# ORIGINAL ARTICLE

# Electronically captured, patient-reported physical function: an important vital sign in obesity medicine

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#### Summary

#### **Objectives**

Impaired physical function (i.e., inability to walk 200 feet, climb a flight of stairs or perform activities of daily living) predicts poor clinical outcomes and adversely impacts medical and surgical weight management. However, routine assessment physical function is seldom performed clinically. The PROMIS Physical Function Short Form 20a (SF-20a) is a validated questionnaire for assessing patient reported physical function, which includes published T-score percentiles adjusted for gender, age and education. However, the effect that increasing levels of obesity has on these percentiles is unclear. We hypothesized that physical function would decline with increasing level of obesity independent of gender, age, education and comorbidity.

#### Materials and Methods

This study included 1,627 consecutive weight management patients [(mean  $\pm$  SEM), 44.7  $\pm$  0.3 years and 45.1  $\pm$  0.2 kg/m<sup>2</sup>] that completed the PROMIS SF-20a during their initial consultation. We evaluated the association between obesity level and PROMIS T-score percentiles using multiple linear regression adjusting for gender, age, education and Charlson Comorbidity Index (CCI).

#### Results

Multiple linear regression T-score percentiles were lower in obesity class 2 (-12.4%tile, p < 0.0001), class 3 (-17.0%tile, p < 0.0001) and super obesity (-25.1%tile, p < 0.0001) compared to class 1 obesity.

#### Conclusion

In patients referred for weight management, patient reported physical function was progressively lower in a dose-dependent fashion with increasing levels of obesity, independent of gender, age, education and CCI.

Keywords: Morbid obesity, PROMIS, risk stratification, weight management.

# Introduction

Despite increasing awareness of the detrimental impact of obesity-related declines in physical function on overall health and quality of life (1–3), clinical practitioners seldom assess physical function in any quantitative manner. Clinically significant declines in physical function are increasingly common among individuals with super obesity (4). Impairments in physical function also predict poor clinical outcomes and may

adversely impact both non-surgical and surgical interventions (5–8). For example, functional impairment prior to bariatric surgery increases the risk for adverse events, including increased 30-day surgical mortality and suboptimal postoperative weight loss (5,6,9,10). Obesity-related declines in physical function are also associated with diminished ability to perform activities of daily living (ADLs) (11), inactivity (12), bodily pain (12), depression (13) and even sexual dysfunction (14).

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The degree of impairment in self-reported physical function and quality of life influences the type of weight management sought, as well as the intensity (15). Individuals seeking bariatric surgery report diminished quality of life in most domains measured, including physical functioning (16,17). Data from the Longitudinal Assessment of Bariatric Surgery-2 (LABS-2) cohort found that patients undergoing bariatric surgery were more than one standard deviation below the mean compared to the general population for self-reported physical function (18). Further, patients seeking bariatric surgery report lower levels of physical function than even those seeking more conservative medical weight management (19). After surgery, quality of life appears to improve, with the some of the most dramatic increases related to physical functioning when measured by the Short-Form 36 (SF-36) (17).

Early identification of patients with clinically significant impairments in physical function at high risk for adverse outcomes could facilitate proper risk stratification, patient counselling, prehabilitative services and optimization of patient treatment plans consistent with the goals of Accountable Care Organizations, Medicare Shared Savings Programs and the Patient Protection and Affordable Care Act (7,20,21). Therefore, routine assessment of patient reported and/or objectively measured physical function as part of standard of care evaluations would be clinically useful and could be thought of as an additional 'vital sign.' However, because of limited resources, the assessment of physical function in patients with obesity referred for medical and surgical weight loss interventions is seldom performed. The National Institute of Health Patient-Reported Outcome Measurement Information System (PROMIS®) has developed efficient, validated and responsive measures for assessing patient-reported outcomes (PROs), including those related to physical function (22,23). The PROMIS Physical Function performs comparably to 'legacy' instruments (i.e. Short Form-36 and the Health Assessment-Disability Index), but also provides T-scores normed on the general population and the ability to tailor the instrument length (24).

Because of the potential confounding effect of obesity on physical function assessed using the PROMIS Physical Function Short-Form 20a (SF-20a) questionnaire, this study aimed to develop T-score percentiles that were adjusted for obesity class, gender, age, education and comorbidity burden (i.e. Charlson Comorbidity Index (CCI)). We hypothesized that physical function scores would decline with increasing level of obesity independent of gender, age, education and comorbidity burden.

# Materials and methods

# Geisinger Center for Nutrition and Weight Management

The PROMIS SF-20a questionnaires and physical function assessments were administered at the Center for Nutrition and Weight Management at Geisinger Medical Center. Geisinger Medical Center is part of the larger Geisinger Health System, an integrated health services organization with multiple hospital campuses. Geisinger Medical Center is located in rural Danville, Pennsylvania. Patients entering the Center for Nutrition and Weight Management clinic for weight-loss/ maintenance may choose to lose weight using conservative or surgical weight-loss interventions. The clinic staff includes credentialed physicians, physician assistants, certified registered nurse practitioners, registered dieticians, clinical nurse specialists, bariatric nurse coordinators, exercise experts and behavioural health specialists who specialize in weight loss. A conservative weight-loss plan may include: meal plans and nutrition education, wellness/fitness goals, behaviour modification, weight loss medications and/or a medically supervised full and partial liquid diet plan.

The bariatric surgery program at the clinic offers three surgical options: Roux-en-Y Gastric Bypass, Sleeve Gastrectomy and Biliopancreatic Diversion. Lifestyle education, support groups, nutritional information and medical care are all incorporated into the program. The bariatric surgery program is recognized by the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS) as part of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MSAQIP), a national accreditation standard for bariatric surgery centres. For more information about the standards required for this accreditation, please refer to the MSAQIP Standards Manual which can be found on the ACS website (25).

#### Study population

Patients entering the medical or surgical weight management programs in the Center for Nutrition and Weight management at Geisinger Medical Center completed a health exam and a battery of self-administered questionnaires including the PROMIS SF-20a as part of their standard of care clinic visit. As part of their standard of care clinic visits, their height and weight were assessed in light-weight clothing in the absence of shoes using calibrated stadiometers and weight scales. BMI was calculated as weight in kg divided by height in m<sup>2</sup>. One thousand six hundred twenty-seven patients with visits occurring between March 2014 and January 2016 were included in this analysis. Overall, the mean  $\pm$  SEM for age and BMI were 44.7  $\pm$  0.3 years and 45.1  $\pm$  0.2 kg/m<sup>2</sup>, respectively. We obtained approval for this retrospective study from the Geisinger Institution Review Board (IRB) prior to receiving and evaluating the de-identified data.

#### Questionnaire

The PROMIS SF-20a questionnaire was administered electronically using a touch screen and stylus. The PROMIS SF-20a questionnaire, manual and scoring algorithm can be found at the Assessment Center website (26). The clinic used a commercially available software package (DatStat, Seattle, WA) to deliver the questionnaire and electronically collect the patient-reported data. To facilitate interpretation, the PROMIS® website has published tables that provide T-score percentiles that are stratified by gender, age and education that were initially derived from a diverse population of over 15,000 participants (27). Moreover, a recent study demonstrates that the PROMIS physical function measures are valid across a diverse patient populations ranging from rheumatoid arthritis to chronic heart failure (28).

#### Data collection and analysis

A retrospective electronic extraction of de-identified data was performed that included BMI (kg/m<sup>2</sup>), gender, age (<35, 35-44, 45-54, 55+), race (white, black, other), education level (<high school, high school, >high school), marital status (married, single, separated/divorced, other), smoking history (Yes = 100+ cigarettes smoked in lifetime), CCI (scores of 0, 1, 2,  $\geq$ 3) and responses to the PROMIS SF-20a questionnaire. Respondents to the PROMIS SF-20a were stratified into obesity class including Class 1 (BMI 30-34.99 kg/m<sup>2</sup>), Class 2 (BMI 35-39.99 kg/m<sup>2</sup>), Class 3 (BMI 40-49.99 kg/m<sup>2</sup>) and super obese (BMI $\geq$ 50 kg/m<sup>2</sup>). We sought to develop T-score percentiles that were adjusted for obesity class, gender, age, education and comorbidity burden (i.e. CCI). The CCI is scoring system for predicting mortality based on presence/absence of 22 medical conditions (29). The CCI was calculated using ICD diagnoses codes reported with outpatient clinic visits and/or when they were added to the patients problem list within the electronic medical record. A score of 0 implies that none of the diseases were present with higher scores implying more severe comorbidity burden. The association between obesity level and PROMIS physical function percentile score was evaluated using multiple linear regression including adjustments for gender, age, education and CCI. SAS version 9.3 (Cary, NC) was used for statistical analysis. For each domain of the demographic profile, Chi-square analysis was used to test statistical significance between each categorical variable by obesity class. All tests were two-sided, and p-values <0.05 were considered significant.

## **Results**

Table 1 presents the demographic profile of the subjects stratified by obesity class. Results are reported for 1,627 total subjects; 181 obesity class 1; 331 obesity class 2; 696 obesity class 3; 419 super obese, with ~77% female. Although there were more females than males at each obesity level, the percentage of females declined going from class 1 obesity to super obese (p < 0.0001). The majority of patients were white with no statistically significant differences in race between obesity levels (p = 0.19). Although most patients (51% to 68%) completed high school or higher, the percentage that completed high school or higher declined from class 1 obesity to super obese (p < 0.001). Moreover, the percentage of subjects that were married also declined from class 1 obesity to super obese (p = 0.002). Finally, approximately half the subjects were smokers with no statistically significant differences in smoking status between obesity levels (p = 0.12).

Figure 1A displays a box plot of unadjusted PROMIS physical function percentiles by obesity level. The median percentile scores were lower with each obesity level. In multiple linear regression including adjustments for gender, age, education and CCI, increasing obesity level was significantly associated with lower PROMIS physical function score (Table 2). The multiple linear regression equations were also used to calculate estimated mean percentiles scores using population averages of gender, age, education and CCI of this study cohort with resulting mean PROMIS percentile scores for class 1, class 2, class 3 and super obesity of 43.3% (95% CI = [39.7, 46.8]), 30.9% (95% CI = [28.1, 33.7]), 26.3% (95% CI = [24.2, 28.4]), 18.2% (95% CI = [15.7, 20.7]), respectively (Figure 1B). Moreover, the univariate analysis revealed that BMI explained 10.3% of the variance in the PROMIS physical function scores, and the multivariate analysis revealed that BMI explained 9.7% of the variance in the PROMIS physical function scores after adjusting for gender, age, education and CCI.

### Discussion

The primary finding of the present study was that self-reported physical function assessed using the PROMIS SF-20a was progressively lower with higher levels of obesity independent of gender, age, education

	Obesity level				
	Class 1 <i>N</i> = 181	Class 2 <i>N</i> = 331	Class 3 <i>N</i> = 696	Super Obese $N = 419$	p-value*
Sex					
Male	25 (14%)	55 (17%)	183 (26%)	105 (25%)	< 0.001
Female	156 (86%)	276 (83%)	513 (74%)	314 (75%)	
Age					
<35 years	39 (22%)	81 (24%)	176 (25%)	113 (27%)	0.42
35–44 years	48 (27%)	85 (26%)	165 (24%)	104 (25%)	
45–55 years	43 (24%)	89 (27%)	167 (24%)	82 (20%)	
>55 years	51 (28%)	76 (23%)	188 (27%)	120 (29%)	
Race					
White	177 (98%)	321 (97%)	681 (98%)	401 (96%)	0.19
Black	2 (1%)	7 (2%)	13 (2%)	16 (4%)	
Other	2 (1%)	3 (1%)	2 (<1%)	2 (<1%)	
Education					
< High school	3 (2%)	18 (5%)	44 (6%)	31 (7%)	< 0.001
High school diploma	55 (30%)	105 (32%)	258 (37%)	175 (42%)	
> High school	123 (68%)	208 (63%)	394 (57%)	213 (51%)	
Marital status					
Married	111 (61%)	187 (57%)	370 (53%)	190 (46%)	0.0012
Single	36 (20%)	66 (20%)	184 (27%)	137 (33%)	
Separated/divorced	27 (15%)	48 (15%)	95 (14%)	59 (14%)	
Other/unknown	7 (4%)	30 (8%)	47 (6%)	33 (7%)	
Smoked >100 cigarettes					
Yes	69 (38%)	163 (49%)	320 (46%)	190 (45%)	0.12
No	112 (62%)	168 (51%)	376 (54%)	229 (55%)	
Charlson Comorbidity Index					
0	120 (66%)	201 (61%)	388 (56%)	232 (55%)	0.034
1	42 (23%)	74 (22%)	175 (25%)	122 (29%)	
2	11 (6%)	26 (8%)	60 (9%)	38 (9%)	
3+	8 (4%)	30 (9%)	73 (10%)	27 (6%)	

 Table 1
 Demographic profile by obesity level of 1,627 consecutive weight management patients who completed the PROMIS Physical Function

 20a Questionnaire at their initial consultation
 Provide the PROMIS Physical Function

\*Chi-square analysis was used to test statistical significance between each categorical variable by obesity class.

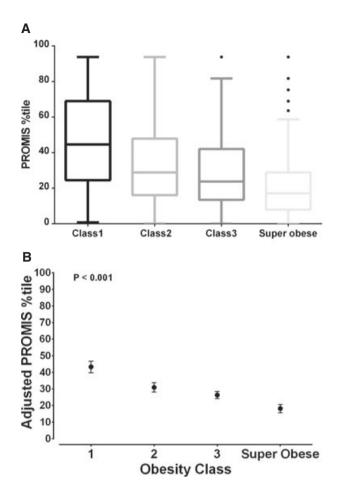
Data presented as n (%).

Class 1 (BMI 30–34.99 kg/m<sup>2</sup>), Class 2 (BMI 35–39.99 kg/m<sup>2</sup>), Class 3 (BMI 40–49.99 kg/m<sup>2</sup>) and super obese (BMI ≥50 kg/m<sup>2</sup>).

and comorbidity burden in patients referred for weight management. Consistent with the present results, reports utilizing the Behavioural Risk Factor Surveillance Survey also suggest strong associations between the level of obesity and the degree of functional impairment (30). Even after controlling for various covariates including demographics, socioeconomic status, lifestyle behaviours, mental health status, joint pain status and comorbid conditions, the odds ratio between obesity and functional impairment remained statistically significant at 1.90 (30). Likewise, compared to non-obese controls, individuals with obesity displayed significantly lower physical performance scores when assessed using objective measures (4). In older adults, progressing from normal weight to overweight to obese exacerbates the normal age-related declines in physical function (31). In a large cohort of

adults aged 65 and older, physical function declined in a dose-response fashion with increasing BMI (31), indicating physical functioning may be a more important indicator of health status than BMI in this population.

Data from the LABS-2 cohort first demonstrated a high prevalence of mobility impairment and disability among bariatric surgery candidates using a standardized 400-m walk test (12). Moreover, bariatric surgery led to significant improvements in pain, self-reported and objectively measured physical function over 3 years in the LABS-2 cohort (32). The present study further extends the findings from these prior studies by demonstrating that the level of obesity is significantly associated with lower self-reported physical function independent of gender, age, education and comorbidity burden in patients referred for weight management who are at increased risk for future mobility



**Figure 1** Panel A presents box plots of unadjusted PROMIS % tiles stratified by obesity level (n = 1,627). Panel B presents PROMIS % iles *stratified by* obesity level after adjusting for gender, age, education and Charlson Comorbidity Index. PROMIS T-score % tiles were calculating using multiple linear regression adjusting for gender, age, education and Charlson Comorbidity Index (CCI). Data presented as mean plus the 95% confidence interval (n = 1,627). Class 1 (BMI 30–34.99 kg/m<sup>2</sup>), Class 2 (BMI 35–39.99 kg/m<sup>2</sup>), Class 3 (BMI 40–49.99 kg/m<sup>2</sup>) and super obese (BMI  $\ge 50 \text{ kg/m}^2$ ).

disability and loss of functional independence. Moreover, our results reinforce the need for consistent and accurate tools for assessing physical function in clinical settings.

In our study, we captured a PRO related to physical function electronically, allowing for integration of these data into the EHR. The use of PROs in the EHR may help to standardize symptom reporting, enhance the completeness of symptom reporting and communicate the patient's perspective or 'voice' directly into the medical record (33). We propose that routinely assessing these PROs along with objective measures of physical function during standard of care clinic visits provides clinically useful data that could be used as an additional 'vital sign.' Patients may also not feel comfortable fully disclosing sensitive health information directly to their physician

**Table 2** Association between PROMIS percentile scores and level of obesity adjusted for gender, age, education and Charlson Comorbidity Index (n = 1,627). PROMIS T-score %tiles were calculating using multiple linear regression adjusting for gender, age, education and Charlson Comorbidity Index (CCI)

Parameter	Estimate	SE	<i>p</i> -value
Intercept	61.9	2.1	< 0.0001
Gender			
Male	Reference	_	_
Female	-5.7%tile	1.2	< 0.0001
Age			
<35 years	Reference	_	_
35–44 years	-7.4%tile	1.4	< 0.0001
45–55 years	-9.9%tile	1.4	< 0.0001
55+ years	-12.8%tile	1.5	< 0.0001
Education			
<high school<="" td=""><td>-8.0%tile</td><td>2.2</td><td>0.0003</td></high>	-8.0%tile	2.2	0.0003
High school diploma	-4.7%tile	1.1	< 0.0001
>High school	Reference	_	_
Charlson Comorbidity Index			
0	Reference		
1	-2.0%tile	1.2	0.103
2	-6.0%tile	1.9	0.0021
3+	-8.2%tile	2.0	< 0.0001
Obesity			
Class 1	Reference	_	_
Class 2	-12.4%tile	1.9	< 0.0001
Class 3	-17.0%tile	1.7	< 0.0001
Super obese	-25.1%tile	1.9	< 0.0001

Class 1 (BMI 30–34.99 kg/m<sup>2</sup>), Class 2 (BMI 35–39.99 kg/m<sup>2</sup>), Class 3 (BMI 40–49.99 kg/m<sup>2</sup>) and super obese (BMI  $\ge$  50 kg/m<sup>2</sup>).

(34). Patient reported outcomes integrated with clinical care have been studied fairly extensively in oncology clinics (34-39). Immediate integration of PRO into the EHR can facilitate symptom reporting as well as referral for psychosocial and supportive care in ambulatory cancer centres (40). PROs can be administered using different mediums including touch screens and/or email (electronic PROs [ePROs]). When physicians utilize PROs of emotional well-being and results are integrated into the EHR, health-related quality of life improves compared to control subjects and subjects who reported outcomes, but received no feedback from physicians (35). Although PROs, including physical function measures, have been extensively studied in oncology clinics, our study was unique in that it measured physical function using ePROs in a weight-loss clinic setting using a validated PROMIS instrument. Finally, incorporation of ePROs has been suggested to not only to facilitate care, but also to enhance comparative effectiveness research (41).

Poorer weight management outcomes in individuals with high BMI may be explained, in part, by functional impairments. Patients who present for bariatric surgery with higher pre-surgical weight experience less excess

© 2016 The Authors Obesity Science & Practice published by John Wiley & Sons Ltd, World Obesity and The Obesity Society. Obesity Science & Practice weight loss postoperatively and report higher pain and functional impairment levels (42). The stress placed on joints related to obesity can result in significant pain. making physical activity challenging. In addition, patients with high BMI are more likely to avoid exercise because of anxiety caused by social discomfort and the somatic symptoms associated with exercise (i.e. shortness of breath, heart palpitations and/or sweating) (42), Avoidant behaviours can lead to sedentary lifestyles, deconditioning, additional weight gain and worsening physical function. Additionally, excess body weight can be a barrier to effectively performing normal ADLs, although ADL assessment was outside the scope of this study. Future studies should examine the potential effects of different distributions of excess body weight (i.e. gynoid vs. android obesity) on patient-reported as well as objective measures of physical function. PROMIS established SF-20a T-score percentiles already account for gender, age and education. However, previously reported results in combination with the results reported in this study indicate that the established PROMIS SF-20a percentile scores should also account for the effect of obesity level.

Interest is increasing regarding the importance of functional impairment as an indicator of disease prognosis and surgical risk. Functional impairment has been identified as a risk factor for poor postoperative outcomes in hepatobiliary surgery (43), vascular surgery (44), abdominal hernia repair (45) and bariatric surgery (7,46). In addition, a prior study suggests that a timed stair climb was the single strongest predictor of operative outcomes including surgical complications and length of hospital stay in patients undergoing abdominal surgery (47). The recognition of the importance of functional assessment in surgical risk management, and the awareness that functional impairments may be modifiable during the preoperative preparation, has prompted multidisciplinary interventions including supervised exercise designed to potentially reduce surgical risk.

# Limitations

The present study has several strengths and limitations. First, this study used electronic data capture to collect self-reported physical function on greater than 1,500 consecutive patients referred for either medical or surgical weight management. Utilizing the electronic health records system enabled us to adjust for comorbidity burden, reducing the likelihood that our findings were because of secondary effects of increased morbidity. Therefore, the present results are generalizable to overweight and obese patients seeking medical and surgical weight management. However, using data acquired from a cohort residing in a rural area may limit the generalizability of the findings to other geographic locations. By design, individuals not seeking weight management were also not included. Another limitation of the present study was the patient population was predominantly Caucasian.

# **Future directions**

Further studies are warranted to address some of the limitations identified above. For example, what is the potential impact that routine assessments of patient reported and/or objectively measured physical function have on clinical practice and outcomes in patients who are overweight/obese seen in primary care clinics as well as specialty clinics? Future studies are also needed to further assess the impact of the level of obesity has on physical function in more racially/ethnically diverse populations. While the PROMIS SF-20a is easy to use, the length of the questions could remain burdensome for patients as well as clinical practitioners. Therefore, further studies are warranted to investigate other renditions of the PROMIS questionnaires (i.e. PROMIS SF-6a) as well as the computer adaptive testing for use in clinical practice. Finally, further research is needed to examine how early identification of patients with impairments in physical function can be referred for prehabilitative services to and optimize treatment plans and clinic outcomes.

# Conclusion

Increasing obesity level was independently associated with a decline in percentile scores on the PROMIS SF-20a, a measure of physical function. The PROMIS SF-20a could serve as a simple clinical tool to assess physical function in a clinical setting. Finally, further studies may be necessary to determine the clinical utility PROMIS physical function scores adjusted for BMI compared to raw PROMIS scores for predicting poor clinical outcomes in overweight/obese populations.

# **Conflict of Interest Statement**

None

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The authors report no conflicts of interests.

BAI, GCW, CDS and PNB contributed to conception and design of analyses. GCW, CS and AC contributed to acquisition data. BAI and GCW contributed to data analysis. BAI, GCW and JF contributed to drafting of manuscript. BAI, GCW, CDS, PNB, ML and JF contributed to critical revisions.

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