Research Square

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Pilot study testing varenicline for promoting smoking cessation and pain management among patients with cancer

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Abstract

Purpose

Many patients with cancer smoke and also experience pain. Smoking offers short-term pain relief but exacerbates pain long-term. We pilot tested the feasibility, acceptability, and preliminary efficacy of adding varenicline to a combined behavioral treatment that addresses smoking cessation and pain management.

Methods

We conducted a single arm pilot study in which we provided varenicline paired with a 4-session behavioral treatment that uses the same techniques to help people quit smoking and manage their pain. Our primary outcome was 7-day point prevalence abstinence at 6-months post-randomization.

Results

We recruited 19 patients with cancer. 80% of the patients who received the intervention rated it as extremely useful (4 or 5 out of 5) in helping them quit smoking; 60% rated it as helpful in managing their pain. Further, 81% would recommend the program to other patients with cancer. Over one-third (35%) reported biochemically validated abstinence at 6 months post-randomization. We did not see improvements in reported pain but did see improvements in pain self-efficacy.

Conclusions

Our pilot data suggest the feasibility, acceptability, and preliminary efficacy of this approach for promoting cessation. We need to refine aspects to help address pain, yet addressing pain in addition to smoking cessation might motivate more patients with cancer to join the program. The next step is to conduct a large randomized controlled trial to fully test the efficacy of the combined behavioral program with varenicline.

Implications for Cancer Survivors:

A combined smoking cessation and pain program paired with varenicline might help patients with cancer quit smoking.

Introduction

Advances in cancer treatment has helped those diagnosed focus on long-term survivorship, including adopting healthier habits. Quitting smoking prevents death, particularly among those with cancer as smoking contributes to cancer recurrence and cardiovascular disease.[1-4] [5, 6] Although many have attempted to help patients with cancer quit smoking, [7] [8-10] most programs have realized only small effects and short-term benefits. [11, 12] One trial tested varenicline with a relatively intensive 7-sesson behavioral treatment and found strong effects,[13] yet participants struggled with adherence. Further, scaling that intensive intervention proves challenging. We argue that effects could become long term and also be delivered in a less intensive program when including other important barriers to quitting, namely pain and its relationship with smoking. Many patients with cancer experience pain. [9-12] Those who have pain report that smoking relieves their pain in the short-term, [14, 15] yet worsens pain in the long-term.[16, 17] Also, including behavioral treatment for pain might help patients' motivation to enroll in a study that promotes smoking cessation.

To promote permanent smoking cessation among those with cancer, combined behavioral programs that include ways to quit smoking and manage pain might have a lasting impact than programs that just address smoking. Indeed, in our pilot work, we found this approach to be feasible and acceptable with a small signal for efficacy at three months post-randomization. However, we did not assess cessation beyond three months and also found only small effects.

To increase the efficacy of our behavioral intervention, we added a 12-week course of varenicline that both can help with smoking abstinence and pain using a non-opioid pathway. Meta-analyses show that varenicline leads to a high rate of smoking cessation.[18] Additionally varenicline has been found to have analgesic properties in animals[19] and to reduce chronic pain in human trials.[20] Varenicline acts a strong antagonist and weak agonist at the α4β2nicotinic-acetylcholine receptor, modulating withdrawal-mediated pain response, and is a full agonists at α7 nicotinic receptor, which down-regulates the liposaccharide-induced inflammatory response, a key component of pain.[21] As such, varenicline appears to be an ideal medication to use for smoking cessation in patients with cancer who have pain.

In the current study, we conducted a proof-of-concept single arm pilot study to test the effect of adding varenicline to a behavioral program that addresses both smoking cessation and pain management (Project HOPES). Our outcomes were feasibility, acceptability, and preliminary efficacy, with smoking cessation, pain management, and quality of life.

Methods

Design

Project HOPES was a single-arm pilot trial to build on our prior pilot trial data in which we compared a 4-session smoking cessation and pain management intervention plus nicotine replacement therapy (NRT) to a waitlist control.[22] In the current study, we used varenicline instead of NRT. We collected data from

participants at the end of treatment and 6-months post-randomization. This study was approved by the IRB at Duke University School of Medicine.

Setting

We recruited patients with cancer from the Duke Cancer Institute (DCI), including the Duke Cancer Network (DCN) and the Duke Smoking Cessation Program. Eligible participants were diagnosed with cancer and were receiving follow-up care at DCI or DCN, reported daily smoking in the past three weeks, were not participating in another smoking cessation trial, reported pain within the last three weeks of 3 or higher on a 10-point pain scale, were age 18 or older, spoke English, and were willing to use varenicline. We excluded individuals who were hearing impaired, deemed too sick to participate, or had evidence of unstable cognitive or mental health problems.

Recruitment

With a Waiver of Consent and HIPAA Authorization, study or clinic staff reviewed patient charts and identified potentially eligible patients. Study staff then screened patients for eligibility. If patients were eligible and interested, staff sent them links with consent forms and the baseline survey. Staff sent participants a follow-up survey approximately two months post- randomization and again 6 months post-randomization. We paid participants a maximum of $100; $30 for the baseline survey, $30 for the post-treatment survey, and $40 for the 6-month post-treatment survey.

Measures

At baseline, we assessed demographics, health history, smoking history, nicotine dependence[23], withdrawal symptoms, pain severity[24] and interference[25], pain medications, self-efficacy for quitting and for pain management[26], outcome expectations (quitting smoking to improve health and to decrease pain level), worry (e.g., smoking affects health, affects pain), perceived stress and coping (subscale of the Rhode Island Stress and Coping Inventory)[27], depression/mood/negative affect (HADS)[28], and physical well-being (Functional Assessment of Cancer Therapy- General: FACT-G)[29].

In the follow-up surveys, we included all the same questions as the baseline except demographics and added questions assessing acceptability of the intervention (e.g., “How helpful was the intervention” and “How likely would you recommend the program to a friend?”) For participants who reported not smoking at the follow-up survey, we mailed them a carbon monoxide monitor and asked them to download an app that will allow us to see their reading.

Study Intervention

A PhD interventionist delivered four weekly 60-minute intervention sessions via telephone. Staff mailed participants a workbook and self-help quitting materials (NCI *Clearing the Air*). The manual served as a

guide during behavioral intervention sessions and included the agenda for each session, guidelines for the intervention activities, and sections for participants to write down “homework” to complete prior to the next session. The first session occurred within 10 days of mailing the manual and self-help materials.

The counseling protocol integrated standardized and overlapping cognitive behavioral strategies for smoking cessation and those for pain management. In addition, counselors incorporated principles of motivational interviewing throughout the sessions [30, 31]. The protocol emphasized psycho-educational and skills-based approaches, including progressive muscle relaxation and guided imagery. The interventionist asked participants to set a quit date during the first or second session.

We provided a 12-week prescription for varenicline to participants using an electronic prescription to the participant’s preferred pharmacy and reimbursed co-pays. We followed a standard dosing regimen (1 mg twice daily) unless patients required a lower dosing to manage side effects. The counselor assessed varenicline side effects with targeted and open-ended questions. If participants reported side effects potentially related to varenicline, the counselor messaged the study physician who stopped or reduced the varenicline dose. The physician entered progress notes into electronic health records describing the participant’s history of varenicline use and prescribed varenicline regimen.

Analysis

This was an exploratory single arm pilot study designed to assess preliminary feasibility, acceptability, and a signal for efficacy. We considered the trial feasible if 50% of eligible patients enrolled in the trial and if 75% of the patients completed the intervention sessions. For the intervention to be deemed acceptable, 75% of participants had to rate the intervention as helpful (“4” or “5” on 5-point scale) and that they would recommend it to a friend (“4” or “5” on 5-point scale). We defined preliminary efficacy of the intervention based on carbon monoxide-confirmed 7-day point prevalence abstinence at the 6-month follow-up survey. We counted participants lost-to-follow-up as smoking unless they were deceased.

Results

Sample characteristics

We recruited 19 patients into the trial (See Table 1). Mean age of the participants was 58, most were female (74%), some were African American (38%), some had more than a high school education (50%), some were lower income (26% with a family income of <$30k), and most were not currently employed (73%). 100% of participants picked up their varenicline.

Table 1
Demographics for HOPES Participants

Patient Characteristics*		**Overall** **N = 19 (%)**
Age, mean (SD)		57 (11)
Race	Black	8 (38)
	White	10 (48)
	Asian	1 (5)
	American Indian/Alaskan Native	2 (10)
Ethnicity	Not Hispanic	19 (100)
Sex	Male	4 (22)
	Female	14 (78)
Education	Less than High School	3 (16)
	Completed high school/GED	7 (37)
	Some college	4 (21)
	College Graduate	3 (16)
	Post-Graduate (e.g., Masters, Doctorate)	2 (11)
Sexual Orientation	Straight, not lesbian or gay	9 (69)
Marital Status	Married	5 (26)
	Living with partner	2 (11)
	Widowed	2 (11)
	Divorced	6 (32)
	Separated	3 (16)
	Never married	1 (5)
Employment	Employed full-time	3 (17)
	Employed Part-time	4 (22)
	Retired	4 (22)
	Unemployed/disabled	6 (33)

*Number of participants with missing data, n = 1 age; n = 1 sex; n = 1 employment; n = 2 income; n = 1 healthcare coverage

Patient Characteristics*		Overall N = 19 (%)
	Homemaker	1 (6)
Income	Less than $30,000	5 (28)
	$30,000 - $59,999	8 (44)
	$60,000- $89,999	2 (11)
	$90,000 or over	2 (11)
Financial Situation	After paying the bills, enough money	5 (26)
	Enough money to pay the bills, but little spare	7 (37)
	Pay the bills, but only because you have cut back	2 (11)
	You are having difficulty paying the bills	5 (26)
Healthcare Coverage	Medicare	6 (33)
	Medicaid	4 (22)
	Private insurance (e.g., HMO, Blue Cross, supplemental)	8 (44)
Not able to see doctor in the past 12 months due to cost (Y/N)	Yes	1 (5)
	No	18 (95)
*Number of participants with missing data, n = 1 age; n = 1 sex; n = 1 employment; n = 2 income; n = 1 healthcare coverage		

Feasibility

Of the 229 patients approached, 10% refused (n = 27), 14% (n = 46) approached were ineligible, and 59% (n = 137) were unable to contact or we stopped trying to recruit as we reached our targeted sample. Of the 27 eligible patients, 21 (78%) consented. One withdrew after consent. Of the 19 participants, 84% completed at least three of the four sessions, while 74% completed all 4.

Acceptability

Most participants (73%) felt the number of sessions was “just right.” Participants found the program to be helpful for quitting smoking (80% rated it a 4 or 5 out of 5) and managing their pain (60% rated it a 4 or 5). Most would recommend the program to a friend, with 94% reporting a 4 or 5 out of 5.

Signal for Efficacy Outcome

Unfortunately, two participants died before the 6-month survey. At six-months post-treatment, using a conservative intent-to-treat analytic approach, 6/17 (35%) participants demonstrated biochemically validated cessation. One more reported being quit but could not provide us with their carbon monoxide reading. Thus, with intent-to-treat analyses, the remaining 11 were counted as smoking.

We found no differences in any of the relevant pain or coping measures from baseline to 6 months post-randomization except that pain self-efficacy improved from baseline to six months (Table 2).

Table 2
Self-reported pain and psychosocial measures.

	Baseline			Post-treatment			6m follow-up		
	N	M	SD	N	M	SD	N	M	SD
Pain Severity	19	4.8	2.2	14	4.8	2.0	10	5.8	2.7
Pain Interference	18	4.9	2.5	14	4.8	2.1	11	6.3	2.7
Pain Medication	18	4.8	2.5	15	5.3	2.7	11	5.1	2.7
Smoking Self-Efficacy	18	5.1	1.6	4	4.3	2.4	4	4.0	2.2
Pain Self-Efficacy	18	54.7	25.4	14	55.1	12.3	11	62.9	22.7
Pain Catastrophizing	18	2.1	1.5	14	1.2	1.1	11	2.4	2.1
HADs Anxiety	14	9.4	4.0	4	8.8	3.1	3	12.0	4.3
HADs Depression	18	7.7	4.6	4	9.0	4.3	3	6.7	1.2
Coping	18	2.4	1.0	15	3.0	0.7	11	3.0	0.9
Physical Well-Being	17	1.7	0.8	13	1.7	0.6	11	1.7	1.0

Adverse Events:

We provided all participants with varenicline. We found moderate to severe emergent adverse events associated with varenicline in 2/19 (11%) participants that included nausea and insomnia. These participants discontinued varenicline due to side effects.

Discussion

This combined smoking cessation and pain intervention with varenicline for patients with cancer resulted in signals that indicate feasibility, acceptability, and preliminary efficacy. Although this is a pilot study, it is worth noting that this is the highest smoking abstinence rate seen thus far among patients with cancer.[7–12] We also provided a 4-session behavioral intervention, which is more scalable that prior work that included 7 sessions that had a comparable cessation rate with varenicline.[13] And we

assessed cessation at 6-months post-randomization, the gold standard in smoking cessation trials. Participants reported being receptive to attempting behavior changes: smoking and pain management, simultaneously. Although the addition of a prescription drug complicates the intervention, participants benefitted from using a high-efficacy medication.

Recruitment went well, in part, perhaps to offering varenicline and by addressing not just smoking but also pain management. Offering varenicline might be preferable to patients with cancer who might be reluctant to use opioids to treat pain. Adding varenicline clearly represented an improvement to our prior work where we offered nicotine replacement therapy.

Participants tolerated varenicline generally well with only 2 participants stopping varenicline due to side effects. The study design did not allow us to experimentally isolate the therapeutic effects of varenicline from behavioral treatment. That said, it is reasonable to conjecture that some component of smoking cessation and reduction may have been due to the use varenicline because smoking abstinence rates were quite high in this study and varenicline is highly efficacious.

Participants rated the intervention more helpful for quitting smoking than managing pain. While significant decreases in pain were not found, self-efficacy for pain management was improved, which represents a strong predictor for participants ability to successfully manage pain that may arise. Enhancing attention to coping skills can lead to elimination of tobacco use as means to manage pain[32]. Increased emphasis on pain coping skills engagement and adherence to practice in future interventions should be considered.

Study limitations

This was a small pilot and needs to be tested in a larger trial. Lessons learned from this pilot include needing to be flexible about when and how to deliver the intervention as patients with cancer juggle many competing demands. We had trouble with one participant with biochemical validation as they could not download an app on their phone. We need to plan for this in future trials. Further, the sample was mostly female. Future studies should devise methods for encouraging males to enroll in the study.

Clinical and research implications

Our findings are in line with current recommendations to provide evidence-based tobacco treatment including pharmacotherapy and behavioral counseling[33]. We had a high biochemically validated cessation rate at 6 months. The effects on pain were less pronounced, but still addressing the pain might have helped facilitate cessation and recruitment and building self-efficacy for pain management is meaningful. In future trials, we should disentangle the effects of the varenicline and the behavioral treatment given the importance of quitting[7]. Overall, this novel intervention was feasible, acceptable and shows promise for efficacy.

Declarations

Clinical Trials Record

NCT06029907

Competing Interests:

The authors have no relevant financial or non-financial interests to disclose.

Ethics Approval:

This study was approved by the IRB at Duke University School of Medicine.

Consent to Participate:

Informed consent was obtained from all individual participants included in the study.

Consent to Publish:

N/A

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Author Contribution

All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by all the authors. The first draft of the manuscript was written by KP and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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None.

Data Availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy restrictions.

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