrary to our hypothesis) supports the contention that low-risk perceptions held by head and neck cancer patients underlie their reluctance to enroll in a cessation program. Low perceived risk from tobacco use may arise from head and neck cancer patients experiencing fewer physical symptoms (head and neck cancer patients, vs lung cancer patients, reported fewer physical symptoms \[F (1, 208) = 3.90, p = .05]\). Thus, head and neck cancer patients experience fewer symptoms attributable to their disease and tobacco use, in turn believing that they are less vulnerable to the adverse effects of tobacco use. As a result, feeling less at risk from continued tobacco use, these patients decline the cessation program. This perspective is congruent with our reports of the association between low perceived risk (eg, of recurrence) and a greater probability of continued smoking among cancer patients and is also consistent with the finding by Ostroff et al.
concerning the link between continued tobacco use and lower disease stage.

Last, consistent with past findings, to close to 50% of decliners preferred to quit on their own. This result is troubling, because the Agency for Healthcare Research and Quality found that the effect of self-help interventions is weak, inconsistent, and small versus other interventions. Despite this, 42 patients approached for this program said that they preferred to help themselves rather than use a formal cessation program. Thus, although a few patients may achieve cessation on their own, motivational interventions should stress to patients that participating in formal cessation programs increases their chance for successful cessation.

These findings should be viewed in the context of limitations. First, we had access to a limited range of correlates of enrollment. The patient intake forms did not assess self-confidence to quit smoking or psychological distress, and we did not track the duration of illness, factors that are linked to smoking among cancer patients. Likewise, we did not have access to decliner’s ethnicity, making it impossible to determine the degree to which our sample’s ethnicity parallels that of the general cancer patient population. Second, we relied on self-report for smoking behavior. Thus, certain patients might not have been included in this study if they failed to report honestly on their initial smoking status. Third, with a small sample, our statistical power is less than ideal and may explain our null findings for variables previously found to be related to enrolling in a smoking cessation program (ie, age, sex). Finally, because we were not permitted to follow decliners over time, we were not able to ascertain the cessation rate in this group to allow for a comparison with the patients who did enroll in the cessation program. However, we found in a previous longitudinal study with cancer patients that smoke that about 25% of patients quit smoking in the absence of formal cessation treatment. This rate can be a useful base rate for comparison with the group of patients who did enroll in the cessation program once our follow-up data are collected.

Despite these limitations, this study makes an important contribution because we are unaware of data on characteristics of cancer patients who decline smoking treatment or on why decliners fail to enroll in cessation programs. In sum, head and neck patients and patients who exhibit fewer physical symptoms report a lower readiness to quit smoking, indicate no intention to quit smoking, and are light smokers at risk for declining a cessation program. Furthermore, most patients decline enrollment because they prefer to quit on their own. As such, we recommend: (1) the integration of MIs within cancer treatment centers to encourage smokers to enroll in cessation programs; (2) the inclusion in MI content of a review of the harmful effects of smoking for cancer patients and statements that even light smokers need formal help to quit and that self-help quitting methods are generally ineffective; (3) the targeting of motivational interventions to head and neck cancer patients and the provision of information about the causal link between tobacco use and their diagnosis; and (4) instruction to medical staff to provide motivational messages to all patients who smoke. Our results also indicate that research is needed to explore whether, as we speculate here, low perceived risk of the harmful effects of smoking underlie reluctance to enroll in cessation programs among head and neck cancer patients, among patients who exhibit fewer symptoms, or among patients who are light smokers. Until such research confirms this assertion, our proposed explanation for this phenomenon must remain provisional. Last, because decliners seem to prefer to quit on their own, research that focuses on how to improve the efficacy of self-help cessation approaches may represent a useful direction for future research. The implementation of these suggestions may increase the rate of accrual among cancer patients into smoking cessation programs, thereby increasing the proportion of patients who may abstain from tobacco use and reducing the potential confounding of study data that can limit external validity because of a selection bias.

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