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Ambulatory activity in men with diabetes: Relationship between self-reported and real-world performance-based measures

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Abstract—The measurement of physical activity, especially walking activity, is important for many outcome studies. In many investigations, the Physical Activity scale of the short-form-36 (SF-36) health assessment questionnaire is used in lieu of an actual physical measurement of walking. This study determined the relationship between the SF-36 questionnaire and the Step Activity Monitor (SAM), a real-world performance-based tool that counts the actual number of steps taken during daily activities. We studied the physical activity of 57 men with diabetes using step count monitoring and the SF-36 questionnaire. The subjects averaged 3,293 steps/day, but had a very wide range (111–11,654) and a large standard deviation (SD = 2,037). The correlations between total daily steps and the SF-36 Physical Component Summary score, and the Physical Function, Bodily Pain, and Vitality scales of the SF-36 were only fair (Pearson's r = 0.376, 0.488, 0.332, 0.380, respectively). The corresponding coefficients of determination range from only 7.7% to 23.8%. Physical activity is a complex concept not completely represented by either the SF-36 or the step counts. The correlation between actual walking activity and the SF-36 is not as strong as many researchers believe. Caution should be exercised with the use of the SF-36 to specifically measure walking activity.

Key words: diabetes mellitus, diabetic neuropathies, health status indicators, locomotion, outcome assessment, walking.

INTRODUCTION

Multidimensional measures for documenting patient outcomes are increasingly important in today's health-care environment. Practitioners are being asked to demonstrate that what they do actually makes a difference in their patients' lives. At the same time, researchers are being asked to employ a broader, more comprehensive array of measures to study health phenomena. This relatively new emphasis on multidimensional outcomes is related to the perceived need to reduce healthcare costs and unwarranted variations in care, as well as develop measures appropriate for monitoring the status of an aging

population with many chronic conditions, including diabetes [1–4]. Despite the emergence of the outcomes movement as a major force for change within the contemporary healthcare system, determining which outcomes are important and how to measure those outcomes remain exceedingly complex and difficult tasks [5–8].

Three outcomes categories of importance to many patients are health-related quality of life, general physical function, and ambulatory activity. The two basic types of tools that have been developed to measure physical activity and walking include self-report measures and performance-based measures. Examples of these different types of tools follow, with an emphasis on how each type independently measures health-related quality of life, physical function, and ambulatory activity.

Self-Report Measures

Self-report measures are designed based on the belief that patient perception is an important part of measuring overall health status and response to treatment. Perhaps the most widely used self-report measure of health-related quality of life is the short-form 36 (SF-36) questionnaire developed within the Medical Outcomes Study (MOS) [9]. The SF-36 relies upon 36 different questions, the answers to which are used to generate a score in eight different scales (Physical Functioning, Role Limitation due to Physical Problems, Bodily Pain, General Health Perceptions, Mental Health, Vitality, Role Limitation due to Emotional Problems, and Social Functioning) and two summary scores (Physical Component Summary [PCS] and Mental Component Summary [MCS]). Average expected norms stratified by age, gender, and diagnosis are available for specific subgroups (for example, diabetic men) from many countries. Although not specifically measures of ambulatory ability, many items within the SF-36 relate to gait activities and to social roles in the context of ambulation.

Unfortunately, the SF-36 is not precise enough to determine small differences in activity level. For example, the Role Limitation/Physical score is measured on a scale of 0 to 100 in 25-point increments, and the Physical Functioning score is measured on a scale of 0 to 100 in 5-point increments, both of which are far too coarse to provide useful statistical data for measuring subtle changes in activity. An additional limitation of the SF-36 and other self-report measures is that large proportions of some groups may score overwhelmingly at the top or bottom of the scale. When large proportions of the population of

interest score at the ceiling or floor of the scale, this makes the tool unresponsive to improvements in conditions for those at the ceiling or to declines in function for those at the floor.

Performance-Based Measures

Performance-based measures reflect the belief that important outcomes exist apart from patient perceptions and are best observed and measured by practitioners and researchers. Performance-based measures include tools that assign scores according to laboratory-based or simulated activities, as well as those that document actual performance during real-world daily activities.

Laboratory-Based and Simulated Measures

Laboratory-based performance measures, including the measurement of joint kinematics, electrical activity of muscles, and ground reaction forces, have been a foundation of the study of ambulatory activity [10]. For simulated performance measures of gait, patients are asked to execute a series of activities designed to mimic the demands of home and community ambulation. For example, the Physical Performance Test (PPT) consists of single repetitions of tasks such as putting a book on a high shelf, walking 50 feet, and picking up a penny from the floor [11]. Because these measures necessarily document activity only within a brief observation period and within a very controlled setting, they do not address the broader issues of what patients actually do in the real-world setting.

Real-World Measures

Real-world performance measures of gait activity, while not widely used, have been available for more than 20 years. In 1979, Holden et al. reported the use of a foot switch and storage device to count steps as an objective measure of rehabilitation after lower-limb amputation [12]. During this same period, Day et al. also developed a foot-switch step counter that, following a 10-day data collection period, could be used to extrapolate the yearly step count of individuals after amputation [13,14]. A more contemporary step counting device is the Step Activity Monitor (SAM), a pager-sized device that attaches to a patient's ankle [15]. The current version of the SAM can record the actual number of steps taken each minute for a period of at least 30 days. This real-world measure can contribute to what we know about how much people actually walk during a day and how

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people vary their walking from hour to hour or from day to day.

Relationships Among Types of Measures

A number of authors have studied the relationship between self-report and laboratory performance-based or simulated performance-based measures. Rueben and colleagues compared several self-report measures (the SF-36, among others) with the simulated PPT [11]. They found that relationships between the different types of self-report measures were generally stronger (correlations from 0.51 to 0.76) than the relationships between any of the self-report measures and the performance-based measures (correlations of 0.26 to 0.55). In a later study, Sherman and Reuben found similar results, documenting high correlations between simulated performance-based measures (PPT and the National Institute on Aging Battery) and only moderate correlations between the simulated performance-based measures and self-report measures (two activities of daily living tools and the SF-36) [16].

Cress and colleagues documented correlations ranging from –0.36 to –0.63 between the self-reported Sickness Impact Profile (SIP)—specifically, the physical dimension summary score and its subscales—and the laboratory-based performance measure of gait of older adults [17]. It is not surprising the self-reported physical function measures, which presumably capture the patient's perception about function across time in real-world settings, are not highly correlated with laboratory-based or simulated performance tests, which capture performance at limited intervals under controlled conditions.

Very little research exists documenting the relationship between self-report and real-world performance measures of physical activity. Day's 20-year-old study relied upon a questionnaire designed by the author and uncovered a significant correlation between step count per annum and the activity score of individuals with lower-limb amputation [14]. Our study explored the relationship between self-reported and real-world performance measures of physical activity and walking.

METHODS

Participants

Male veterans with diabetes identified from our facility were enrolled in this study. Eligibility criteria included that participants be male, be older than 18 years of age, be ambulatory, test positive for diabetes, test positive for peripheral neuropathy, have lower-limb amputation or both, and have the cognitive ability to fill out questionnaires. Diabetes was considered present if diagnosed by a physician or if the patient received oral hypoglycemic medication or insulin. A total of 57 men completed the study (average age 68 years, range 41 to 85 years). All amputee participants had been using prostheses, if required, for at least 1 year prior to their participation in this study.

Instrumentation

We performed step-count gait assessment using the SAM to record the number of right footsteps the subjects took every 2.5 minutes for 14 continuous days. We normalized the data to 1-minute intervals for analysis. This instrument is a small, self-contained, waterproof device that attaches to the patient's right ankle and continuously records step counts over successive, discrete time intervals. With steps measured in small units of time, the data gave the researcher insight into the speed of walking and into the patients' varying levels and patterns of activity in a real-world setting. This tool has 99 percent accuracy in counting steps on level surfaces and 97 percent on stairs and hills [15].

We used the SF-36 questionnaire to determine health-related quality of life. Participants completed the standard English language version, which instructs participants to answer each question in the context of the last 4 weeks.

Procedures

Participation involved three separate visits. At the first visit, eligibility for the study was determined and informed consent for participation was obtained. The second visit entailed fitting and calibrating a SAM to each participant. Participants were instructed to wear the device continually for a 2-week period except when sleeping and bathing. At the third visit, at the end of the 2-week period following the step-count data collection, participants returned their SAM and completed the SF-36 questionnaire.

Data Analysis

We measured the step-count data as the discrete number of steps taken by the participant in each small block of time. For statistical analysis, the step data was calculated into four different measures of walking activity for

each participant. For the first of these measures, the average number of steps taken per day was calculated as an overall summary score. The device records only the steps of the right leg; therefore, a rate of 60 steps/min with this device corresponds to a walking cadence (individual right and left steps) of 120 steps/min.

Second, we calculated the amount of time spent at various rates of walking to determine the average number of minutes spent per day being inactive (no steps/min), in very low ambulatory activity (1 to 2 steps/min), in low activity (3 to 10 steps/min), in moderate activity (11 to 30 steps/min), in high activity (31 to 60 steps/min), and in very high activity (>61 steps/min). Third, we measured the percentages of time spent at the various activity levels. Fourth, we added up the percentage of time spent at moderate, high, and very high levels of activity to provide a value showing the proportion of time spent at or above moderate level activities.

The SF-36 questionnaires were scored according to standard scoring algorithms. Scores for each of the eight general scales and for the two summary scores were calculated [18].

We gauged descriptive statistics for the variables, including the percentage of participants who were at the floor or ceiling values for variables in which a floor or ceiling existed. For the eight different SF-36 scales, the floor was a score of 0 and the ceiling a score of 100. For the two summary scores, each of which was normalized with the general U.S. population to an average score of 50 with a standard deviation (SD) of 10, floor and ceiling effects are essentially eliminated.

For the step-count data, floor values were noted when the patient did not take any steps at the given activity level. Even though a theoretical ceiling exists for these data, in practice, there is no given value at which the variables typically "top out," so only floor percentages were reported. We used 1-group *t*-tests to establish whether or not the SF-36 summary scores for this sample were significantly different from various population norms. Alpha was set at 0.05 for these comparisons.

Relationships among the SF-36 variables and the step-count variables were verified with the use of Pearson Product Moment Correlations (PPMCs). Because the pattern of correlations was the same no matter how the step-count data were presented (percentage of time at a given level, minutes at a given activity level, or percentage of active time at a given level), only the correlations between the SF-36 data and the percentage of time at a given level are presented here. Correlations that were significant at $p = 0.01$ and $p = 0.05$ are noted in the results. Because of the possibility of associations between subject age, the SF-36 score, and the step-count variables, we calculated PPMC between age and these variables.

RESULTS

Table 1 shows the descriptive statistics for the step-count data. The average number of steps per day for the

Table 1.
Descriptive statistics for step-count variables.

Variable	Mean	SD	Minimum	Maximum	% at Floor
Total Steps	3292.8	2036.6	111.0	11654.0	0.0
Minutes with No Steps	1094.0	132.6	765.4	1391.3	0.0
Minutes at Very Low Step Rate	86.3	43.9	31.9	221.0	0.0
Minutes at Low Step Rate	139.8	50.6	6.0	249.3	0.0
Minutes at Moderate Step Rate	103.4	59.5	4.6	297.7	0.0
Minutes at High Step Rate	16.5	23.8	0.0	117.7	5.3
Minutes at Very High Step Rate	0.005	0.23	0.0	2.0	93.0
Percentage of Time with No Step Rate	76.0	9.2	53.2	96.6	0.0
Percentage of Time at Very Low Step Rate	6.0	3.1	2.2	15.4	0.0
Percentage of Time at Low Step Rate	9.7	3.5	0.4	17.3	0.0
Percentage of Time at Moderate Step Rate	7.2	4.1	0.3	20.7	0.0
Percentage of Time at High Step Rate	1.1	1.7	0.0	8.17	5.3
Percentage of Time at Very High Step Rate	0.004	0.02	0.0	0.1	93.0
Percentage of Time at Moderate, High, or Very High Step Rate	8.3	5.3	0.3	28.9	0.0
SD = standard deviation					

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57 subjects was 3,293. However, the range (111 to 11,654) and SD (SD = 2,037) reveal tremendous variation in ambulatory activity between these subjects. The percentage of inactive time for the subjects averaged 76.0 percent (SD = 9.2), the percentage of time spent walking at very low levels of ambulation (1 to 2 steps/min) = 6.0 percent (SD = 3.1), low levels of activity (3 to 10 steps/min) = 9.7 percent (SD = 3.5), moderate activity (11 to 30 steps/min) = 7.2 percent (SD = 4.1), high activity (31 to 60 steps/min) = 1.1 percent (SD = 1.7), and very high activity (>61 steps/min) = 0.004 percent (SD = 0.02). The percentage of time spent when adding moderate, high, and very high levels of activity was 8.3 percent (SD = 5.3). It should be noted that 3 out of 57 participants recorded no activity at high step-count levels, and 51 out of 57 participants recorded no activity at very high step-count levels.

Table 2 shows the descriptive statistics for the SF-36 data. Nearly half the participants scored at the floor in both the Role Limitation/Physical and Role Limitation/Emotional variables. One-fifth of the participants scored at the ceiling of the Role Limitation/Physical, and one-third of participants scored at the ceiling of the Social Function and Role Limitation/Emotional variables. The PCS sample mean of 34.1 for our study population was significantly different than the means for men aged 65 and older from the U.S. population (PCS mean of 41.95, $t = -6.196$, $p = 0.000$), for individuals with diabetes in the general U.S. population (PCS mean of 39.30, $t = -4.114$, $p = 0.000$), and for individuals with diabetes in the MOS study (PCS mean of 41.52, $t = -5.858$, $p = 0.000$) [18]. The MCS sample mean of 48.3 was significantly different than the published means for men aged 65 and older from the U.S. population (MCS mean of 52.51, $t = -2.925$, $p =$ 0.005) and for individuals with diabetes in Ware's MOS (MCS mean 51.90, $t = -2.502$, $p = 0.015$), but not for individuals with diabetes in the general U.S. population (MCS mean of 47.90, $t = 0.272$, $p = 0.786$) [18].

Table 3 shows the PPMCs among the SF-36 variables and selected step-count variables. Because the step-count data for the high and very high levels of activity were not normally distributed within our sample, the assumptions required for generating valid correlations with these variables were not met. Of the 60 PPMCs shown in **Table 3,** the 11 that range from 0.488 to 0.356 are significant at 0.01 and an additional eight that range from 0.338 to 0.273 are significant at 0.05.

In general, the strongest relationships (those that are significant at 0.01) are the correlations between the Physical Function scale, PCS score, and Vitality scale with the total number of steps, the percentage of inactive time, the percentage of time with moderate activity, and the percentage of time with moderate and higher levels of activity. The somewhat weaker relationships (those that are significant at 0.05) are the Bodily Pain and Role Limitation/Emotional scales when correlated with a variety of step-count variables. The coefficients of determination values (r^2) calculated from the significant relationships show that from 7.8 percent to 23.8 percent of the variability in scores is shared among the SF-36 variables and the various step-count variables. The **Figure** shows a scatter plot of the total steps per day against the SF-36 Physical Function score.

Finally, the subject's age was not strongly associated with the SF-36 scores or the step-count variables. In fact, there were only two significant correlations between age and these variables. Increasing age was associated with

Table 2.
Descriptive statistics for SF-36 variables.

Variable	Mean	SD	Minimum	Maximum	% at Floor	% at Ceiling
PCS Score	34.1	9.6	9.8	55.3	0.0	0.0
Physical Function	42.2	27.8	0.0	95.0	1.8	0.0
Role Limitation/Physical	32.9	39.3	0.0	100.0	45.6	19.3
Bodily Pain	58.0	23.9	0.0	100.0	1.8	7.0
General Health	47.6	22.9	0.0	92.0	1.8	0.0
MCS Score	48.3	10.9	20.5	67.6	0.0	0.0
Vitality	48.3	22.7	5.0	100.0	0.0	1.8
Mental Health	73.4	18.3	8.0	100.0	0.0	1.8
Social Function	69.7	26.3	0.0	100.0	1.8	29.8
Role Limitation/Emotional	42.1	45.2	0.0	100.0	47.4	33.3

PCS = Physical Component Summary   MCS = Mental Component Summary   SD = standard deviation

Table 3.
Pearson's correlations between step-count measurements and SF-36 scales.
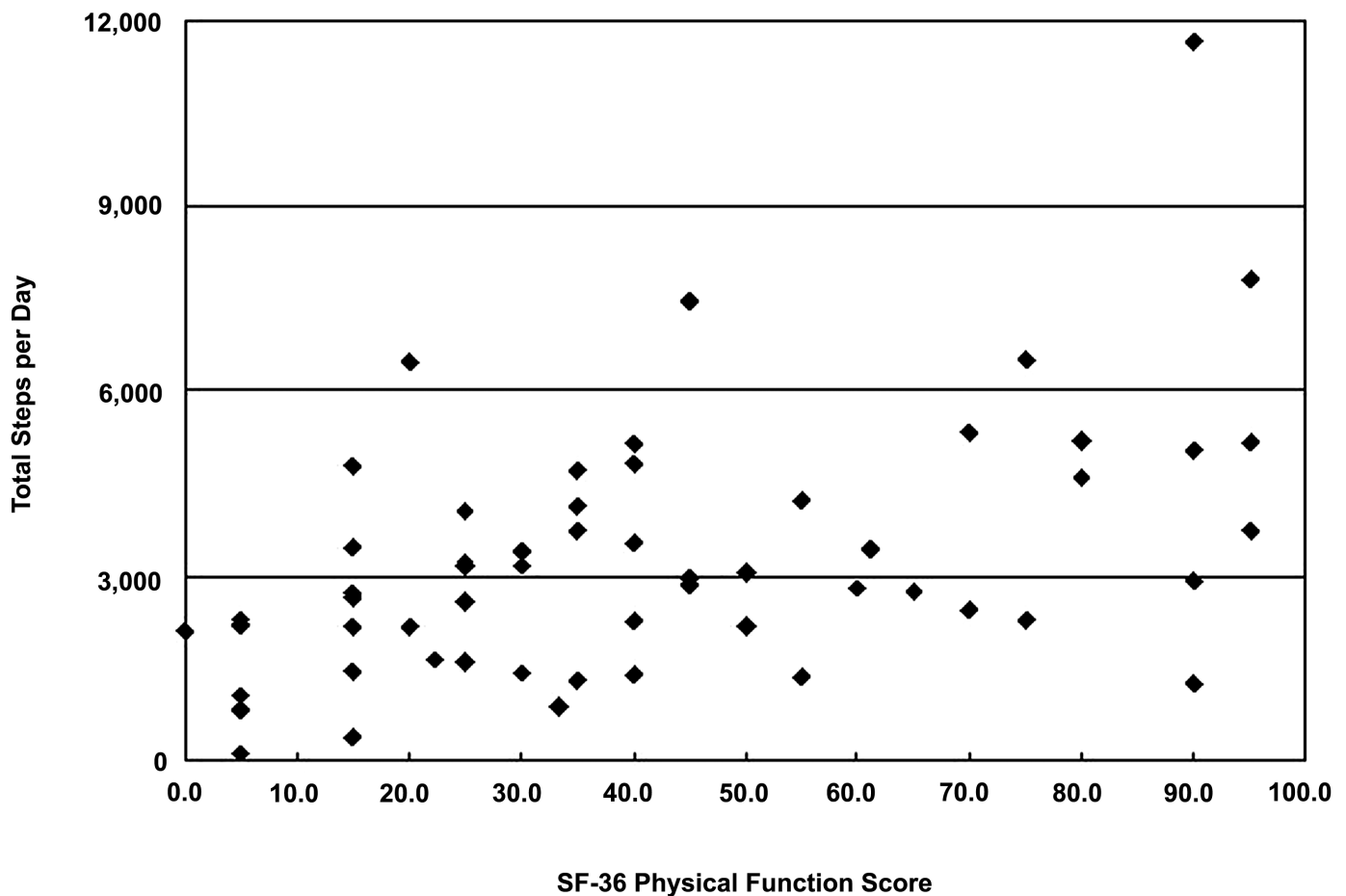
Variable	PCS	Physical Function	Bodily Pain	Role Physical	General Health	MCS	Vitality	Mental Health	Role Emotional	Social Function
Total Steps/Day	0.376*	0.488*	0.332†	0.082	0.134	0.101	0.380*	0.069	0.242	0.056
% of Inactive Time	−0.324†	−0.391*	−0.319†	−0.042	−0.211	−0.157	−0.427*	−0.186	−0.154	−0.089
% Time Spent at Very Low Level of Activity	0.055	0.028	0.222	−0.083	0.131	0.142	0.244	0.216	−0.020	0.056
% Time Spent at Low Level of Activity	0.246	0.279†	0.203	0.021	0.196	0.094	0.338†	0.192	0.014	0.053
% Time Spent at Moderate Level of Activity	0.356*	0.461*	0.240	0.138	0.206	0.170	0.388*	0.106	0.284†	0.129
% Time Spent at Moderate or Higher Levels of Activity	0.371*	0.483**	0.294†	0.107	0.163	0.129	0.381*	0.073	0.273†	0.087

*Correlation is significant at the 0.01 level (2-tailed). PCS = Physical Component Summary
†Correlation is significant at the 0.05 level (2-tailed). MCS = Mental Component Summary

Figure.
Scatter plot of steps per day versus Physical Function component of the SF-36.

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decreased self-reported Physical Function ($r = -0.337$, $p = 0.016$). Increasing age was associated with higher self-reported pain (represented by lower scores on the Bodily Pain scale, $r = -0.292$, $p = 0.038$).

The coefficients of determination show that from 8.5 percent to 11.4 percent of the variability in scores is shared between age and the Physical Function and Bodily Pain scales.

DISCUSSION

Measurement Characteristics

Our first goal was to examine the measurement characteristics of both instruments used in this study. We found that the SAM objectively measures activity in ways that are attractive to practitioners and researchers. First, the data can take an infinite number of values, making it potentially very sensitive to small changes in status. Second, ceiling effects essentially have no problems and few problems with floor effects, meaning that either improvements or declines in ambulatory function should be measurable for most individuals. In our sample, although we saw floor effects at the higher levels of activity, the other step-count variables, such as total number of steps and percentage of time spent in moderate level gait activity, demonstrated a range of scores that neither "topped out" nor "bottomed out" the scale.

For this group of patients, we found the SF-36 questionnaire to be a less effective means of measuring activity, a phenomenon consistent with problems reported in the previous literature. Chief among these problems is that substantial proportions of our participants were at either the floor or ceiling value for the various SF-36 scales [19]. This decreased the variability for each scale, and thereby reduced the possibility for high correlations with any other variables. This problem is additionally confounded by the fact that if used to track change over time, these particular SF-36 scales are not sensitive to improvements or declines. Our data also confirm the benefits of using the summary scores (PCS and MCS) with SF-36 data, since floor and ceiling effects for these summated, normalized summary scales were eliminated.

One benefit of the SF-36 is the large number of groups to which study data can be compared. The SF-36 data for the participants in this study showed lower levels of health-related quality of life than several relevant comparison groups, including men over the age of 65 years

from the general U.S. population (significant difference for the PCS and MCS), individuals with diabetes from the general U.S. population (significant difference on the PCS), and individuals with diabetes from the MOS (significant difference on the PCS and MCS). This finding does not surprise us, because all the participants had experienced at least one serious complication related to diabetes, including peripheral neuropathy, lower-limb amputation, or both. These low SF-36 scores may also be related to the participants' status as veterans. Kazis and associates found that veterans receiving care with the Department of Veterans Affairs (VA) Health Care System had significantly lower SF-36 scores than age-matched non-VA populations [20].

Relationships Between Measures

The correlations we identified between SF-36 variables and step-count variables ranged from 0.273 to 0.488. PPMCs lie within the range of -1 to $+1$, with the midpoint of zero indicating no linear association between the two variables. While a real correlation exists, it is not as strong as many researchers have assumed. Evaluation of the scatter plots can be very insightful to reveal the tremendous variation that exists within this data set (**Figure**).

Another method useful for putting PPMCs into perspective is to calculate the percentage of the variability of the data that are "explained" by the association between the two variables. For the step-count data and the SF-36 data, the corresponding coefficients of determination range from only 7.7 percent to 23.8 percent. Given the wide range of physical skills that are used in items within the SF-36, it is important to note that gait performance (measured here as actual step counts) may account for only one-quarter of the variability in perceptions of physical function as a self-reported measure. Interestingly, the age of our participants was not correlated to most of the SF-36 and step-count variables, with the exception of the Physical Function and Bodily Pain scales. Perhaps the fact that all subjects had the chronic disease of diabetes might have blunted any expected association between age and step counts.

Two important conclusions can be drawn from this finding. First, ambulation status appears to be an outcome that matters to patients. This conclusion should not be surprising, because the patient's difficulty with ambulation is frequently cited as the reason for consulting health care providers. Our data support this anecdotal evidence and provide supports that ambulation status, as measured

by step counts, is an important component of self-reported health-related quality of life. Notably, the correlations we found between SF-36 scores and step counts were lower than the correlations that other investigators have documented between various self-reported and laboratory-based physical activity measures [11,16–17].

The second important conclusion to be drawn from our finding is that although related, ambulation status and self-reported health-related quality of life capture different components of the overall construct of health. For example, the large variation in actual steps per day for a given SF-36 Physical Function score reveal the SF-36's limitations in capturing daily ambulatory activity for an individual subject (**Figure**). Examining the individuals at the extremes of the SF-36 Physical Function category, those with scores of 90 and 15, respectively, illustrates this point. The four individuals with SF-36 scores of 90 in Physical Function had a wide range of average daily step counts ranging from 1,261 to 11,654 steps per day. The seven individuals with SF-36 scores of only 15 in Physical Function had average daily step counts ranging from 393 to 4,790 steps per day. This example illustrates that there is a great deal of overlap in the exact number of steps taken per day by individuals with very different self-reported health status.

Although significant correlations were found between the step-count variables and the SF-36 PCS score and two of its scales (Physical Function and Bodily Pain), the correlations were only fair. Also of interest was that two scales of the MCS score (Vitality and Role Limitation/Emotional) were also related to some of the step-count variables. This study provides evidence of a limited relationship of actual ambulatory activity to self-reported measures related to energy, fatigue, and emotional roles.

SUMMARY AND CONCLUSIONS

Step-count data revealed great variation in ambulatory activity and few problems with floor or ceiling effects for men with diabetes. SF-36 data revealed substantial deviations from population norms for the PCS, minor deviations for the MCS, and ceiling and floor effects on several subscales for many participants. From 7.7 percent to 23.8 percent of the variability in scores is shared among the SF-36 and step-count variables. From these results, we conclude that physical activity is a complex concept that is not completely represented by either the SF-36 tool or

by step counts. Researchers should exercise caution when using the SF-36 to specifically measure walking activity.

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