

# Change in Health-Related Quality of Life Among Individuals With Cancer Undergoing Smoking Cessation Treatment Involving Varenicline

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**OBJECTIVES:** To determine whether health-related quality of life (HRQOL) among individuals with cancer is undermined by smoking cessation treatment involving varenicline.

**SAMPLE & SETTING:** Participants (N = 103) were daily smokers with cancer (up to five years postdiagnosis) who completed a placebo-controlled trial of standard versus extended duration varenicline.

**METHODS & VARIABLES:** For this secondary study, participants were selected based on having completed the SF-12® at weeks 0, 1, 12, and 24. Using separate repeated measures multivariate analysis of variance, change in SF-12 scores was evaluated by time and by cancer treatment, varenicline duration, and quit status at week 24.

**RESULTS:** There was no change in any of the three HRQOL scores by time or by cancer treatment status, varenicline duration, or quit status. Average emotional HRQOL score across time was significantly higher for quitters versus smokers.

**IMPLICATIONS FOR NURSING:** Varenicline, including long-term treatment, does not appear to adversely affect HRQOL, which is highly relevant to oncology nurses who are well positioned to assist with the pharmacologic treatment of tobacco dependence.

**KEYWORDS** cancer; oncology; nursing; varenicline; quality of life; smoking cessation

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Continued smoking following a cancer diagnosis is associated with adverse cancer treatment outcomes, such as increased risk of second primary cancers and increased all-cause mortality (Jassem, 2019; U.S. Department of Health and Human Services, 2014). Continued smoking after a cancer diagnosis is also associated with reduced health-related quality of life (HRQOL) (Cataldo et al., 2010; Chen et al., 2012; Duffy et al., 2012; Garces et al., 2004). As many as 50% of individuals who smoked prior to their cancer diagnosis continue to smoke after diagnosis (Jassem, 2019).

Oncology nurses have a valuable role in promoting smoking cessation with their patients because of the many intervention opportunities in the oncology care model (Cooley et al., 2008, 2009; Sarna & Bialous, 2016). Smoking cessation interventions initiated by nurses are effective (Rice et al., 2017). The National Comprehensive Cancer Network (NCCN) Guidelines® for Smoking Cessation recommend that providers on the oncology care team refer patients to behavioral counseling and assist with medication, of which varenicline is a first-line option (NCCN, 2020; Shields, 2015). The current authors and others have shown that varenicline is safe and effective for individuals with cancer (Schnoll et al., 2019). Despite the safety and efficacy of guideline-based treatment and the strong recommendation that treatment be offered as a core component of cancer care (Croyle et al., 2019), fewer than 40% of oncology providers assist their patients in quitting, either by prescribing a medication or referring to treatment (Price et al., 2019; Warren et al., 2015). In addition to concern about the psychological and physical symptoms of

tobacco withdrawal and associated distress, providers report concerns that smoking cessation treatment may eliminate a primary coping strategy in the midst of a stressful major life event, further diminishing HRQOL (Trout et al., 2018).

HRQOL encompasses the impact of an individual's health status on their physical and emotional/mental well-being. It is assessed by gathering self-reported indicators of perceived health from patients and provides a measure of the burden of disease and associated treatment (Yin et al., 2016). This value is increasingly seen as a fundamental component of cancer care and a critical treatment outcome by oncologists, arguably as important as disease control and survival (Thomas, 2016). Individuals with cancer often experience reduced HRQOL because of lifestyle changes resulting from a cancer diagnosis and the effects of treatment (Chambers et al., 2017; Liao et al., 2019; Nayak et al., 2017).

Despite the critical importance of smoking cessation and maximizing HRQOL among individuals with cancer, little is known about the impact of smoking cessation on HRQOL in this population. Few recent studies have examined the impact of smoking cessation on HRQOL among individuals with cancer, and the available studies have focused on lung cancer (Balduyck et al., 2011; Chen et al., 2012; Garces et al., 2004). No study has examined the effect of smoking cessation treatment involving varenicline on HRQOL among individuals with cancer or examined the extent to which smoking cessation, treatment duration, or concurrent cancer treatment modifies any effect of varenicline on HRQOL. With the goal of addressing these knowledge gaps, the authors analyzed data collected as part of a completed clinical trial to determine the extent to which HRQOL among individuals with cancer was adversely affected by smoking cessation treatment involving varenicline.

## Methods

### Sample and Setting

The current study was conducted among a subset of participants from a clinical trial conducted by Schnoll et al. (2019). The parent trial assessed the safety and efficacy of standard duration (12 weeks) versus extended duration (24 weeks) treatment with varenicline among individuals with cancer (ClinicalTrials.gov: NCT01756885). Candidates for the parent trial were identified through provider referrals and the electronic health record system of two National Cancer Institute–designated comprehensive cancer centers, the Robert H. Lurie Comprehensive

Cancer Center of Northwestern University in Chicago, Illinois, and the University of Pennsylvania Abramson Cancer Center in Philadelphia. Participants eligible for the parent trial had to be aged 18 years or older, smoke five or more cigarettes per week for the past six months, and have a diagnosis of cancer within the past five years. An additional inclusion criterion for the current study was that participants had to have HRQOL data at weeks 0, 1, 12, and 24. One hundred and three participants were eligible, which represented 50% of 207 participants in the parent trial. Exclusion criteria included daily use of a nicotine product other than cigarettes and having a contraindication to varenicline.

After completing the informed consent process and baseline assessments, participants were randomized to either 12 weeks of varenicline plus 12 weeks of placebo (standard treatment) or 24 weeks of varenicline (extended treatment). Both arms included seven 20- to 30-minute behavioral counseling sessions delivered over 18 weeks. Varenicline was started at week 0 (pre-quit session) using the standard dosing schedule for varenicline (Shields, 2015). At week 12, standard treatment participants received 12 weeks of placebo pills, and extended treatment participants received another 12 weeks of varenicline. The institutional review boards of the University of Pennsylvania and Northwestern University approved all procedures. See Schnoll et al. (2019) for full details regarding the parent trial.

### Measures and Variables

Participant demographics, cancer history and treatment, and smoking history were obtained through participant self-report at the first intake session and through the electronic health record. A carbon monoxide (CO) breath sample was obtained to measure smoking exposure, and the Fagerström Test for Cigarette Dependence (FTCD) was administered to assess degree of tobacco dependence (Fagerström, 2012; Heatherton et al., 1991). HRQOL was assessed using the paper-and-pencil version of the SF-12<sup>®</sup> (Jenkinson et al., 1997) at weeks 0 (pre-quit), 1 (target quit date), 12 (end of open-label phase), and 24 (end of randomized double-blind treatment phase). The SF-12 contains 12 questions, each rated from 1 (poor) to 5 (excellent), that assess health and its impact on daily activities and functioning (e.g., moving a table, pushing a vacuum cleaner, climbing a flight of stairs). The SF-12 assesses overall HRQOL and two independent dimensions: physical (physical functioning, role functioning, bodily pain, and general health) and emotional (vitality, social functioning, role functioning,

**TABLE 1. Baseline Characteristics for the Full Sample and by Quit Status at 24 Weeks**

Characteristic	Smoking (N = 44)		Quit (N = 59)		Full Sample (N = 103)		Stat	p
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD		
Age (years)	59.1	8.1	61.5	8.9	60.5	8.6	2.07	0.15
Time between cancer diagnosis and intake (days)	20.7	17.3	18.8	18.7	19.6	18.1	0.27	0.61
Number of cigarettes smoked per day at baseline	14.7	8.7	13.4	7.3	13.9	7.9	0.71	0.4
FTCD score	5	1.7	4.2	2.3	4.5	2.1	3.7	0.06
Characteristic	n	%	n	%	n	%	Stat	p
<b>Sex</b>							0.07	0.8
Female	22	50	28	48	50	49		
Male	22	50	31	53	53	51		
<b>Race</b>							0.02	0.89
White	30	68	41	70	71	69		
Minority group	14	32	18	31	32	31		
<b>Education</b>							0.3	0.58
Below college	26	59	38	64	64	62		
College or beyond	18	41	21	36	39	38		
<b>Marital status</b>							0.01	0.93
Unmarried	22	50	30	51	52	51		
Married	22	50	29	49	51	50		
<b>Employment</b>							11.19	0.001
Employed	28	64	18	31	46	45		
Unemployed	16	36	41	70	57	55		
<b>Income (\$)</b>							0.11	0.74
Less than 75,000	29	66	37	63	66	64		
75,000 or greater	15	34	22	37	37	36		
<b>Tumor site</b>							0.01	0.93
Other	34	77	46	78	80	78		
Head and neck, or lung	10	23	13	22	23	22		
<b>Cancer treatment status</b>							3.5	0.06
Receiving treatment	23	52	20	34	43	42		
Not receiving treatment	21	48	39	66	60	58		
<b>Level of functioning</b>							1.55	0.21
Normal activity	36	82	42	71	78	76		
Requires effort or assistance	8	18	17	29	25	24		

FTCD—Fagerström Test for Cigarette Dependence; stat—statistic (F or  $\chi^2$ )

**Note.** Statistical tests compared participants classified as quit (n = 59) versus those who were smoking (n = 44) at week 24. F symbolizes the statistical value for the analysis of variance tests for continuous variables, and  $\chi^2$  symbolizes the statistical value for the chi-square tests for categorical variables. Possible FTCD scores range from 0 to 10, with higher scores reflecting greater tobacco dependence.

**Note.** Range is 35–79 for age, 1–73 for time between cancer diagnosis and intake, 1–40 for number of cigarettes smoked per day at baseline, and 0–10 for FTCD score.

**Note.** Because of rounding, percentages may not total 100.

and mental health). HRQOL scores were generated separately for the physical and emotional subscales, and a total score was computed. The SF-12 has been widely used to evaluate HRQOL among medical populations, including individuals with cancer (McCorkle et al., 2009), and has established reliability and validity (Bhandari et al., 2018; Gandek et al., 1998). As done in the parent trial, smoking abstinence at 24 weeks was defined as a self-report of no smoking (even a puff) within the 7 days prior to the week 24 visit and a breath CO level less than 10 parts per million.

### Statistical Analyses

The authors used chi-square tests for categorical variables and independent sample *t* tests for continuous variables to characterize the sample and to test for differences in demographic, cancer, and smoking characteristics by quit status at week 24. Repeated measures multivariate analyses of variance (MANOVAs) were used to evaluate change in SF-12 subscale scores (total, physical, and emotional) by time (weeks 0, 1, 12, and 24). The total SF-12 score and the physical and emotional subscale scores were examined separately. Separate MANOVAs were conducted for the three between-group variables of interest: quit status at 24 weeks (quit versus smoking), varenicline duration (12 weeks versus 24 weeks), and cancer treatment status at baseline (active treatment versus beyond active treatment). Degrees of freedom were corrected using Greenhouse–Geisser estimates of sphericity. For analyses involving quit status at 24 weeks, any baseline differences between quit status groups were included as covariates using repeated measures multivariate analysis of covariance.

### Results

Table 1 presents demographic characteristics, cancer disease and treatment, and smoking variables for the overall sample ( $N = 103$ ) and by quit status at 24 weeks. Participants reported smoking an average of 13.9 cigarettes per day ( $SD = 7.9$ ). Twenty-three percent of participants ( $n = 24$ ) were diagnosed with cancer stages 0–II and 18% with stages III–IV ( $n = 18$ ); 23% were in remission ( $n = 24$ ), and stage was unknown for 36% of participants ( $n = 37$ ). Forty-two percent of participants ( $n = 43$ ) were receiving cancer treatment (radiation therapy, chemotherapy, surgery, or hormonal therapy). Seventy-five percent of participants ( $n = 77$ ) were considered adherent to study medication (i.e., taken 80% or greater of the 333 varenicline pills prescribed), and 91% of participants ( $n = 94$ ) completed all seven behavioral counseling

sessions. Quit status at 24 weeks groups differed significantly on baseline employment status. A greater proportion of participants who were quit at week 24 had been unemployed prior to starting varenicline treatment (70% versus 36% for participants who were smoking at week 24).

Tables 2 and 3 present mean and standard deviation values for the SF-12 total score and the physical and emotional subscale scores by time (weeks 0, 1, 12, and 24) and by cancer treatment status, varenicline treatment duration, and quit status at 24 weeks. SF-12 total score and physical and emotional subscale scores at baseline did not differ between participants with ( $n = 103$ ) and without ( $n = 104$ ) complete SF-12 data.

For physical HRQOL, there were no differences in scores by time ( $F[2.6, 265.7] = 1.98, p = 0.13$ ) or time  $\times$  cancer treatment status ( $F[2.6, 265.7] = 0.59, p = 0.6$ ). Results were similar for the separate analyses involving varenicline treatment duration (time:  $F[2.6, 265.7] = 2.13, p = 0.11$ ; time  $\times$  treatment duration:  $F[2.6, 265.7] = 0.68, p = 0.55$ ) and quit status (time:  $F[2.6, 265.7] = 2.05, p = 0.12$ ; time  $\times$  quit status:  $F[2.6, 265.7] = 0.17, p = 0.89$ ). For the analysis involving quit status adjusted for employment status, time and time  $\times$  quit status remained nonsignificant (both  $p > 0.05$ ). There was, however, a statistically significant effect of employment status ( $F[1, 99] = 4.77, p = 0.03$ ) on physical HRQOL. Participants who were unemployed prior to treatment had lower physical scores on average across time as compared with those who were employed ( $\bar{X} = 19.4$  [standard error = 0.44] versus  $\bar{X} = 20.8$  [standard error = 0.45], respectively).

The overall pattern of results was similar for emotional HRQOL. For the analysis involving cancer treatment status, there was no difference in scores by time ( $F[2.5, 256.7] = 0.84, p = 0.46$ ) or time  $\times$  cancer treatment status ( $F[2.5, 256.7] = 0.66, p = 0.56$ ). Similarly, for the analysis involving varenicline treatment duration, the effects of time ( $F[2.5, 257.4] = 0.75, p = 0.5$ ) and time  $\times$  treatment duration ( $F[2.5, 257.4] = 0.64, p = 0.56$ ) were statistically nonsignificant. Regarding the analysis involving quit status at 24 weeks, there were no significant effects of time ( $F[2.5, 255] = 0.92, p = 0.42$ ) or time  $\times$  quit status ( $F[2.5, 255] = 0.39, p = 0.73$ ). There was a significant effect of quit status ( $F[1, 101] = 6.03, p = 0.02$ ), such that participants who were quit at week 24 had a higher average emotional HRQOL score across treatment as compared with those who were smoking. Results were unchanged after adjusting for employment status, which was statistically nonsignificant ( $F[1, 99] = 0.42, p = 0.52$ ).

For overall HRQOL, as assessed by the SF-12 total score, none of the three analyses resulted in statistically significant effects of time, time × cancer treatment status, time × varenicline treatment duration, or time × quit status at 24 weeks (all  $p > 0.05$ ), indicating that overall HRQOL did not change across treatment and was not affected by these cancer- or smoking-related treatment factors.

## Discussion

The authors found that HRQOL overall, as well as the physical and emotional dimensions, remained stable across treatment, regardless of whether participants were being treated for their cancer at baseline, whether participants received 24 weeks of varenicline treatment, or whether participants had quit smoking at 24 weeks. The stability of HRQOL during intensive treatment involving varenicline, the most effective single agent for smoking cessation and first-line recommendation for individuals with cancer (NCCN, 2020), is promising and should ease concerns among nurses that smoking cessation treatment may further diminish HRQOL among individuals undergoing cancer treatment or in remission (Chambers et al., 2017; Liao et al., 2019; Nayak et al., 2017). The authors also observed that individuals who were quit at week

24 had a higher average emotional HRQOL during treatment as compared with those who were smoking at week 24, consistent with prior studies (Martínez et al., 2019). Although preliminary, this observation could indicate that individuals with higher emotional HRQOL may be more likely to achieve successful smoking cessation. Emotional HRQOL contributors, such as mental health and social functioning, may contribute more to quitting smoking than higher physical HRQOL measures, and further investigation on this topic is needed (Yang et al., 2013).

The high-risk period for smoking relapse among individuals with cancer may extend up to four months after quitting (Walker et al., 2004), making an extended course of varenicline an important consideration. The primary outcome of the parent trial was that extended duration varenicline (24 weeks), as compared with standard duration (12 weeks), did not increase risk of medication side effects and increased long-term smoking cessation among individuals who were treatment adherent (Schnoll et al., 2019). The current study extends what is known about the effects of intensive smoking cessation treatment involving varenicline among individuals with cancer by showing that HRQOL was not adversely affected, even among individuals undergoing cancer treatment.

**TABLE 2. SF-12® Total and Subscale Scores by Time and by Cancer Treatment Status, Varenicline Duration, and Quit Status at 24 Weeks for Weeks 0 and 1**

Variable	Week 0						Week 1					
	Total		Physical		Emotional		Total		Physical		Emotional	
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
<b>Cancer treatment status</b>												
Active (n = 43)	37	5.7	19.3	3.8	22	3.3	37.4	5.8	19.8	3.6	21.9	3.4
Beyond treatment (n = 60)	38.2	5.2	20.3	3.4	22.5	3.1	38.9	4.9	20.6	3.1	22.9	2.9
<b>Varenicline duration</b>												
Standard (n = 49)	38.5	5.9	20.4	3.8	22.7	3.2	38.9	5	20.4	3.3	22.9	2.8
Extended (n = 54)	36.9	4.9	19.4	3.3	21.9	3	37.7	5.5	20.1	3.4	22	3.4
<b>Quit status at 24 weeks</b>												
Smoking (n = 44)	36.9	5.4	19.8	3.4	21.5	3.4	37.5	5.4	20.1	3.4	21.8	3.4
Quit (n = 59)	38.3	5.4	19.9	3.7	22.8	2.8	38.8	5.2	20.4	3.3	23	2.9

**Note.** Active cancer treatment was defined as receiving cancer treatment at baseline, and beyond treatment was defined as no active treatment/in remission. Varenicline duration was 12 weeks for standard and 24 weeks for extended. Quit status at 24 weeks was self-reported as no smoking in the past 7 days and a breath carbon monoxide reading of 10 parts per million or less.

The authors also observed that individuals who were unemployed at the start of treatment experienced a lower level of physical HRQOL (physical functioning, role functioning, bodily pain, and general health) across treatment. There is limited research on the influence of employment status on cancer treatment outcomes, and this finding suggests that smokers with cancer who are unemployed or underemployed may require more support as part of their cancer care, including tobacco cessation treatment (Parkinson & Maheu, 2019). Further research is needed to identify nurse-delivered interventions to assist patients in navigating changes to employment status following a cancer diagnosis (Frazier et al., 2009).

### Limitations

An important limitation should be noted. The study sample represented only about 50% of participants involved in the parent trial. Participants with complete HRQOL data were comparable to those without complete data on baseline HRQOL overall, as well as on the physical and emotional dimensions, but the authors are unable to rule out the possibility that assessment noncompletion or treatment dropout was associated with a decrease in HRQOL during treatment. Despite this limitation, this study represents

### KNOWLEDGE TRANSLATION

- Combined with behavioral counseling delivered over 18 weeks, varenicline did not undermine health-related quality of life among individuals with cancer.
- Health-related quality of life was unaffected by extending the duration of varenicline from 12 weeks (standard duration) to 24 weeks.
- Individuals who were quit at week 24 had a higher average emotional health-related quality of life (e.g., role functioning, mental health) score across treatment as compared with those who were smoking, suggesting that interventions that promote emotional health-related quality of life may also improve smoking cessation treatment outcomes.

the first evaluation of the effects of smoking cessation treatment involving varenicline on HRQOL, and these findings should be reassuring to oncology providers who care for individuals who smoke.

### Implications for Nursing

Nurses have a critical role to serve in promoting smoking cessation among cancer survivors (Rice et al., 2017), with many intervention opportunities within the oncology care model (Cooley et al., 2009; Sarna & Bialous, 2016). Best practice for promoting

**TABLE 3. SF-12® Total and Subscale Scores by Time and by Cancer Treatment Status, Varenicline Duration, and Quit Status at 24 Weeks for Weeks 12 and 24**

Variable	Week 12						Week 24					
	Total		Physical		Emotional		Total		Physical		Emotional	
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
<b>Cancer treatment status</b>												
Active (n = 43)	36.5	6.7	19.5	3.7	21.3	4.3	37.5	7.1	19.7	4.1	22	4.3
Beyond treatment (n = 60)	38.9	4.5	20.7	3.1	22.7	2.8	39.5	5.1	21.2	3.1	22.9	3.1
<b>Varenicline duration</b>												
Standard (n = 49)	38.4	5.5	20.4	3.4	22.5	3.4	38.9	6.2	20.7	3.7	22.6	3.7
Extended (n = 54)	37.4	5.8	20.1	3.4	21.8	3.7	38.5	6	20.5	3.6	22.5	3.7
<b>Quit status at 24 weeks</b>												
Smoking (n = 44)	36.7	5.7	19.9	3	21.1	4.1	37.8	5.5	20.3	3.1	21.9	3.5
Quit (n = 59)	38.8	5.5	20.4	3.7	22.9	3	29.3	6.4	20.8	4	23	3.7

**Note.** Active cancer treatment was defined as receiving cancer treatment at baseline, and beyond treatment was defined as no active treatment/in remission. Varenicline duration was 12 weeks for standard and 24 weeks for extended. Quit status at 24 weeks was self-reported as no smoking in the past 7 days and a breath carbon monoxide reading of 10 parts per million or less.

smoking cessation in the oncology setting is to assess smoking status in every individual at every visit and then refer individuals who smoke to evidence-based treatment consisting of pharmacologic therapy and behavioral counseling (Shields, 2015). Although most nurses (73%) ask about smoking and assist their patients to quit, only 24% recommend pharmacologic therapy (Sarna et al., 2009). The current findings help to address an important gap in the literature and a known barrier to care—uncertainty about the effect of smoking cessation treatment, specifically varenicline and behavioral counseling, on HRQOL in a population at risk for diminished HRQOL. This is particularly relevant given the growing attention to HRQOL as a key patient-reported outcome measure (Thomas, 2016) and the major individual- and treatment-related benefits to be gained from quitting smoking (Croyle et al., 2019; U.S. Department of Health and Human Services, 2014; Warren et al., 2014). Intensive treatment involving varenicline does not appear to undermine HRQOL and should encourage nurses to recommend varenicline for their patients who smoke.

## Conclusion

Oncology nurses should use their frequent interactions with patients and ask about smoking and either provide treatment or facilitate the connection to treatment. The current study provides a novel and preliminary evaluation of the impact of smoking cessation treatment with varenicline on HRQOL and suggests that HRQOL remains stable regardless of cancer treatment status at the start of treatment, duration of varenicline treatment, or success in achieving or maintaining abstinence. This is particularly relevant given the adverse effects of continued smoking and cancer treatment on HRQOL among individuals with cancer (Cataldo et al., 2010; Chen et al., 2012; Duffy et al., 2012; Garcés et al., 2004; Warren et al., 2014). Oncology nurses who assist with smoking cessation should consider recommending varenicline and an extended course of treatment for individuals with a high degree of tobacco dependence.

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May, McCarter, Klass, Pearman, Leone, Schnoll, and Hitsman contributed to the conceptualization and design. Jao and Hitsman completed the data collection and provided statistical support. May, Jao, McCarter, Pearman, Schnoll, and Hitsman provided the analysis. All authors contributed to the manuscript preparation.

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