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Actigraphy as an assessment of performance status in patients with advanced lung cancer

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Abstract

Objective. Wearable devices such as a wrist actigraph may have a potential to objectively estimate patients' functioning and may supplement performance status (PS). This proof-of-concept study aimed to evaluate whether actigraphy data are significantly associated with patients' functioning and are predictive of their survival in patients with metastatic non-small cell lung cancer.
Method. We collected actigraphy data for a three-day period in ambulatory patients with stage IV non-small cell lung cancer. We computed correlations between actigraphy data (specifically, proportion of time spent immobile while awake) and clinician-rated PS, subjective report of physical activities, quality of life (the Functional Assessment of Cancer Therapy – Trial Outcome Index), and survival.
Result. Actigraphy data (the proportion of time awake spent immobile) were significantly correlated with Functional Assessment of Cancer Therapy – Trial Outcome Index ($r = -0.53$, $p < 0.001$) and with the Eastern Cooperative Oncology Group PS (ECOG PS) ($r = 0.37$, $p < 0.001$). The proportion of time awake spent immobile was significantly associated with worse survival. For each 10% increase in this measure, the hazard ratio (HR) was 1.48 (95% confidence interval [$CI_{95\%}$] = 1.06, 2.06) for overall mortality, and odds ratio was 2.99 ($CI_{95\%} = 1.27, 7.05$) for six-month mortality. ECOG PS was also associated with worse survival (HR = 2.80, $CI_{95\%} = 1.34, 5.86$). Among patients with ECOG PS 0-1, the percentage of time awake spent immobile was significantly associated with worse survival, HR = 1.93 ($CI_{95\%} = 1.10, 3.42$), whereas ECOG PS did not predict survival.
Significance of Results. Actigraphy may have potential to predict important clinical outcomes, such as quality of life and survival, and may serve to supplement PS. Further validation study is warranted.

Introduction

Performance status (PS) may be one of the most critical pieces of medical data in making decisions in oncology. Oncologists use PS to determine patients' eligibility for clinical trials as well as the initiation and continuation of chemotherapy (Orr & Aisner, 1986). PS has been known to predict physical functioning before and after chemotherapy (Chen et al., 2003), treatment responses (Sengelov et al., 2000), and survival (Albain et al., 1991).

Despite its importance, PS is determined by oncologists' subjective observation, and there is no standardized process for assessment. Not surprisingly, some concerns have been raised about the accuracy of oncologist-rated PS scores (Loprinzi et al., 1994). A few studies demonstrated that PS rated by oncologists frequently disagree with the patients' subjective rating of their functioning, with a tendency for patients to score themselves as worse than the oncologists' rating (Ando et al., 2001; Blagden et al., 2003).

Identifying objective measures of functioning has the potential to improve the determination of patients' performance status. With recent advancement of technology, wearable devices have been drawing increasing attention in medical field (Bansal & Joshi, 2018; Tedesco et al., 2017; Wang & Hu, 2018) and can serve to monitor physical activity (as well as inactivity). For example, a wrist actigraph is a portable wristwatch-sized accelerometer that records movement over time in the form of activity counts. In the field of oncology, actigraphy has been applied for measuring sleep quality (Madsen et al., 2015) and physical activities (Beg et al., 2017). With its safety and ease of use, it has been used for measuring sleep quality and physical activity (Broderick et al., 2014; Gresham et al., 2018; Madsen et al., 2015). A few studies attempted to examined association between actigraphy results and survival in colorectal cancer (Innominato et al., 2012; Levi et al., 2014) and newly diagnosed lung cancer (Chang et al., 2018); however, to the best of the authors' knowledge, no study has been conducted in advanced lung cancer.

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As a first step to evaluate the feasibility of using wrist actigraph as an objective measure of PS in patients with advanced lung cancer, we conducted this proof-of-concept study. We sought to investigate whether the actigraphy data were associated with clinician-rated PS, patients' quality of life (QOL), and survival. We focused on the percentage of time that the patient was immobile while awake, called "time awake spent immobile," given its face validity with Eastern Cooperative Oncology Group PS (ECOG PS).

Methods

Sample

Participants were required to have a diagnosis of stage IV non-small cell lung cancer (NSCLC), confirmed by the electronic health record; be at least 18 years old; have the ability to complete self-report instruments in English; and have survival estimated by their oncologists to be at least two months. Patients who had cognitive impairment or active psychotic disorders were excluded. Because a range of PS scores was necessary for this study, patients could be at any time from diagnosis and on any type of treatment.

Procedure

We recruited patients with stage IV NSCLC to participate in this prospective observational study. Potential participants were referred by their treating medical oncologists between January 1, 2014, and August 31, 2014, in the thoracic oncology clinic at the Massachusetts General Hospital Cancer Center. After completing informed consent, participants were given a wrist actigraph. They were instructed to wear it on their nondominant wrist for four consecutive days before their next scheduled clinic visit to ensure data were collected for three full days (72 hours). Participants were also asked to complete an activity log, recording the times they went to bed, turned out lights, woke up, got out of bed, took naps, and removed the actigraph. At their subsequent oncology appointment, participants returned the wrist actigraph and completed self-report instruments, receiving $25 remuneration for their time completing the study assessments. Study staff collected participant sociodemographic and clinical information from the electronic health record. Follow-up data were collected until October 25, 2015, with a minimum follow-up period of 14 months for all participants. The Dana Farber/Harvard Cancer Care institutional review board approved the study procedures before initiation.

Measurements

Wrist actigraph

We used Actiwatch 2 (Philips Respironics) to record participants' activity. Actiwatch 2 is a watch-sized wearable accelerometer. Data were analyzed using default computer scoring with Philips Respironics' Actiware software, version 6.0.1. The setting and algorithm for analysis are described in detail elsewhere (Boyne et al., 2013; Philips Respironics' Actiware Tutorials). In brief, acceleration was measured in a unit of one minute (an "epoch"). For each epoch, activity scores were calculated by summing the activity counts recorded during the immediate epoch plus weighted activity counts of previous and successive epochs. An epoch was recorded as "awake" if the activity score of the epoch was above the threshold of 40. An epoch was recorded as "rest" if the activity score was below 40. An epoch was coded as immobile when the activity count within the epoch was zero. A consecutive 10 minutes of immobile epochs were considered sleep onset. An epoch with an activity score of zero while the participant was not asleep was defined as "time spent awake immobile."

ECOG PS

ECOG PS is a clinician's assessment of a patient's current functional status (Oken et al., 1982). It has five ordinal categories with anchors for level of impairment (0, fully active, to 4, completely disabled). ECOG PS is widely used in clinical trials of cancer therapies as an eligibility criterion and has been found to be predictive of survival (Paesmans et al., 1995). ECOG PS was rated by the participant's treating oncologist who was blind to actigraphy data and the participant's self-administered questionnaires.

Physical activity questionnaire

This questionnaire asks participants to report the frequency and intensity of 11 types of physical activities (Chasan-Taber et al., 1996). Responses to the questions can be converted into a metabolic equivalent task score. This questionnaire has been used in studies that examined physical activity and survival of patients with breast and colon cancers (Colditz et al., 2003; Meyerhardt et al., 2009).

Functional Assessment of Cancer Therapy-Lung (FACT-L)

The FACT-L is one of the most widely used QOL instruments in lung cancer studies. It measures physical, emotional, social, and functional well-being as well as lung cancer–specific symptoms (the Lung Cancer Scale) over the past week (Cella et al., 1995). We used the FACT-Trial Outcome Index (FACT-TOI), which is the sum of the scores on the Lung Cancer Scale and the physical well-being and functional well-being subscales of the FACT-L, to measure QOL of the participants. The FACT-TOI has been shown to be sensitive to changes in PS in patients with lung cancer.

Statistical analysis

Descriptive statistics were compiled for all study variables. We tested associations among actigraphy data (i.e., percent time awake spent immobile), clinician-rated EGOG-PS, physical activity (measured by the physical activity questionnaire), and QOL (FACT-TOI) using Spearman's correlations. Survival was examined using unadjusted Cox proportional hazards models, and six-month survival was examined using unadjusted logistic regression models. Because we only had small number of participants with PS = 2, we conducted the analyses both by using the whole sample and by using only patients who had a PS of 0-1.

We conducted our sample size calculation based on an estimated ECOG PS standard deviation (*SD*) of 0.53 in patients with stage IV NSCLC and the *SD* of mean activity scores in adults measured by Actiwatch 2 devices obtained by Philips Respironics (*SD* = 89 activity counts) (Philips Respironics Actiware Tutorials). We estimated that with 40 participants, we would have 80% power to detect a difference of 76 units in mean activity scores per ECOG PS level. Analyses were conducted using SPSS 16, with significant level of $p < 0.05$.

Results

We approached 59 eligible patients, and 51 provided written informed consent and were enrolled (consent rate = 86.4%).

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Seven participants withdrew from the study before they started wearing the actigraph (one because of death, three from progressive symptom burden, and three were no longer interested). Forty-four participants completed the study assessments (complete rate = 86.2%). Data from three participants were not retrievable because of device malfunction; therefore, data from 41 participants were included in the analyses.

The characteristics of the participants are summarized in Table 1. The mean age was 68.8 years, one-half were male, and the mean time from cancer diagnosis was 22.0 months (SD = 23.6). The majority of participants had good ECOG PS. Mean percentage of time awake spent immobile was 18.0% (SD = 10.6).

Associations of actigraph with measures related to functioning

Correlations among the percentage of time awake spent immobile and the measures of functioning are presented in Table 2. actigraphy data (the proportion of time awake spent immobile) was significantly correlated with FACT-TOI ($r = -0.53$, $p < 0.001$) and with ECOG PS ($r = 0.37$, $p < 0.001$). It was not significantly associated with total metabolic equivalent tasks/week.

We then categorized percentage of time awake spent immobile in intervals of 10% and compared it with ECOG PS categories (Table 3). Patients with good performance status (ECOG PS 0-1) were dispersed across the categories of percentage of time awake spent immobile.

Association of actigraph and survival

At the time of the analyses, 13 (32%) of the participants had died. Percentage of time awake spent immobile was significantly associated with worse survival. The hazard ratio (HR) was 1.48 ($CI_{95\%}$ = 1.06, 2.06, $p < 0.05$) for each 10% increment of time awake spent immobile. ECOG PS was also associated with survival with HR = 2.80 ($CI_{95\%}$ = 1.34, 5.86, $p < 0.05$). Among the participants with ECOG PS 0-1, ECOG PS did not discriminate differences in survival, but percentage of time awake spent immobile did significantly predict worse survival, with HR = 1.93 ($CI_{95\%}$ = 1.10-3.42, $p < 0.05$).

Among all participants, eight patients had died at the six-month follow-up. Percentage of time awake spent immobile was significantly associated with death within six months. For each 10% increment of time awake spent immobile, the odds ratio (OR) was 2.99 ($CI_{95\%}$ = 1.27, 7.05; $p < 0.05$). ECOG PS was also associated with worse six-month survival with OR = 9.23 ($CI_{95\%}$ = 1.67, 51.06; $p < 0.05$). Among patients with good performance status ratings (ECOG PS 0-1), however, ECOG PS did not discriminate differences in survival, but percentage of time awake spent immobile did predict worse six-month survival with OR = 5.09 ($CI_{95\%}$ = 1.06, 24.36; $p < 0.05$).

Table 1. Participant characteristics

	N (%)
Age, year	M = 66.8, SD = 10.6
Male	20 (49)
White	37 (90)
Married	25 (61)
Time since diagnosis	M = 22.0, SD = 23.6
Charlson Comorbidity Index	M = 9.7, SD = 1.7
Brain metastases	13 (32)
ECOG PS	
0	9 (22)
1	26 (63)
2	5 (12)
3	1 (2)
METs/week	M = 15.3, SD = 20.1
Actigraphy - Time awake spent immobile	M = 18.0, SD = 10.6

ECOG PS, Eastern Cooperative Oncology Group performance status; *M*, mean; METs, metabolic equivalent tasks; *SD*, standard deviation.

Table 2. Correlations among assessments

	Actigraphy (% time awake spent immobile)	ECOG PS	METs/ week	FACT-TOI
Actigraphy		0.365*	−0.306	−0.531†
ECOG PS			−0.496†	−0.689†
METs/week				0.524†
FACT-TOI				

ECOG PS, Eastern Cooperative Oncology Group performance status; FACT-TOI, Functional Assessment of Cancer Therapy-Trial Outcome Index; METs, metabolic equivalent tasks.
*Spearman's rho $p < 0.05$.
†Spearman's rho $p < 0.01$.

Discussion

The current study demonstrated that actigraphy data (time awake spent immobile) was associated with measures related to functioning and QOL, and was predictive of survival. The actigraphy data were more strongly associated with QOL and more strongly predicted survival than PS.

Evaluation of PS is a critical component of patient care in oncology, and the development of objectives measures of functioning can reduce the variability of assessments and enhance treatment decisions. Wrist actigraph, specifically time awake spent immobile, may potentially be an objective measure of PS.

Moreover, percentage of time awake spent immobile was superior to ECOG PS in predicting six-month survival in our overall sample as well as overall and six-month survival in participants rated as having good performance status (ECOG PS 0-1). Although an ECOG rating of 0 versus 1 in a patient with good PS may not seem that meaningful to an oncologist, that for every 10% of awake time these patients are immobile may double their odds of mortality in six months and may provide important information in making clinical decisions.

There have been a few proposed assessment methodologies to supplement or replace PS. For example, Stotter et al. (2015) found that a comprehensive geriatric assessment with four components (i.e., cognitive decline, basic and instrumental activities of daily living, fitness grade) predicted patients' three-year survival in a large sample of elderly patients with breast cancer. Although these assessments may better predict survival than ECOG PS (Decoster et al., 2015; Kenis et al., 2014), they can take a considerable amount of time, limiting their feasibility in busy oncology

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Table 3. Number of participants categorized by % time awake spent immobile and ECOG performance status

	% time awake spent immobile					
ECOG PS	<10	10-19	20-29	30-39	40-49	≥50%
0	3	4	2	0	0	0
1	10	5	8	3	0	0
2	0	2	1	1	0	1
3	0	0	0	1	0	0

ECOG PS, Eastern Cooperative Oncology Group performance status.

clinics. Another example, the six-minute walk test, has been shown to be predictive of survival in patients with metastatic NSCLC (Jones et al., 2012); however, almost one-half of the patients eligible for the study declined the test because they were not feeling well enough or they didn't have time, potentially limiting its use in clinical practice.

Actual recordings of patients' physical activity and sedentary behavior using actigraphy might be easier to use in clinical practice. Requesting patients to wear a wrist actigraph and then downloading the data remotely or at clinical visits seems both feasible and scalable in clinical oncology. Patients and oncologists could view and discuss the data together to make informed and transparent decisions about treatment.

This proof-of-concept study has several limitations, and further research on the use of actigraphy is needed. First, this was a small sample of patients at a single academic cancer center, so the findings need to be evaluated in larger and more diverse populations. The small number of patients with poor PS might have also affected our findings. Second, we collected actigraphy data for three consecutive days only, mostly for practical reasons (e.g., to avoid excessive burden on the participants, duration of battery life of the device). Patients' activity level may fluctuate throughout a week. This may explain why we observed only a modest correlation between actigraphy data and ECOG PS in the current study. Appropriate length of data collection time needs to be verified. Third, because of the small number of participants, we were not able to control clinical variables such as age, cancer histology, or received treatments. Also, we collected data on patients at different points in their disease trajectory, which didn't allow us to explore actigraphy as a predictor of response to or tolerability of cancer treatments. Fourth, analytical methodology of actigraphy data is only preliminary. We used time awake spent immobile as the primary outcome, categorizing it by 10%; however this categorization is arbitrary and needs further verification. For example, a French research group used a parameter called the dichotomy index, which represents ratio of time in bed and time out of bed, as a predictor of survival in colorectal cancer (Innominato et al., 2012; Levi et al., 2014). Future studies in this filed include comparison between different parameters.

Despite these limitations, this is the first study that evaluated the relationship among actigraphy data, PS, and survival in patients with advanced lung cancer. This study adds to few early data that show actigraphy may represent a simple, noninvasive, and objective assessment in determining PS, which could provide meaningful clinical information in making oncology treatment decisions. Further research is warranted to confirm these findings in larger sample with more comprehensive assessments that may influence patients' survival.

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Conflicts of interest. J.A.G. received royalties from Springer Publishing. All other declare no conflicts of interest.

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