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The six-minute walk test as a measure of postoperative recovery after colorectal resection: further examination of its measurement properties

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Abstract

Introduction Patients, clinicians and researchers seek an easy, reproducible and valid measure of postoperative recovery. The six-minute walk test (6MWT) is a low-cost measure of physical function, which is a relevant dimension of recovery. The aim of the present study was to contribute further evidence for the validity of the 6MWT as a measure of postoperative recovery after colorectal surgery.

Methods This study involved a sample of 174 patients enrolled in three previous randomized controlled trials. Construct validity was assessed by testing the hypotheses that the distance walked in 6 min (6MWD) at 4 weeks after surgery is greater (1) in younger versus older patients, (2) in patients with higher preoperative physical status versus lower, (3) after laparoscopic versus open surgery, (4) in patients without postoperative complications versus with postoperative complications; and that 6MWD (5) correlates cross-sectionally with self-reported physical activity as measured with a questionnaire (CHAMPS). Statistical analysis was performed using linear regression and Spearman's correlation. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist was used to guide the formulation of hypotheses and reporting of results.

Results One hundred and fifty-one patients who completed the 6MWT at 4 weeks after surgery were included in the analysis. All hypotheses tested for construct validity were supported by the data. Older age, poorer physical status, open surgery and occurrence of postoperative complications were associated with clinically relevant reduction in 6MWD (>19 m). There was a moderate positive correlation between 6MWD and patient-reported physical activity ($r = 0.46$).

Conclusions This study contributes further evidence for the construct validity of the 6MWT as a measure of postoperative recovery after colorectal surgery. Results from this study support the use of the 6MWT as an outcome measure in studies evaluating interventions aimed to improve postoperative recovery.

Keywords Six-minute walk test · Validity evidence · Postoperative recovery · Physical function · Colorectal surgery · Laparoscopy

Major abdominal surgery evokes a physiologic stress and is associated with a period of disability. Patients commonly ask about the time it will take them to recover from surgery and return to their normal employment and leisure activities, and many perioperative innovations are said to "improve recovery" [1]. Yet little information is available for clinicians and researchers on how best to quantify recovery after surgery [2]. Recovery is a complex construct which comprises multiple dimensions of health (i.e., physical, mental and social) and follows a defined trajectory (a rapid

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deterioration of health status followed by a gradual return toward baseline) [3]. Length of stay (LOS) has been extensively used to measure recovery, as discharge from hospital presumes good pain control, ability to self-care, as well as tolerance of oral nutrition [4]. However, this measure is influenced by many nonclinical factors (e.g., surgeons' preference and hospital tradition), and only captures the early phase of recovery. It is clear that patients are not fully recovered to their baseline status when they leave the hospital [3, 5] and full recovery takes weeks to months [6].

One key dimension of recovery is physical function, as it affects the ability to perform activities of daily living, return to work and resume social leisure life. The six-minute walk test (6MWT), which measures the total distance that a patient is able to walk in 6 min (six-minute walk distance, 6MWD), is a performance-based measure of functional walking capacity. This test was originally developed to assess exercise tolerance in patients with cardiac and respiratory diseases [7], but it is now extensively used in a variety of settings [8, 9]. As opposed to more sophisticated exercise tests [e.g., cardio-pulmonary exercise testing (CPET)], the 6MWT is simple, does not require expensive equipment or specialized personnel, and can be performed in nearly any clinical location [10]. Previous studies have demonstrated a positive correlation of the 6MWD with CPET results (i.e., VO2 max) in different surgical populations [11, 12].

A preliminary study supported the construct validity and responsiveness of the 6MWT as an indicator of recovery after colorectal surgery [13]. This study, however, relied on a limited number of patients undergoing exclusively open colorectal resection. At that time, minimally invasive surgery and standardized perioperative care protocols (i.e., enhanced recovery pathways) were not part of routine care, which significantly differs from current practice [14]. Validation of a measurement instrument is a continuous process of evidence accumulation in order to support the use of the tool in a variety of surgical populations and contexts. Therefore, the aim of the present study is to contribute further evidence for the validity of the 6MWT as a measure of postoperative recovery in patients undergoing elective colorectal surgery in the context of laparoscopy and an enhanced recovery program.

Materials and methods

Participants and setting

This validation study involved a sample of 174 patients enrolled in one published [15] and two recently completed randomized controlled trials (RCT) (ethics board approval codes 11-240-SDR and GEN11-004) aimed at investigating the role of nutrition and physical prehabilitation on recovery after colorectal surgery. These RCTs included adult patients scheduled for colorectal cancer resection at a university teaching hospital between September 2011 and September 2014. During this period, all patients were treated according to an enhanced recovery program as previously described [14]. Exclusion criteria were premorbid conditions that contraindicated patient exercise, and inability to speak English or French. Eligible consenting patients underwent preoperative assessment within 4 weeks of the scheduled operation completing baseline questionnaires, as well as biochemical and functional testing. Postoperative evaluations took place at 4 weeks after surgery. At both time points, patients performed the 6MWT and responded to a physical activity questionnaire [the Community Healthy Activities Model Program for Seniors (CHAMPS)]. Demographic and baseline patient characteristics including body mass index (BMI), comorbidities, American Society of Anesthesiologists (ASA) score, operative and postoperative parameters were also recorded. Patients converted from laparoscopic to open surgery were treated as open surgery patients in the analysis. Postoperative complications and hospital readmissions were recorded up to 30 days after surgery. Complication severity was graded according to the Clavien–Dindo classification [16]. Complications graded as III–V were defined as major.

Measures

Patients performed the 6MWT along a 15 m stretch of a flat corridor and were instructed to walk for 6 min at the pace that will make them feel tired. The hallway was marked with meter tacks, allowing a precise recording of the total distance covered by the patient in meters (m). Standardized encouragements were given minute-by-minute according to the guidelines by the American Thoracic Society [10]. Age- and sex-specific predicted 6MWD was calculated using the following formula: predicted distance walked in 6 min (m) = 868 − (age × 2.9) − (female × 74.7),
where age is in years, and the value "1" is assigned for females and "0" assigned to males [7]. The minimal important difference (MID) for 6MWD (i.e., "the smallest change in an outcome measure perceived as beneficial by patients or physicians" [17]) has been estimated at 19 m for between-group comparisons in patients undergoing colorectal surgery [18].

The CHAMPS is a self-reported measure of physical activity. It comprises a 41-item questionnaire that was originally developed to assess the effectiveness of interventions aimed at increasing the level of physical activity in the elderly [19]. The frequency and time spent

performing a range of physical and social activities during the past week are weighted according to the metabolic value of each activity. Total caloric expenditure per kilogram per week is then estimated. A previous study supported the validity of the CHAMPS as a measure of recovery of physical function after abdominal surgery [20].

Construct validity

This validity study was conducted according to the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist [21]. This checklist was designed to evaluate the methodological quality of studies on measurement properties and set minimal standards for design and reporting. The COSMIN describes two types of validity that are relevant to performance-based measures: criterion-related validity (degree to which a measure is an adequate reflection of a gold standard measure of the construct of interest) and construct validity (degree to which the measure is consistent with hypotheses based on the assumption that it measures the construct of interest) [21]. As there is no gold standard measure of the construct "recovery," this study focused on construct validity. According to the COSMIN, hypotheses tested for construct validity revolve around the degree to which the measure of interest (1) can demonstrate differences between relevant groups (i.e., groups known to differ on the construct of interest) and/or (2) is related to other measures of the same construct. It is recommended that hypotheses testing be based on the expected direction and magnitude of differences or correlations rather than on sample size-dependent statistics, such as p values [22].

Construct validity of the 6MWT as a measure of postoperative recovery was assessed by testing the hypotheses that the 6MWD at 4 weeks after surgery is greater (1) in younger patients (<75 years old) versus older patients (≥75 years old), (2) in patients with higher preoperative physical status (ASA < 2) versus lower preoperative physical status (ASA ≥ 3), (3) after laparoscopic versus open surgery, (4) in patients without postoperative complications versus with postoperative complications; and that the 6MWD (5) correlates cross-sectionally with self-reported physical activity as measured with the CHAMPS questionnaire. We hypothesized that the magnitude of differences between groups would be equal or greater than the MID of 19 m [18], and that the correlation between 6MWD and CHAMPS scores would be positive and moderate (correlation coefficient 0.2–0.5) [23]. All the hypotheses tested in this study were formulated prior to merging the databases and analyzing the data.

Statistical analysis

We conducted a complete case analysis including patients who performed the 6MWT at baseline and at 4 weeks after surgery. The characteristics of the included patients and those lost to follow-up were compared using Chi-square test or Fisher's exact test (for categorical data) and Student's t test or Mann–Whitney U test (for continuous data). Hypotheses 1–4 were tested using multiple linear regression where 6MWD at 4 weeks after surgery was the dependent outcome variable. Analyses were adjusted for patient baseline 6MWD to take into account preoperative functional walking capacity as a potential confounder. Linear regression coefficients were interpreted as mean difference in 6MWD between groups. Hypothesis 5 was tested using Spearman's rank correlation. All statistical analyses were performed using STATA® version 13.1 software (StataCorp, College Station, TX, USA).

Results

Of the 174 patients enrolled in the three RCTs, a total of 151 (87 %) performed the 6MWT preoperatively and 4 weeks after surgery and were included in this validity study. Patients lost to follow-up ($n = 23$) were older [73 (95 % CI 68–77) versus 67 (95 % CI 65–69), $p = 0.019$] and less likely to have received laparoscopic surgery (74 vs. 91 %, $p = 0.023$). No difference was found regarding other baseline and operative characteristics, including preoperative 6MWD and CHAMPS scores (Table 1). After surgery, excluded patients had higher rates of overall complications (61 vs. 31 %, $p = 0.005$), severe complications (35 vs. 5 %, $p < 0.001$) and 30-day readmissions (32 vs. 12 %, $p = 0.02$) (Table 2).

All the four hypotheses involving group comparisons were confirmed by the data. At 4 weeks after surgery, 6MWD was greater in younger versus older patients (mean difference 28.3 m, 95 % CI −8.1 to 64.7), in patients with higher preoperative physical status versus lower (mean difference 44.2 m, 95 % CI 15.5–72.8), after laparoscopic versus open surgery (mean difference 58.8 m, 95 % CI 11.5–106.0) and in patients without postoperative complications versus with postoperative complications (mean difference 27.1 m, 95 % CI −1.9 to 56.1) (Table 3). The hypothesis involving cross-sectional relationship between 6MWD and CHAMPS scores was also confirmed as we found a moderate positive correlation between the measures ($r = 0.46$).

Table 1 Baseline patient characteristics and operative data in included and excluded patients

Variable	Included $n = 151$	Excluded $n = 23$	p value
Age, years	67 (65–69)	73 (68–77)	0.019
75+	34 (23 %)	13 (57 %)	0.002
Gender, male sex	98 (65 %)	15 (65 %)	0.976
Body mass index, kg/m^2	28 (27–28)	29 (22–37)	0.218
ASA physical status			
I–II	100 (66 %)	14 (61 %)	0.341
III+	51 (34 %)	9 (39 %)	
Diabetes	24 (16 %)	3 (13 %)	1.000
Malignancy	139 (92 %)	19 (83 %)	0.234
TNM cancer stage			0.168*
1	38 (25 %)	5 (22 %)	
2	43 (29 %)	6 (26 %)	
3	52 (34 %)	3 (13 %)	
4	4 (3 %)	2 (9 %)	
No cancer	12 (8 %)	4 (17 %)	
Missing pathology data	2 (1 %)	3 (13 %)	
Mode of surgery			
Laparoscopy	138 (91 %)	17 (74 %)	0.023
Laparoscopy converted to open	7 (5 %)	2 (9 %)	0.339
Open	6 (4 %)	4 (17 %)	0.029
Type of procedure			0.289**
Colonic surgery			
Right hemicolectomy	48 (32 %)	8 (35 %)	
Left hemicolectomy	9 (6 %)	2 (9 %)	
Sigmoidectomy	10 (7 %)	2 (9 %)	
Subtotal/total colectomy	4 (3 %)	1 (4 %)	
Other	4 (3 %)	1 (4 %)	
Rectal surgery			
Anterior resection	64 (42 %)	6 (26 %)	
Abdominoperineal resection	10 (7 %)	3 (13 %)	
Proctocolectomy	2 (1 %)	0	
Stoma creation	39 (26 %)	7 (30 %)	0.641
Albumin serum levels, g/L	39 (39–40)	39 (37–41)	0.619
C-reactive protein serum levels, mg/L	9 (5–12)	10 (4–16)	0.772
6MWT, meters	429 (411–447)	415 (367–464)	0.565
6MWT, % predicted	66 (64–69)	66 (58–73)	0.896
Physical activity, kcal/kg per week	30 [11–63]	25 [10–45]	0.460

Data are presented as mean (95 % CI), number of patients (%) or median [25th–75th percentile]

ASA American Society of Anesthesiologists, *TNM* tumor–node–metastasis, *6MWT* six-minute walk test

* Refers to Chi-square test for trend for TNM cancer stage between groups

** Refers to Chi-square test for colon versus rectal resections

Discussion

The present study contributes evidence for the construct validity of the 6MWT as a measure of postoperative recovery after elective colorectal resection. As we hypothesized, 6MWD at 4 weeks after surgery was able to discriminate between younger and older patients, patients with higher versus lower preoperative physical status, patients treated with laparoscopic versus open surgery and patients who experienced postoperative complications versus those with an uneventful postoperative course. The 6MWT was also found to have a moderate positive

Table 2 Postoperative outcomes and measurements in included and excluded patients

Variable	Included $n = 151$	Excluded $n = 23$	p value
Patients with at least one 30-day complication	47 (31 %)	14 (61 %)	0.005
Surgical site infection	7 (5 %)	2 (9 %)	0.339
Ileus	21 (14 %)	6 (26 %)	0.133
Abscess	5 (3 %)	2 (9 %)	0.232
Anastomotic leak	4 (3 %)	2 (9 %)	0.180
Urinary tract infection	2 (1 %)	2 (9 %)	0.085
Urinary retention	3 (2 %)	1 (4 %)	0.436
Bleeding requiring transfusion	2 (1 %)	1 (4 %)	0.348
Cardiopulmonary complication	3 (2 %)	2 (9 %)	0.131
Intestinal ischemia	1 (1 %)	0	1.000
Grade of most severe complication			
Clavien I	21 (14 %)	3 (13 %)	<0.001*
Clavien II	19 (13 %)	3 (13 %)	
Clavien III	5 (3 %)	5 (22 %)	
Clavien IV	3 (2 %)	2 (9 %)	
Clavien V	0	1 (4 %)	
Length of hospital stay, days	4 [3–6]	4 [3–16]	0.116
30-day hospital readmission	18 (12 %)	7 (32 %)	0.020
4 weeks after surgery 6MWT, meters	404 (384–422)	na	
4 weeks after surgery physical activity, kcal/kg per week	24 [8–43]	na	
Missing 4 weeks questionnaire	21 (14 %)		

Data are presented as number of patients (%), median [25th–75th percentile], or mean (95 % CI)

6MWT six-minute walk test

* Refers to Chi-square test for major complications (Grade III–V)

Table 3 Hypotheses tested for known-groups construct validity of the 6MWT as an outcome measure of postoperative recovery after colorectal resection

Comparisons	Number of patients	Coefficient*	95 % CI	Hypothesis confirmed
Younger (<75 years) versus older patients (≥75 years)	117 versus 34	+28.3	−8.1 to +64.7	Yes
Higher physical status (ASA I–II) versus lower physical status (ASA III+)	100 versus 51	+44.2	+15.5 to +72.8	Yes
Laparoscopic versus open surgery	138 versus 13	+58.8	+11.5 to +106.0	Yes
No postoperative complication versus any postoperative complication	104 versus 47	+27.1	−1.9 to +56.1	Yes

ASA American Society of Anesthesiologists

* Should be interpreted as mean difference (meters) between groups 4 weeks after surgery; regression analysis adjusted for preoperative 6-min walk distance

correlation with patient-reported physical activity using the CHAMPS questionnaire.

Physical function represents a crucial dimension of recovery. This dimension can be measured either through performance-based measures (e.g., 6MWT, handgrip test, 30-s sit-to-stand test) or through patient-reported outcome (PRO) measures (e.g., CHAMPS, Short-Form 36 physical component scale) [6, 24]. As walking is essential to everyday activities and integrates different components of functional capacity (i.e., balance, speed and endurance) [25], it is possible that the 6MWT captures a wider spectrum of recovery than expected. Although this test may miss the patient's perspective and other health-related quality of life domains that are unique to PRO measures, the 6MWT has the advantage of providing an objective measure that avoids bias associated with PRO measures such as "response shift" (i.e., a change in patients' values, internal standards and conceptualization interfering with

PRO responses) [26] and "floor and ceiling effect" (i.e., PRO responses achieving maximal or minimal levels reducing sensitivity to change) [27]. In fact, a previous study suggested that performance-based measures capture postoperative functional impairment more accurately than PRO measures [6].

In this cohort, only 13 % of patients did not perform the test at 4 weeks after surgery, a relatively low rate of missing data in comparison with previous studies assessing recovery through PROs [28, 29]. Patients who failed to perform the test at 4 weeks were older, had a higher rate of open surgery and experienced more postoperative complications. This suggests that poor postoperative physical status was a common reason for patients being lost to follow-up. The exclusion of these patients from the analysis might have biased our comparisons, but toward the null hypothesis (i.e., differences in 6MWD between groups would likely be even larger if these patients were included). This strengthens our conclusions regarding the validity of the 6MWT as a measure of recovery.

Our results corroborate some of the findings of the validation study by Moriello et al. [13], which also found an association of postoperative 6MWD with age, ASA scores and presence of postoperative complications after colorectal surgery. Previous research has shown that advanced age and poor physical status are associated with a slower return to baseline functional status [6, 30]. Similarly, postoperative morbidity appears to have a detrimental effect on quality of life early after surgery and in the long-term, affecting mostly the mobility and physical function domains [29, 31]. An additional finding of the current study is the positive cross-sectional correlation between the 6MWD and self-reported physical activity as measured using the CHAMPS questionnaire. As the CHAMPS covers a wide range of lifestyle activities (e.g., household activities, cleaning, yard work) [19], this finding reinforces the idea of using the 6MWT as a proxy measure for the ability to perform activities of daily living after surgery.

A novel and relevant finding of this study is that the 6MWT was able to capture differences in recovery between patients undergoing laparoscopic versus open surgery at 4 weeks postoperatively. Previous evidence suggests that patients treated with laparoscopy have reduced pain scores, faster recovery of bowel function and earlier hospital discharge in comparison with conventional open surgery [32]. However, the benefits of laparoscopy have appeared to be limited to the very early phase of recovery, as studies using PRO measures [e.g., SF-36 and the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire] have failed to show any significant difference in recovery by 2 weeks after surgery [28, 33, 34]. This could also reflect the use of questionnaires that are not sensitive enough to detect differences in recovery. The 6MWT specifically targets physical function, which may be the domain of recovery that is most influenced by open surgery, as it involves lengthier incisions, greater tissue trauma and greater physiological stress in comparison with laparoscopy [35]. This would explain why the 6MWT remains sensitive to differences between these approaches even in the longer term.

Strengths and limitations

Strengths of this study include the adoption of accepted guidelines to test the measurement properties of the 6MWT [21] and the use of MIDs to formulate hypotheses involving group comparisons. Moreover, our sample size was relatively large in comparison with previous studies [12, 13] allowing us to test multiple hypotheses. As this study involved patients undergoing colorectal resection in a referral center for laparoscopic surgery and enhanced recovery, our results contribute evidence for the validity of the 6MWT in the context of modern surgical and perioperative care.

The main limitation of this study was the lack of a gold standard measure of postoperative recovery to test criterion validity; thus, we needed to rely on construct validity. In addition, because we used secondary data from three previous RCTs, the hypotheses tested for construct validity were not formulated prior to data collection as recommended by the COSMIN checklist [21]. To limit potential bias related to selective reporting, we formulated our hypotheses before the databases were merged and reported all the hypotheses tested. Another potential limitation of this study is the relatively low proportion of patients receiving open surgery in this series. To reduce the possible patient selection bias (i.e., open surgery patients may have different baseline walking capacity compared to laparoscopic patients), the analysis was carried out adjusting for baseline 6MWD values. Nonetheless, the sensitivity of the 6MWT to detect differences in recovery after open and laparoscopic colorectal surgery should be further assessed in a larger cohort of patients including a greater number of open procedures. Finally, the results of this validity study are only generalizable to patients who were accounted for in the selection criteria of the RCTs. It is also important to note that the 6MWT remains a test of functional exercise capacity that does not account for other relevant domains for recovery such as pain, cognitive and gastrointestinal function. These domains should be measured using other validated instruments.

Conclusions

The present study contributes further evidence for the construct validity of the 6MWT as a measure of recovery after colorectal resection. Older age, poorer physical status, complications and open surgery are associated with shorter 6MWD at 4 weeks after surgery. We also found a positive cross-sectional correlation between 6MWD and patient-reported physical activity. These findings should encourage the adoption of this test as an outcome measure in studies evaluating interventions aimed to improve postoperative recovery.

Compliance with ethical standards

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