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Accuracy of Self-Reported Tobacco Use Status among Hematopoietic Stem Cell Transplant (HSCT) Patients

Shawna L. Ehlers, Ph.D[1,2], **Carrie A. Bronars, Ph.D.**[1,2], **Christi A. Patten, Ph.D.**[1,2], **Tabetha Brockman, M.A.**[2], **Christine Hughes, B.S.**[2], **Paul A. Decker, M.S.**[3], **James R. Cerhan, M.D., Ph.D.**[4], **William Hogan, M.D.**[5], **Angela Dispenzieri, M.D.**[5], **Stephen Ansell, M.D.**[5], **Jon Ebbert, M.D.**[6,7], and **Dennis Gastineau, M.D.**[5,8]

[1]Department of Psychiatry and Psychology, Mayo Clinic College of Medicine, Rochester, MN

[2]Behavioral Health Research Program, Mayo Clinic College of Medicine, Rochester, MN

[3]Division of Biomedical Statistics and Informatics, Mayo Clinic College of Medicine, Rochester, MN

[4]Division of Epidemiology, Mayo Clinic College of Medicine, Mayo Clinic, Rochester, MN

[5]Division of Hematology, Mayo Clinic College of Medicine, Rochester, MN

[6]Nicotine Dependence Center Research Program, Mayo Clinic College of Medicine, Rochester, MN 55905, USA

[7]Department of Internal Medicine, Mayo Clinic College of Medicine, Rochester, MN

[8]Human Cellular Therapy Laboratory, Mayo Clinic College of Medicine, Rochester, MN

Abstract

Tobacco use is a risk factor for adverse outcomes among Hematopoietic Stem Cell Transplant (HSCT) patients. Accurate identification of tobacco use offers a vital opportunity to treat this risk factor. The current study compared self-reported tobacco use status to serum cotinine levels among HSCT patients at time of pre-transplant evaluation. A total of 444 participants completed both assessments; 44 participants (9.9%) were classified as tobacco users with serum cotinine concentrations > 2ng/Ml versus 29 with self-report. Sensitivity and specificity of self-report were 65.9% and 100%. Positive predictive and negative predictive values were 100% and 96.4%. Comparing tobacco use documented in the medical record with cotinine, sensitivity and specificity were 51.2% and 99.2%. Factors associated with tobacco use were male gender, single relationship status, less education, and younger age. In summary, utilization of serum cotinine assays increased detection of tobacco use cases more than 50% over self-report. Results are discussed in context of translation to care, including clinical and ethical implications, and current tobacco use treatment

Corresponding Author: Shawna L. Ehlers, Ph.D., Mayo Clinic Rochester, 200 First St. SW, Rochester, MN 55905; Phone: (507) 284-2933; Fax: 507-284-4158; Ehlers.Shawna@mayo.edu.

Conflict of Interest

The authors declare no conflict of interest.

guidelines. When cotinine assays are not available, self-report of any tobacco use in the year prior to HSCT should trigger brief advice and cessation or relapse prevention counseling.

Keywords

Cotinine; Tobacco; Smoking; Transplant; Cancer

Introduction

Approximately 35–44% of hematopoietic stem cell transplant (HSCT) patients have a history of tobacco use, with 14–17% self-reporting smoking within the year prior to HSCT and 7–17% self-reporting smoking across the survivorship period.[1–5] Tobacco use is associated with adverse HSCT outcomes such as increased mortality rates, complications, hospitalization days, and comorbid medical conditions.[2, 6–9] Tobacco screening and counseling are recommended as part of standard HSCT survivor care,[10] especially to reduce respiratory, oral, and cardiovascular risk. Therefore, accurate identification of current or recent tobacco use among HSCT patients provides a timely opportunity to deliver interventions targeted at tobacco cessation and relapse prevention.

Self-report of tobacco use status remains a widely employed strategy for assessing and identifying tobacco users in clinical practice. Accuracy of self-reported tobacco use status among the general population tends to vary. Results from the literature suggest self-reported tobacco abstinence false negative rates of 1.3% to 9.8% when biochemically verified.[11–15] Among populations of smokers diagnosed with a chronic illness, false negative rates are higher, for example, among individuals with diabetes (15%),[16] chronic obstructive pulmonary disease (8.5%);[17]surgical patients (18%);[18] patients with cervical cancer (4.9%)[19] or head and neck cancer (10.4%);[20]and heart (50%)[21]and liver (11%)transplant patients.[22] Reasons for higher false negative rates of smoking status among chronically ill smokers are unclear, and may be impacted by exposure to second-hand tobacco smoke, use of nicotine replacement therapy, societal pressure to report cessation, and distress related to continued smoking while ill.[16, 18, 23, 24] Smokeless forms of tobacco are rarely reported.[25]

Cotinine, the major metabolite of nicotine, is the recommended biochemical marker for confirming self-reported tobacco use status.[26] Cotinine assays may be conducted using biological samples collected from urine, blood, or saliva. The half-life of cotinine extends from 18–20 hours, and can detect tobacco exposure (both smoking and smokeless)over the last 7 days[26, 27] at a rate greater than 90% (sensitivity=96.3%, specificity=97.4%).[14, 17, 28, 29] Despite the accuracy of cotinine measures, obtaining assays requires additional processing time as well as resources. Thus, it is important to assess the accuracy of self-reported tobacco use status among HSCT patients to inform patient assessment and clinical care.

Though self-reported tobacco use is associated with adverse HSCT outcomes, no study to date has explored the validity and reliability of self-reported tobacco use status among HSCT patients. The proposed study compared the validity of self-reported tobacco use to serum cotinine concentrations among HSCT patients prior to their transplant.

Methods

Participants

All study procedures were approved by the Mayo Clinic IRB. All patients undergoing multi-disciplinary pre-transplant evaluation for an outpatient based HSCT program from June 8, 2009 to May 5, 2011 were offered the opportunity to participate in a prospective cohort study of lifestyle factors among HSCT recipients, including providing an extra tube of blood for research during a blood draw initiated for clinical care. Patients were considered eligible if they (a) were 18 years of age or older; (b) displayed no evidence of active psychotic or neurologic disorder; (c) were able to speak and read standard English; and (d) provided written informed consent. A total of 615 HSCT candidates were eligible for this study, 565 provided informed consent (92% consent rate), 540 provided a valid cotinine sample, 532 provided self-report data, and 444 self-reported tobacco use status within 7 days of a valid cotinine assay (83.5% of consented). Reasons for not consenting to participate in this study included lack of interest (n=39), not wanting to complete surveys (n=10), and not wanting to have extra blood drawn (n=1).

Measures

The current study compared pre-HSCT self-reported tobacco use status to serum cotinine concentrations among HSCT patients. Cotinine was chosen as the gold-standard for ability to detect both smoke and smokeless tobacco use within the prior 7 days.[26] Serum assay was chosen for ease in this population that has routine blood draws as part of standard clinical care.

Cotinine concentrations greater than or equal to 2 ng/mL were considered to reflect tobacco use within the past 7 days. This cut-off is the standard calibrated within Mayo Clinic Laboratories and recommended by Moyer and colleagues (2002) for ability to detect daily tobacco use, as well as less than daily use.[30] Benowitz and colleagues (2009) recommend a range of serum cotinine levels between 0.5 ng/mL and 13.9 ng/mL to detect less than daily use. Environmental tobacco exposure was also assessed in the past 7 days via self-report to help distinguish heavy environmental exposure from direct use. Cotinine assays were repeated 15 days post-HSCT infusion to document persistence of use.

Self-reported tobacco use status was evaluated via research survey: “When is the last time you used any type of tobacco (1=never; 2=more than 12 months ago; 3=6–12 months ago; 4=8 days to 6 months ago; 5= 0–7 days ago). If respondent endorsed tobacco use, he or she was asked, “What kind of tobacco use did/do you use? (Cigarettes, Chew/snuff, Cigar/pipe, or Other).” If the respondent endorsed smoking cigarettes, he or she was asked, “How many cigarettes did you smoke per day, on average in the past 7 days, the past 6 months, and the past 12 months (0; 10 or less; 11–20; 21–30; 31 or more).” Individuals who reported tobacco use in the past 7 days were considered current users. Lastly, respondents who reported current tobacco use were asked, “How soon after you wake up do you have your first cigarette/tobacco? (0 to 5 minutes; 6 to 30 minutes; 31 to 60 minutes; or more than 60 minutes)?”

As standard of care at out institution self-reported tobacco use is recorded in the clinical medical record. HSCT patients with use in the past year are given advice to quit or remain quit in context of HSCT-specific literature,[2, 6–9, 25] and offered respective treatment in form of cessation counseling and pharmacotherapy, or relapse prevention counseling.[31] Cotinine assays were administered only for research purposes, and stored within a restricted access database. All clinicians remained blind to individual patient cotinine status.

Sociodemographic and clinical information were collected as part of transplant program statistics and the medical record. This included age, gender, marital status, employment status, education level, transplant status, disease type, transplant type (autologous/allogeneic), remission status (active disease versus remission), and time since transplant related diagnosis.

Data Analysis

Tobacco use rates across assessment methods were summarized using frequency, percent. The sensitivity, specificity, positive predictive value and negative predictive value of self-reported tobacco use were calculated compared to serum cotinine as the gold-standard. Predictors of tobacco use were assessed using logistic regression. In all cases p-values $\leq$0.05 were considered statistically significant.

Results

The mean age of participants with self-report data was 55.7± 12.1 years, and they were predominately married (85.6%), Caucasian (95.3%), men (61.1%), and pursuing autologous transplant (77.4%); 49.8% were employed at the time of diagnosis. Multiple myeloma (36.4%) and lymphoma (Hodgkin Disease/Non-Hodgkin Lymphoma/Chronic Lymphocyte Leukemia; 30.0%) were the most common diagnoses. Thirty-four participants (7.0%) self-reported using tobacco use within the past seven days (91.1% cigarettes, 20.6% chewing tobacco; 14.7% cigars), of which 48% used tobacco within the first 30 minutes of awakening in the morning. More than half of self-reported users (74.2%) reported smoking 10 or fewer cigarettes a day. Further demographic characteristics can be found in Table 1. Note: 61 out of 540 participants with valid cotinine assays were categorized as tobacco users (11.5%), but only those with self-report data are included in this report (N= 532).

Validity of Tobacco Assessments

Of study participants, 444 (82%) provided self-reported tobacco use status within 7 days of a valid cotinine assay and constitute the sample for validity analyses. Reasons for unanalyzable serum were order error (n= 5), unspecified reason (n= 11), insufficient sample (n= 8), and study withdrawal (n=1).

Using cotinine, 9.9% (n= 44) of participants were classified as tobacco users versus 6.5% with self-report (7 day point prevalence) (see Table 2). Survey results correctly identified 29/44 users (65.9% true positives) and misclassified 15 as non-tobacco users (34.1% false negatives). Of the 15 false negative cases, 13 reported former use (8 within the past year, 5 greater than 1 year ago), and 2 reported never use. Resultant sensitivity and specificity were 65.9% and 100%. Positive predictive and negative predictive values were 100% and 96.4%

(see Table 2). Fifteen days post-transplant, near peak HSCT symptom burden, repeat cotinine analyses suggested further reduction in the prevalence of tobacco use (4.1%), with 5 continuing false negatives based on pre-transplant self-report.

Among the 44 cotinine-verified users at time of pre-transplant evaluation, medical record data (see Table 3) correctly identified 22 tobacco users (51.2% true positives) and misclassified 21 as non-tobacco users (48.8% false negatives); one participant did not have tobacco use documented in their medical record. Of the 21 false negative cases, 18 reported former use and 3 reported never use. The prevalence estimate based on medical record alone was 5.7%. Among participants with a valid cotinine assay, only 3 had positive tobacco status in the medical record and negative cotinine (<1% false positive, probable cessation between medical record creation/update and pre-transplant evaluation).

Possible Confounding Variables

Among the 15 participants with positive cotinine and negative self-report tobacco status (false negatives) at pre-HSCT evaluation, second hand smoke exposure, nicotine replacement therapy, use of smokeless tobacco products, cigar use, and completion time between survey and cotinine sample were explored. Mean cotinine value was 87.5 with a range of 2.3 to 410 for these 15 false negatives reports. One individual who reported quitting smoking over a year ago also reported significant exposure (being both in a room and a car with a smoker, 7 out of 7 days prior to query). Four participants reported minimal exposure to tobacco. Two individuals had reported the use of nicotine replacement therapy at the time of the pre-transplant evaluation; however, only one had documented nicotine patch and gum use in their medical record. Duration of time between cotinine sample blood draw and pre-transplant survey averaged 1 ± 2.1 days.

Correlates of Tobacco Use and False Negative Self-Report

Demographic and clinical variables were analyzed via logistic regression in association with tobacco use and false negative report of tobacco use. Tobacco use was significantly associated with male gender, single relationship status, younger age, and less education across all three tobacco assessments. False negative reports were not associated with any clinical or demographic variable.

Discussion

This is the first study to verify self-reported tobacco use status among HSCT patients. This is also the first study to report biochemical tobacco use status among HSCT patients (or any hematologic cancer population), with a prevalence rate of 9.9%at time of pre-HSCT evaluation and 4.1%near the point of peak HSCT side effects. Prior self-report studies report a range of 14–17% prevalence within one year prior to HSCT, without standardized time points.[1–4, 6–9]

In this sample of HSCT patients, biochemical validation of tobacco use status significantly increased the accuracy of detecting tobacco use versus self-report alone, particularly among self-reported former smokers. Cotinine assay identified 44 users (9.9% prevalence rate), while self-report identified 29 users (29/44, 65.9% true positive reports; 15/44, 34.1% false

negative reports). Thus 15 more users were identified with serum cotinine, resulting in over a 50% increase in detected cases. On the other hand, individuals who self-reported tobacco use did not benefit from biochemical verification (29 self-reported users; 100% positive predictive value). Tobacco assessment sensitivity incrementally increased from standard of care medical record assessment (51.2% of cotinine verified users detected) to pre-HSCT self-report research survey (65.9% of cotinine verified users detected) to pre-HSCT cotinine assay (i.e., the gold-standard comparison designed to detect any use in past 7 days).

Tobacco use declined in the first 2 weeks post-transplant, likely related to the context of symptom burden and hospitalization. However, studies of HSCT survivors document self-report tobacco prevalence rates of 7–17% with a wide time range of 1.8–27.7 years post-HSCT.[4, 5] Cotinine-verified relapse rates among other oncology patients range from 25–38% at 1-year post-treatment and 36.2–37.5% among heart transplant recipients.[21, 32–35] Taken with the current study, these studies suggest that relapse to tobacco use may be prevalent between the time of peak symptom burden and survivorship regardless of assessment method, though underestimated by self-report. Former use and active disease are associated with higher false negative rates in other populations, e.g.[36] Based on the current study youth, males, and patients with lower education are at risk for tobacco use consistent with HSCT literature[5] and the general tobacco literature.[31] Adding cotinine analyses to standardized lab protocols would likely increase accurate identification of this risk factor for adverse HSCT outcomes.

Strengths of this study include a large prospective, consecutively enrolled cohort with a consent rate of 92%. Methodological strengths include use of standardized tobacco assessment instruments at a standardized time point. Limitations include recruitment at a single study site and low ethnic diversity of the sample. Future research should also employ standardized assessment instruments and time points. Additionally, future studies should focus on multi-site replication and outcome analyses within prospective cohorts to better estimate adverse outcomes and risks associated with tobacco in HSCT populations, and tobacco relapse rates. If these results are replicated, the true impact of tobacco on HSCT outcomes may be greater than that based on the existing self-report smoking literature.

Implications for clinical practice can be framed within the goal of treating all known risk factors. At minimum patients should receive education on the risks associated with tobacco use in terms of HSCT outcomes and access to treatment utilizing current practice guidelines[31] starting at time of pre-HSCT evaluation. The “5As” are a useful pneumonic to cue providers to 1) Ask about tobacco, 2) Advise cessation, 3) Assess willingness to make a quit attempt, 4) Assist in quit attempt, 5) Arrange follow-up. For patients unwilling to make an attempt, the “5Rs” help providers increase patient motivation for quitting via discussion of 1) Relevance to the individual patient (e.g., HSCT outcomes, health of family), 2) Risks to health, 3) Rewards of quitting (e.g., ease of breathing, improved taste and smell, example for children), 4) Roadblocks to quitting, 5) Repetition of discussion at each visit. The guidelines emphasize that tobacco dependence is a chronic disease that should be treated within every primary and specialty care setting; assessment may be included with vital sign assessment. Anecdotally and congruent with the above guidelines, we find a collaborative approach focused on risk reduction to maximize patient engagement. We first confirm that

each individual patient has received general advice to quit from a medical provider, and then state, “Good. Has anyone told you about HSCT specific risks yet?” Identified users receive care per the “5As” and “5Rs” above. This is congruent with the teachable moment literature in which health context and personal relevance motivate behavior change.[37]

Collecting a biological sample that may reveal inaccurate self-report requires careful program design to respect patient autonomy and promotion of just care. Individual HSCT program discussions framed with tenets of health care ethics are recommended to start protocol planning.[38] Programs that decide to utilize cotinine are advised to do so with complete transparency based on the collaborative goal of detecting and minimizing all known risk factors for every patient. If tobacco use is a factor in candidacy decision making cotinine should be required of all candidates, not just those that self-report use historically.

This study suggests that cotinine assay increases accurate identification of tobacco use as a risk factor for adverse HSCT outcomes by over 50%. Such magnitude of improved detection rates would enable a significant proportion of patients to receive tobacco use treatment, with potential to improve outcomes. In terms of research, decreasing unexplained statistical variability due to undetected tobacco use cases would increase the predictive power of HSCT outcome modeling. Results need replication before translation to clinical practice. For current practice, identification of patients with any tobacco use in the year prior to HSCT is a reasonable alternative supported by a consistent literature base. This approach supports both tobacco cessation and tobacco relapse prevention during a period of known vulnerability.

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Table 1

Demographic Information of Participants

	Total (N=532)
Gender	
F	207 (38.9%)
M	325 (61.1%)
Age at transplant	
N	532
Mean (SD)	55.7 (12.1)
Median	58.0
Q1, Q3	50.0, 64.0
Range	(19.0–76.0)
Race	
Missing	62
Non-White	22 (4.7%)
White	448 (95.3%)
Employment	
Missing	20
Not Employed	257 (50.2%)
Employed	255 (49.8%)
Education	
Missing	27
No high school diploma	14 (2.8%)
High School Diploma or GED	123 (24.4%)
Some college or 2 year degree	155 (30.7%)
4 year college graduate	102 (20.2%)
Post graduate studies	111 (22.0%)
Tobacco use based on pre-transplant survey	
Missing	47
Current	34 (7.0%)
Former	224 (46.2%)
Never	227 (46.8%)
Tobacco use based on Patient Provided Information Form	
Smoker	38 (6.7%)
Quit use	262 (46.3%)
Never used	266 (47%)
Marital status	
Missing	19
Not in committed relationship or married	74 (14.4%)
Married/committed relationship	439 (85.6%)
Diagnosis	
Missing	46

	Total (N=532)
Acute leukemia/Myeloid/CML	86 (17.7%)
Lymphoma (HD and NHL)/CLL	146 (30.0%)
Amyloid and POEMS	51 (10.5%)
Multiple Myeloma	177 (36.4%)
Other (solid tumors/aplastic anemia/metabolic)	26 (5.3%)
Transplant type	
Not transplanted	46
Allogeneic	109 (22.4%)
Autologous	376 (77.4%)
Syngeneic	1 (0.2%)
Time from diagnosis date to survey date, months	
N	444
Mean (SD)	25.2 (37.9)
Median	7.7
Q1, Q3	4.3, 26.8
Range	(12 days to 274.6)
Time betweenpre-transplant survey to cotinine assessment, days	
N	450
Mean (SD)	−0.5 (1.4)
Median	0.0
Q1, Q3	0.0, 0
Range	−7 – 6

Table 2

Tobacco status: Accuracy of research survey versus serum cotinine at time of pre-HSCT evaluation

Cotinine/Survey	+	−	
+	29	0	100% PPV
−	15	400	96.4% NPV
	65.9% sensitivity	100% specificity	

PPV, positive predictive value; NPV, negative predictive value

Table 3

Tobacco status: Accuracy of most recent annual medical record form versus serum cotinine at time of pre-HSCT evaluation

Cotinine/Medical record	+	−	
+	22	3	88.0% PPV
−	21	395	95.0% NPV
	51.2% sensitivity	99.2% specificity	

PPV, positive predictive value; NPV, negative predictive value