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Randomized Trial of a Pre-Surgical Scheduled Reduced Smoking Intervention for Patients Newly Diagnosed with Cancer

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Abstract

Objective—Cancer patients are advised to quit smoking to reduce treatment complications and future cancer risk. This study's main objective was to evaluate the efficacy of a novel, pre-surgical cessation intervention in newly diagnosed cancer patients scheduled for surgical hospitalization.

Methods—We conducted a parallel-arm, randomized controlled trial comparing the efficacy of our hospital-based, tobacco cessation “best practices” treatment model (BP; cessation counseling and nicotine replacement therapy) with BP enhanced by a behavioral tapering regimen (scheduled reduced smoking; BP+SRS) administered by a handheld computer before hospitalization for surgery. Cessation outcomes were short (hospital admission and three months) and longer-term (6 months) biochemically-verified smoking abstinence. We hypothesized that BP+SRS would be superior to BP alone. One hundred eighty-five smokers were enrolled.

Results—Overall, 7-day-point prevalence, confirmed abstinence rates at six months for BP alone (32%) and BP+SRS (32%) were high; however, no main effect of treatment was observed. Patients who were older and diagnosed with lung cancer were more likely to quit smoking.

Conclusions—Compared to best practices for treating tobacco dependence, a pre-surgical, scheduled reduced smoking intervention did not improve abstinence rates among newly diagnosed cancer patients.

Keywords

Smoking cessation; patients with cancer; scheduled reduced smoking; hospitalized smokers

Continued smoking by tobacco dependent cancer patients is associated with greater risk of recurrence (Fleshner et al., 1999; Kenfield, Stampfer, Chan, & Giovannucci, 2011), reduced

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survival (Murin & Inciardi, 2001; Parsons, Daley, Begh, & Aveyard, 2010; Waggoner et al., 2006; Warren, Kasza, Reid, Cummings, & Marshall, 2012) and quality of life (Garces et al., 2004; Peppone et al., 2011); and an increased risk of peri-operative complications during treatment(Dresler, Bailey, Roper, Patterson, & Cooper, 1996; Moller, 2006; Theadom & Cropley, 2006; Warner, 2006).

While cancer diagnosis is considered to be a “teachable moment” for smoking cessation (McBride & Ostroff, 2003) and often leads to spontaneous quitting, persistent smoking is a serious and prevalent clinical problem (IOM, 2012; Mayer & Carlson, 2011; Underwood, Townsend, Tai, et al., 2012). About 15.1% of all adult cancer survivors are current smokers (Underwood, Townsend, Stewart, et al., 2012). Persistent smoking among those who smoked prior to diagnosis varies widely by cancer type (Coups & Ostroff, 2005; Cox et al., 2002; Demark-Wahnefried, Aziz, Rowland, & Pinto, 2005; Gritz et al., 2006; Mayer et al., 2007; Ostroff et al., 2000; Park et al., 2012) with continued smoking rates ranging from a low of 20% among lung cancer patients(Cox et al., 2002) to a high of 65% among bladder cancer patients (Ostroff et al., 2000). Thus, cancer-specific health risks and the prevalence of persistent smoking argue for the importance of providing evidence-based treatment of tobacco dependence as a standard of quality care in cancer settings (American Society for Clinical Oncology, 2009; Cox, Africano, Tercyak, & Taylor, 2003; Fleshner et al., 1999; Gritz, Dresler, & Sarna, 2005; National Comprehensive Cancer Network, 2007).

Smoking Cessation Trials with Cancer Patients

Despite the serious risks of persistent smoking, there is little data on how best to promote cessation among cancer patients. Prior randomized controlled cessation trials of pharmacologic and counseling interventions conducted with cancer patients generally have not found statistically significant treatment effects, with 6-month point abstinence rates ranging from 14-30% among those in the intervention conditions (Nayan, Gupta, & Sommer, 2011).

Given the acute and long-term risks and the high rates of persistent smoking, efficacious cessation interventions are needed for cancer patients (de Moor, Elder, & Emmons, 2008). The pre-hospitalization period represents a largely unexplored opportunity for smoking cessation treatment that can capitalize on oncologic providers' advice to quit and leverage a “teachable moment” for smoking cessation among tobacco dependent cancer patients (McBride & Ostroff, 2003). To date, no known trials have focused on preparing cancer patients to quit smoking prior to hospitalization.

Scheduled Reduced Smoking (SRS)

Scheduled reduced smoking (SRS) is a behavioral strategy for preparing to quit in which smokers gradually reduce their daily smoking rate by adhering to predetermined smoking times. Over days or weeks, the inter-cigarette intervals are gradually increased and smoking is delayed until the next scheduled cigarette. As the nonsmoking interval increases, smokers practice behavioral coping with smoking urges (Cinciripini, Wetter, & McClure, 1997). SRS may increase quitting self-efficacy as smokers experience less reward from smoking

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scheduled cigarettes and successfully manage smoking urges (Catley & Grobe, 2008). To date, two trials conducted with “healthy” smokers have shown that SRS is efficacious (Cinciripini et al., 1994; Cinciripini et al., 1995) with higher abstinence rates and greater coping with smoking urges and quitting self-efficacy for smokers using SRS than those who either quit abruptly, gradually reduced on their own, or smoked on a schedule without reduction (Cinciripini et al., 1995). SRS was chosen as a potential enhancement of the hospital's routine cessation treatment because of the promise of prior work, expectation that SRS would improve self-efficacy, and advantages of using a handheld computer for intervention delivery to reduce patient burden with clinic visits.

The main study goal was to evaluate the efficacy of the SRS intervention combined with best practices (SRS+BP) when compared with BP alone (BP: cessation counseling and pharmacotherapy) on short- and long-term abstinence rates in smokers newly diagnosed with cancer and awaiting hospitalization for surgical treatment. It was hypothesized that patients assigned to the SRS+BP intervention arm would have higher rates of smoking abstinence than those who received BP alone.

Methods

Participants and Procedures

Participants were smokers with newly diagnosed cancer who were scheduled for hospitalization and surgical resection at a comprehensive cancer center in New York City. The study was approved by the Center's institutional review board. Eligible patients were English-speaking adults with a localized solid mass likely to be cancer; awaiting surgical treatment no less than 7 days from study entry[1]; smoked at least 8 cigarettes per day (cpd) within the past week and had sufficient visual acuity and manual dexterity use a handheld computer. Exclusion criteria included evidence of psychopathology or cognitive impairment severe enough to prevent informed consent or completion of the study. Potential participants were screened via the electronic medical record and recruited from surgical clinics by a trained research assistant (RA). Physicians gave approval to approach their patients.

Randomization/Design

The trial design involved two parallel arms with an equal allocation ratio. Computerized permuted-block randomization was conducted independently by the Centers' Data Management Group. Patients were stratified by baseline daily cigarette consumption (≥ 20 cpd vs < 20 cpd) prior to random assignment. Participants were offered $20 to defray parking expenses incurred.

[1]Patients were surgical candidates at the time of study entry and some were later determined not to be candidates for imminent surgical treatment. Of this group, six patients received neoadjuvant chemotherapy prior to surgery and seven were unresectable during surgery. These patients were retained in the study. To align the delivery of the intervention components and assessment timelines for surgically resected and non-surgical patients, we treated non-surgically treated patients' treatment start date as the equivalent of the hospitalization date.

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Intervention Conditions

Best Practices Only—Consistent with best practices (BP) for treating tobacco dependence (USDHHS, 2008), smokers assigned to the BP condition received our hospital's multi-component tobacco cessation treatment. In this setting, smokers are routinely advised to quit smoking by their attending surgeon during their work-up and pre-surgical consultations. All smokers are offered telephonic and bedside cessation counseling on the benefits of cessation for cancer patients, potential barriers to quitting, and behavioral strategies for managing smoking urges, recommendations for use of cessation pharmacotherapy and self-help materials (Ostroff, Burkhalter, O'Brien, Hay, & Dhingra, 2005)[2]. Individual cessation counseling is provided by designated oncology nurses trained and certified as tobacco treatment specialists (TTS). For this trial, two Tobacco Treatment Specialists (TTS), with at least two years prior clinical experience with cessation treatment, provided the counseling sessions. The TTSs underwent four hours of training using a treatment fidelity checklist. Training was conducted by the PI (JO) and a postdoctoral clinical psychology fellow (LD) using role-play exercises. A demonstration and intervention protocol checklist guided the performance of 16 counseling behaviors based on motivational interviewing for cessation (e.g., dealing with resistance, enhancing self-efficacy, steps to quitting, coping with urges). To minimize protocol drift, group supervision by the PI was conducted weekly.

Participants were offered five individual cessation counseling sessions and nicotine replacement therapy (NRT) at no cost. The first session was prior to surgery and focused on enhancing motivation, preparedness to quit prior to hospitalization, and providing education about cessation pharmacotherapy and adverse effects. The second counseling contact prior to surgery addressed pharmacotherapy use and provided support for patients' quitting efforts. A third counseling session occurred during hospitalization and focused on inpatient management of acute nicotine withdrawal and coping with urges to smoke. Two more counseling sessions were provided during the month after hospital discharge and focused on assessing cessation progress, adherence to pharmacotherapy, reinforcing behavioral strategies for coping with smoking urges, and preventing relapse. All counseling sessions were delivered by telephone with the exception of the third session which was generally delivered in person during the patient's hospital stay. The planned duration of each counseling session was: (Session 1: 30-45 mins; Session 2: 5-10 mins; and Sessions 3, 4 and 5: 15-20 mins). Based on the number and duration of counseling sessions, the BP condition can be classified as consistent with an intensive level (Level 4 out of a Maximum Level 4) of cessation treatment found to be effective for treating hospitalized smokers (Rigotti, Munafo, & Stead, 2008).

The primary aim was to test the effectiveness of a novel behavioral intervention and NRT use was recommended but not required for study participation. To be most representative of actual clinical care, cessation pharmacotherapy recommendations were tailored to the specific needs and preferences of patients. The study provided free NRT to all participants, and evaluated equivalence in NRT use between the treatment groups.

[2]Available by request from the authors.

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Best Practices + Scheduled Reduced Smoking (BP+SRS)—The BP+SRS treatment condition included all of the best practices described above plus a handheld computer pre-programmed to administer the SRS pre-surgical gradual tapering regimen (Cinciripini et al., 1994; 1995). Participants randomized to BP+SRS were trained by the RA to use the handheld computer, or "QuitPal". Training sessions concluded with an assessment of QuitPal mastery, and each participant received a helpline number and instructional manual. In addition, the RA contacted each participant within 3 days after enrollment to answer any questions about QuitPal use. Each patient's individualized SRS schedule was tailored to three parameters: a) typical waking and bedtimes; b) daily average smoking rate; and c) number of days from enrollment until hospitalization, with a quit date planned at least 24 hours prior to an inpatient admission. Patients were instructed to smoke within 10 minutes of the auditory prompt and all entries and events were time-stamped. Patients were instructed to use the QuitPal daily prior to their hospital admission and return it upon admission.

Measures

Patients' medical charts were reviewed to collect data on disease and treatment characteristics. Demographic and tobacco use characteristics were also assessed. Nicotine dependence was assessed at baseline by the *Fagerstrom Test for Nicotine Dependence* (Fagerstrom, Heatherton, & Kozlowski, 1990; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991), a 6-item scale, with scores > 6 indicating heavy nicotine dependence. The *Commitment to Abstinence Scale* (Hall, Havassy, & Wasserman, 1990) measured baseline commitment to one of six smoking abstinence goals ranging from 1 ("*I have no goal/intentions to quit*") to 6 ("*My goal is total abstinence*"). Ten items from the *Confidence Questionnaire Form* (Baer & Lichtenstein, 1988) assessed baseline self-efficacy appraisals for coping with smoking urges in tempting situations. Patients rated the likelihood of being able to resist smoking in each context on a 0-100% scale, with higher scores indicating greater quitting self-efficacy.

Smoking Cessation Outcomes

The primary study outcome was 7-day point prevalence abstinence assessed at six months post-hospitalization and verified by cotinine assays using saliva samples as recommended for cessation clinical trials (Hughes et al., 2003; Velicer, Prochaska, Rossi, & Snow, 1992). Secondary abstinence outcomes were assessed at hospital admission (24-hour point-prevalence abstinence) and verified by carbon monoxide (CO) breath test, and at three months post-hospitalization (7-day point abstinence) and verified by salivary cotinine assays. To minimize misreporting, patients were informed that their breath (or saliva) would be tested for recent tobacco smoke exposure before smoking status was self-reported. Patients with CO levels < 10 ppm were classified as point abstinent (SRNT Subcommittee on biochemical verification, 2002). Patients with salivary cotinine levels < 15ng/ml were classified as abstinent (SRNT Subcommittee on biochemical verification, 2002). ITT principal was applied to biochemical verification of abstinence so that a participant is coded as smoking unless biochemically verified. Thus, missing abstinence data and incidences of misreporting were coded as smoking. Additionally, the self-reported number of cigarettes smoked per day (cpd) and an overall assessment of recent changes in their smoking rate

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(reduced, about the same, increased) were measured at hospital admission and at the three- and six-month (post-hospital admission) follow-up assessments.

Treatment Implementation Fidelity, Usage, and Program Evaluation

To confirm that cessation treatment conditions were delivered as intended (Bellg et al., 2004), four treatment components were assessed: advice to quit, offering of NRT, behavioral counseling delivery, and training for use of the handheld computer (BP+SRS participants only). Patient-reported receipt of advice to quit from the surgical oncologist was collected at baseline. Counseling and medical records were audited to confirm that NRT was offered. The number of counseling sessions provided and their duration were recorded by the TTS. In addition, counseling sessions were audio-recorded and 12% of the participants were randomly sampled and their counseling sessions checked for adherence to the content of the clinical intervention checklist. For patients assigned to SRS, records of QuitPal training were audited for training adherence.

Patient reports on the use of NRT and the level of adherence were collected at each counseling session. The number of days of SRS use and the percentage of cigarettes actually smoked on schedule compared to the total number of scheduled cigarettes planned were computed. A program evaluation including a 15-item (for BP) and a 27-item (BP+SRS) survey assessed patients' perceptions of treatment quality and satisfaction.

Statistical Methods

To address the primary study aim, a series of Fisher's exact test statistics were used to compare biochemically-verified abstinence between the treatment conditions at hospital admission, and the 3- and 6-month follow-up assessment points. A participant was considered to be a current smoker unless his or her self-reported 24-hour or 7-day point abstinence was biochemically verified. Consistent with Intention-To-Treat (ITT) principles (Nagelkerke, Fidler, Bernsen, & Borgdorff, 2000), group comparisons were made based on the initial group assignment, regardless of intervention completion.

Comparisons of baseline differences across the two intervention conditions were based on independent-sample t-tests and exact tests of sample proportions. Treatment efficacy over time was evaluated by a Generalized Estimating Equation (GEE) model of longitudinal smoking abstinence (Zeger & Liang, 1986) as a function of the intervention condition and discrete time points, using a logit link for the binomial distributional family data, assuming unstructured working correlations over time. Robust variance estimates for the coefficients were calculated to guard against inflated Type-I error in an over-dispersed correlation matrix (Williams, 2000). In the secondary analyses, reduction in cigarette consumption from baseline to the three follow-up points was assessed with paired t-tests. Self-reported smoking outcomes were also examined. All statistical analyses were conducted in SAS version 9.2. (SAS Institute Inc., 2000-2008) and R version 2.13.1 (R Development Core Team, 2011) software packages.

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Results

Participant enrollment and retention data are presented in Figure 1. Newly diagnosed cancer patients seeking surgical consultation were screened for smoking status, and 264 patients meeting all eligibility criteria were identified. Of those, 79 (29.9%) declined participation. Refusers were older (M = 69.3, SD = 13.9, $p < 0.001$) and less likely to be diagnosed with either lung or head and neck cancers ($p < .001$). The most prevalent reasons for refusal (more than one could be reported) included: not interested in study (54.4%), not motivated to quit smoking before surgery (38.0%), not motivated to quit smoking (35.4%), wants to quit on own (24.1%), and too stressed (20.3%). There was no significant difference between group sizes at allocation. Retention at the 6-month follow-up was high and comparable across the two conditions (84% BP vs 85% BP+SRS).

Participant characteristics are presented in Table 1. The sample was predominantly white (87%), with a mean age of 55.9 years, about half were women (53%) and lung cancer was the most prevalent diagnosis (30%). At baseline, the mean number of cigarettes smoked daily was 19.5 (SD = 10.5) and the overall mean pack-years was 35.4 (SD = 12.2). The mean Fagerstrom score was 4.9 (SD =1.9), indicating moderate nicotine dependence, and 38% reported smoking their first cigarette within 5 minutes of waking. There were no statistically significant differences in baseline characteristics between the intervention conditions. Internal consistency for the baseline Confidence Questionnaire Form assessment was 0.88.

Based on biochemical verification, only 13 (7.5%) participants misreported smoking status at hospital admission, 5 (3.4%) at the 3-month follow-up and 4 (2.5%) at the 6-month follow-up. There were no group differences in misreporting of smoking status.

Treatment Implementation Fidelity, Usage, and Program Evaluation

Overall, 84% of patients reported discussing their smoking with their surgeon, and 78% reported being advised to quit prior to surgery. NRT was offered to 99.4%, and 72.5% reported actual usage of NRT during the trial. Of those using NRT, 91% reported full adherence to the standard dose and usage recommendations.

The timing for the delivery of the five cessation counseling sessions was planned relative to each patient's surgery date. The median intake counseling session occurred 12 days before surgery. Of the planned sessions, 98% of scheduled calls were made by the TTS. Patients received on average 4.1 counseling sessions (SD = 1.3) with a mean duration of 16.7 minutes each. At least four of the five counseling sessions were received by 71.3% of BP and 76.3% of BP+SRS participants. Only 13.8% of BP and 9.7% of BP+SRS participants received two or fewer sessions. In addition, 89% of the targeted content from the treatment checklist was verified in the sampled calls. There were no statistically significant group differences found in either rates of quitting advice, use of NRT, or the number, duration, and satisfaction with counseling sessions.

In the BP+SRS condition, 96.7% of patients received the planned QuitPal training. In terms of SRS adherence, participants smoked 50% of the scheduled cigarettes, on average, with

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daily within-person variability averaging 24%.[3] Patients used the QuitPal for a median of 16 days (inter-quartile range: 12 to 28 days) prior to surgery. Completion of a morning start-up routine was considered a minimal indicator of daily use of the QuitPal. Overall, a median of 73% of participants used the QuitPal daily (inter-quartile range: 36-93%). However, 22 patients assigned to the BP+SRS condition did not have evaluable QuitPal use data because of technical problems (n=3), withdrawal from the study prior to using the QuitPal (n=5), or battery depletion (n=14). Patients reported that QuitPal was helpful in quitting smoking and was not particularly inconvenient (M = 3.8, SD = 1.2 and M = 3.2, SD = 1.3, respectively, on a 1 to 5 scale).

The assessment of patient satisfaction with the quality of cessation counseling had high internal consistency (standardized Cronbach's alpha of 0.83 and 0.88 for the BP and BP +SRS groups, respectively). The overall average score was high (M = 3.44 on a 1 to 4 scale, SD = 0.70). Almost all (97%) reported that they would recommend the cessation counseling to others.

Effect of the Intervention on Primary and Secondary Smoking Cessation Outcomes

Table 2 summarizes results of the ITT analyses of abstinence rates for treatment conditions and assessment points. At hospital admission, 40 of 89 patients (45%) in the BP condition were verified 24-hour abstainers, compared to 43 of 95 patients (45%) in the BP+SRS condition (p = 1.0 by Fisher's test, OR=0.987, 95% CI: 0.530, 1.839). At 3-month follow-up, the 7-day point abstinence rates were also similar between the conditions, with 34% and 36% abstinent in the BP and BP+SRS conditions, respectively (p = 0.878, OR=0.944, 95% CI: 0.490, 1.816). At 6-month follow-up, the 7-day point abstinence rates were 32% for both treatment conditions (p = 1.0, OR=1.028, 95% CI: 0.525, 2.012). The analysis of self-reported smoking status yielded comparable null results. These outcome analyses were based on unadjusted Fisher's tests comparing ITT abstinence rates across treatment conditions without covariates.

Daily cigarette smoking reduction was observed in both treatment conditions. Smokers randomized to BP substantially reduced their daily smoking rate from 20.6 to 6.1 cpd between baseline and hospital admission. BP+SRS participants reduced from 18.5 to 4.4 cpd during the same time period. The overall reduction averaged over hospital admission, 3- and 6-month follow-up time points was 12.2 cpd for BP and 12.2 cpd for BP+SRS, respectively. A repeated-measures ANOVA comparing the two profiles of cpd reduction over the three assessment time points, controlling for baseline cpd, yielded no significant difference (p= 0.091). At enrollment, 51% of BP and 37% of BP+SRS participants reported that they had reduced their overall smoking rate since cancer diagnosis (Table 1). Whereas at hospital admission, BP+SRS participants were more likely to report that they had reduced their daily smoking than those in the BP only condition (62% vs. 39%; OR = 2.5, 95% CI: 0.98 – 6.53, p=0.054) (Table 2).

The GEE model on the longitudinal abstinence outcomes over time shows that none of the coefficients and corresponding odds ratios were statistically significant. The Treatment-by-

[3]Adherence to SRS intervention did not impact primary cessation outcome.

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Time interaction terms show no treatment differences for longitudinal abstinence rates (Table 3).

Baseline predictors of smoking abstinence at six months following hospitalization

Given the lack of an overall treatment effect, participants from both intervention conditions were combined and sociodemographic, disease, and baseline tobacco-use variables were examined as predictors of smoking abstinence at the 3-month and 6-month follow-up time points. Gender, age, education, income, employment status, cancer site (thoracic vs others), time since diagnosis, time to first cigarette, baseline cpd, baseline quitting self-efficacy, and baseline commitment to abstinence on smoking abstinence were examined as potential predictors of smoking abstinence. Only age was significantly related to smoking abstinence at both 3-month and 6-month follow-up time points, such that older patients were more likely to be abstinent (OR at 3 months = 1.045, CI: 1.012 – 1.080, p = 0.007; OR at 6 months = 1.036, CI: 1.003 – 1.070, p = 0.032). Cancer site (thoracic vs other sites) also had a significant association with abstinence at 3 months (OR = 2.16, CI: 1.116 – 4.183, p = 0.022) such that patients diagnosed with thoracic cancers were more likely to quit smoking. At the 6 months follow-up, the association between cancer site and smoking abstinence remained marginally significant (OR = 1.915, CI: 0.979 – 3.746, p = 0.058).

Discussion

This randomized controlled trial tested the efficacy of adding a scheduled reduced smoking (SRS) component to best practices (BP) for cancer patients who smoke and were awaiting hospitalization for surgical treatment. Smokers were randomly assigned to receive either BP only (counseling sessions and cessation pharmacotherapy) or BP+SRS. Although relatively high rates of biochemically verified smoking abstinence were found, the SRS intervention in addition to BP did not yield superior quit rates at either 3 or 6 months following hospitalization. Nevertheless, as this was the first known study to test SRS with medically ill patients in a pre-surgical context, the study contributes to knowledge on the therapeutic benefit of SRS.

What factors might explain the null findings in contrast to previous work demonstrating efficacy of SRS? First, despite efforts to maintain treatment integrity, participants in both treatment conditions substantially reduced their daily smoking rate immediately following diagnosis of cancer, most rapidly prior to hospitalization. Unlike Cinciripini's prior study (1995) conducted with healthy volunteers, participants in the current trial were newly diagnosed cancer patients advised to quit by their surgical oncologists. Second, as all patients were scheduled for cancer surgery, there was a somewhat shorter duration of time between the start of the SRS intervention and hospitalization resulting in a shorter duration of SRS intervention than delivered in prior studies (approximately 2 versus 4 weeks). Further, whereas a prior SRS study required smokers to deposit $110, with repayment contingent on SRS adherence (Cinciripini et al., 1995), the current study was conducted without monetary incentive for adherence. Cinciripini and colleagues (1995) observed high (93%) SRS adherence (defined as the proportion of actual cigarettes smoked out of the total number of cigarettes scheduled to smoke). In comparison, SRS adherence for cancer patients

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enrolled in our study was lower, averaging 50%, which may have also contributed to the lack of intervention effect. This observed difference in SRS adherence rates may be due to the lack of monetary incentives for SRS adherence as well as the potential burden on medically ill smokers to adhere to the SRS regimen in the context of numerous medical care appointments and life disruptions that restricted opportunities to smoke on schedule. Finally, while participants in the prior SRS study received no cessation medications, all participants in this trial were offered NRT at no cost and were strongly encouraged to use cessation medications following their quit date.

Regarding the current study's trial design, the “control” group received an unusually robust treatment dose compared to prior hospital-based, cessation studies (Rigotti, Clair, Munafo, & Stead, 2012). It was deemed unethical to withhold best practices for tobacco cessation treatment from pre-surgical cancer patients with a medical urgency for quitting. Consequently, this trial design set a high standard for testing the superior efficacy of an experimental intervention. With few exceptions, prior cessation studies conducted with cancer patients have typically used usual care (no-treatment) or physician advice as control conditions (Duffy et al., 2006; Griebel, Wewers, & Baker, 1998; Gritz et al., 1993; Park et al., 2011; Schnoll et al., 2005; Schnoll et al., 2003; Wakefield, Olver, Whitford, & Rosenfeld, 2004; Wewers, Bowen, Stanislaw, & Desimone, 1994). For example, using a no-treatment control condition, Wewers et al. showed that a nurse-managed, smoking cessation counseling intervention yielded a superior quit rate among tobacco dependent cancer patients (Griebel, Wewers, & Baker, 1998; Stanislaw & Wewers, 1994; Wewers, Jenkins, & Mignery, 1997). Similarly, Park et al. demonstrated higher (though nonsignificant) quit rates among thoracic cancer patients who received varenicline and intensive counseling compared with those patients who received usual (unspecified) care (34.4% vs. 14.3% abstinence at 3-month follow-up, $p = .18$) (Park et al., 2011). In contrast, current study participants assigned to the BP condition received physician advice to quit, multiple counseling sessions by a trained TTS, and cessation pharmacotherapy consistent with evidence-based guidelines (USDHHS, 2008). Thus, the BP condition of this trial was more akin to intensive experimental intervention conditions offering evidence-based counseling and cessation pharmacotherapy that have been found to be efficacious in prior clinical trials with hospitalized smokers (Rigotti, Munafo, & Stead, 2008). In fact, the 32% overall biochemically-verified abstinence rate observed at 6 months represents one of the highest cessation rates found in a cessation trial with tobacco-dependent cancer patients (Nayan, Gupta, & Sommer, 2011) and is also consistent with the highest cessation rates reported with hospitalized smokers (Rigotti, Munafo, & Stead, 2008). In summary, participant characteristics, the absence of participant incentives for SRS adherence, unanticipated similarities in the rate of pre-surgical smoking reduction, and the intensity of the best practices control group may have contributed to cessation outcomes divergent from earlier SRS studies.

Despite the null trial results, the study contributes to the knowledge base on behavioral interventions for smoking cessation and the clinical care of recently diagnosed, tobacco-dependent cancer patients. First, the results argue for current implementation of best practices for treating tobacco dependence among hospitalized smokers. These findings underscore the value of integrating tobacco treatment into standards of quality cancer care

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(American Society for Clinical Oncology, 2009; Morgan et al., 2011) and support the pre-hospitalization period as a feasible entry point for delivery of smoking cessation interventions among medically ill smokers. However, there remains considerable room for improvement in increasing adherence to smoking cessation interventions (implementation) and smoking relapse prevention (maintenance) following hospital discharge (France, Glasgow, & Marcus, 2001), and this remains a high priority area for future research. Although most oncology provider believe that tobacco cessation should be a standard part of clinical care (Warren et al., 2013), most cancer care settings have not yet established tobacco cessation treatment as standard care (Goldstein, Ripley-Moffitt, Pathman, & Patsakham, 2012), and oncology providers miss many opportunities to promote tobacco cessation (Coups, Dhingra, Heckman, & Manne, 2009; Sabatino et al., 2007). Our findings support the need for continued development and evaluation of novel smoking cessation interventions that are acceptable and efficacious for cancer patients. Consistent with a recent publication by Berg and colleagues (Berg, Carpenter, Jardin, & Ostroff, 2013), the observation of marked smoking reduction from enrollment (cancer diagnosis) to hospitalization suggests cancer patients' acceptability of behavioral cessation treatment efforts that allow for tapering and reducing daily smoking, perhaps as preparation for quitting. In a review of smoking reduction studies with healthy smokers, the authors emphasize the potential benefit of behavioral treatment that emphasizes gradual tapering of smoking as a prerequisite for quit attempt (Hughes & Carpenter, 2006). Second, this study is noteworthy for its inclusion of smokers with tobacco-related as well as non-tobacco-related cancers, a subgroup of smokers typically under-represented in prior work that has focused predominantly on cessation outcomes in lung or head and neck cancer patients.

Limitations and Recommendations for Future Studies

Although the study had a relatively low refusal rate (29%), younger patients and to some extent those diagnosed with tobacco-related cancers were more likely to enroll. Future trials should address barriers to participation in cessation trials among older patients and those diagnosed with non-tobacco related cancers who may be less cognizant of the risks of persistent smoking. In our sample, 30% of patients were diagnosed with lung cancer. These patients tend to quit smoking at higher rates than those diagnosed with other cancers (Cox et al., 2002) and their inclusion may have created a potential ceiling for finding experimental treatment effects. Future cessation trials should address cessation among patients diagnosed with tobacco- and non-tobacco-related cancers. Although we found low rates of misreporting, another study limitation is that not all participants (5% missing data) provided samples for biochemical verification of self-reported smoking abstinence. The two-arm study design did not enable isolated examination of the potential benefit of self-monitoring of daily cigarette smoking. Ideally, future SRS trials should include a third study condition in which participants would self-monitor their daily rate and patterns of cigarette smoking without following a structured smoking reduction regimen. While the SRS intervention was designed to improve quitting self-efficacy, daily interaction with the QuitPal may have been taxing for some patients dealing with the life disruptions associated with diagnosis and imminent surgical treatment.

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These limitations should be balanced against the study's considerable methodological strengths and clinical importance including the randomized design, relatively high rate of enrollment, inclusion of newly diagnosed patients with non-tobacco-related cancers typically under-represented in cessation trials, relatively large sample size, biochemical verification of smoking abstinence, and the use of best practices well-integrated into the cancer treatment setting as the control condition. To facilitate advances in tobacco cessation treatment for hospitalized cancer patients, it is recommended that future cessation trials benchmark their proposed treatment enhancements with best practices (USDHHS, 2008) rather than no treatment controls. Given the risks of persistent smoking, further research is needed to develop and evaluate cessation intervention components that enhance current best practices for treating tobacco dependent cancer patients.

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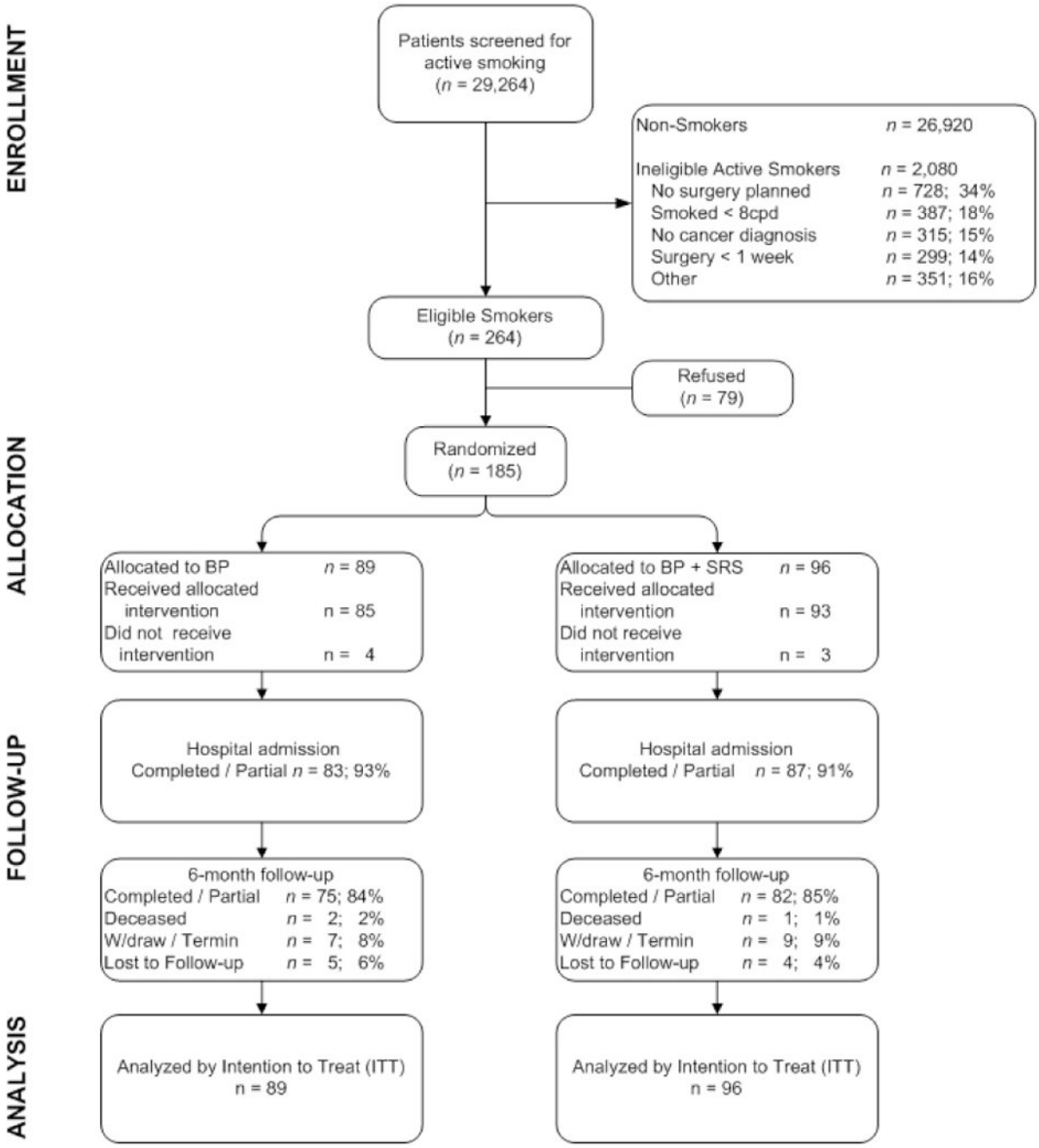

Figure 1. CONSORT flow diagram of the BP vs BP+SRS intervention for cancer patients scheduled for hospitalization for cancer surgery

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Table 1
Patient Demographic, Disease, and Tobacco-Use Characteristics at Study Enrollment

Characteristics		BP N = 89	BP+SRS N = 96	Total N = 185
Gender (Female)		51 (57%)	47 (49%)	98 (53%)
Age (yrs. mean, SD)		55.4 (10.1)	56.4 (10.3)	55.9 (10.2)
Ethnicity (White)		79 (89%)	82 (85%)	161 (87%)
Marital status (Married or living with a partner) [1]		48 (54%)	58 (62%)	106 (58%)
Education (High school graduate or below) [1]		34 (38%)	37 (39%)	71 (39%)
Income (below $50,000/year) [1]		38 (44%)	34 (37%)	72 (40%)
Employment status (Employed) [1]		47 (53%)	52 (54%)	99 (54%)
Cancer site [2]	Thoracic	30 (34%)	25 (26%)	55 (30%)
	Head & Neck	9 (10%)	8 (8%)	17 (9%)
	Breast	8 (9%)	14 (14%)	22 (12%)
	GYN	11 (12%)	11 (12%)	22 (12%)
	Urology	18 (20%)	20 (21%)	38 (20%)
	Other	13 (15%)	18 (19%)	31 (17%)
Time since diagnosis (Months mean, SD) [3]		2.4 (7.9)	2.0 (5.0)	2.2 (6.5)
Treatment	Surgery	79 (89%)	76 (79%)	155 (84%)
	Neoadjuvant Chemotherapy + Surgery	1 (1%)	5 (5%)	6 (3%)
	Unresectable tumor	3 (3%)	4 (4%)	7 (4%)
Smoking-related variables	Cigarettes per day (mean, SD) [1]	20.6 (12.1)	18.5 (8.7)	19.5 (10.5)
	Fagerstrom Test for Nicotine Dependence (mean, SD) [1]	5.2 (2.1)	4.7 (1.7)	4.9 (1.9)
	Smoke first cigarette within 5 minutes after wake up [1]	36 (40%)	34 (34%)	70 (38%)
	Number of years smoking (mean, SD) [1]	35.5 (11.7)	35.3 (12.7)	35.4 (12.2)
	Quitting self-efficacy (mean, SD)	47.6 (20.1)	52.3 (19.9)	50.0 (20.0)
Change in smoking rate since diagnosis [1]				
	About the same	33 (37%)	45 (48%)	78 (43%)
	Reduced	45 (51%)	34 (37%)	79 (43%)
	Increased	11 (12%)	14 (15%)	25 (14%)
Commitment to Quit Smoking [1]		37 (44.0)	41 (44.1)	78 (44.1)

Statistics are N and percentages unless otherwise noted. GYN=gynecological cancers

No statistically significant differences in baseline characteristics were found between the two intervention conditions.

[1]Frequency of missing data on patient characteristics: education (2 patients), marital status (2), income (7), employment (3), cigarettes per day (6), Fagerstrom (8), number of years smoking (9), quitting self-efficacy (8), commitment to smoking abstinence (8), and change in smoking rate since diagnosis (3).

[2]Twenty-eight patients ***(15%)*** were ultimately found to have a nonmalignant mass, but are included in the analyses because inclusion criteria specified eligible pre-surgical patients as having a solid mass deemed by their oncologist as “likely” to be cancer.

[3]If a definitive diagnosis was not possible, we used the date of first consultation with oncologist as the presumptive date of diagnosis.

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Table 2

Comparison of Smoking Cessation Outcomes by Treatment Conditions

	BP		BP+SRS		OR	95% CI
	Sample Size	**Outcome**	**Sample Size**	**Outcome**		
Surgery admission						
Intention-to-treat analysis (N, %)[1]	89	40 (45%)	95[5]	43 (45%)	0.98	0.53 – 1.84
Self-report (N, %)[1,2]	85	49 (58%)	89	47 (53%)	1.21	0.64 – 2.31
Cigarettes per day (mean, SD)[2]	60	6.1 (8.1)	58	4.4 (4.6)	-	-
Self-reported reduction[4] (N, %)	46	18 (39%)	42	26 (62%)	0.40	0.15 – 1.01
3 Month follow-up						
Intention-to-treat analysis[3]	87[5]	30 (34%)	95[5]	34 (36%)	0.94	0.49 – 1.82
Self-report[2,3]	69	30 (43%)	78	37 (47%)	0.85	0.42 – 1.72
Cigarettes per day (mean, SD)[2]	46	8.4 (8.8)	51	6.2 (7.6)	-	-
Self-reported reduction[4] (N, %)	39	26 (67%)	41	31 (76%)	0.65	0.22 – 1.90
6 Month follow-up						
Intention-to-treat analysis[3]	87[5]	28 (32%)	95[5]	30 (32%)	1.03	0.52 – 2.01
Self-report [2,3]	75	28 (37%)	82	34 (41%)	0.84	0.42 – 1.68
Cigarettes per day (mean, SD)[2]	56	11.3 (11.4)	56	9.3 (8.8)	-	-
Self-reported reduction[4] (N, %)	57	27 (47%)	48	29 (60%)	0.59	0.25 – 1.38

[1] 24 hour point prevalence abstinence;

[2] Participants were excluded from the denominator if they provided no usable follow-up data;

[3] 7 day point prevalence abstinence;

[4] Participants self-reported that they were smoking regularly. Abstainers were excluded;

[5] One patient in BP+ SRS arm died prior to data collection at hospital admission, two patients in BP arm died prior to the 3 month follow-up data collection.

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Table 3

Coefficients of the GEE model on the longitudinal Intention-To-Treat abstinence outcomes as a function of treatment assignment and time (maximum of 3 longitudinal observations per each of the n=185 randomized participants)

Parameter	Effects	Coef	SE	Odds Ratio		p-value
				OR	OR 95% CI	
Intercept		-0.20	0.21	-	-	-
Treatment (Tx)						
	BP +SRS vs. BP at hospital admission	0.01	0.30	1.01	0.56, 1.81	0.965
Time						
	3 month effect (vs. hospital admission) [1]	-0.42	0.28	0.65	0.38, 1.13	0.128
	6 month effect (vs. hospital admission) [1]	-0.52	0.28	0.59	0.34, 1.03	0.063
Time * Tx						
	3 month effect for BP+SRS (vs. BP)	0.03	0.38	1.03	0.49, 2.15	0.933
	6 month effect for BP+SRS (vs. BP)	-0.06	0.36	0.94	0.46, 1.92	0.874

Unstructured working correlation		Admission	3 months	6 months
	Admission	1.0		
	3 months	0.24	1	
	6 months	0.31	0.53	1

[1] The GEE coefficients for the discrete time effects can only be evaluated when treatment has a coding of zero. Thus, this 3 months effect represents the drop in abstinence rates in the BP group as compared to hospital admission.