



Determining the minimal clinically important difference for the six-minute walk test and the 200-meter fast-walk test during cardiac rehabilitation program in coronary artery disease patients after acute coronary syndrome.

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Vincent Gremeaux, Odile Troisgros, Sylvie Benaïm, Armelle Hannequin, Yves Laurent, et al.. Determining the minimal clinically important difference for the six-minute walk test and the 200-meter fast-walk test during cardiac rehabilitation program in coronary artery disease patients after acute coronary syndrome.. Archives of Physical Medicine and Rehabilitation, 2011, 92 (4), pp.611-9. 10.1016/j.apmr.2010.11.023 . hal-00702219

HAL Id: hal-00702219

<https://u-bourgogne.hal.science/hal-00702219>

Submitted on 4 Jun 2012

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**DETERMINING THE MINIMAL CLINICALLY IMPORTANT
DIFFERENCE FOR THE SIX-MINUTE WALK TEST AND THE 200-
METER FAST WALK TEST DURING CARDIAC REHABILITATION
PROGRAM IN CORONARY ARTERY DISEASE PATIENTS AFTER
ACUTE CORONARY SYNDROME**

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Walk tests are often used in the assessment of functional capacity in patients with
pulmonary and cardiac diseases ¹. They require less technical expertise than laboratory tests ²,
are inexpensive and easy to administer, and employ an activity that individuals perform on a
daily basis, *i.e.* walking ³. The 6-Minute Walk Test (6MWT) is the most validated field test in
cardiorespiratory diseases ⁴, and is widely used to assess functional exercise capacity and
prognosis since it is reproducible and well tolerated in patients with chronic heart failure
(CHF) ^{2, 5} and with CAD ⁶. Recent data showed that, in CAD patients, this test is submaximal

exercise, approximately corresponding to the first ventilatory threshold (VT)^{6, 7}. It can be performed early after a myocardial infarction (MI)⁸, and can be used to assess cardiac rehabilitation programs^{9, 10}.

The 200-Meter Fast Walk Test (200MFWT) has recently been developed in healthy elderly people and in CAD patients^{7, 11}. It has also been used to assess improvements in functional capacity after a training program in elderly¹² and CAD patients⁷. The 200MFWT explores higher exercise intensities than does the 6MWT, both of which could be of interest in cardiac rehabilitation. Indeed, recent studies suggest that vigorous exercise training and/or high intensity aerobic interval exercise may be superior to moderate intensity exercise in that they increase aerobic capacity to a greater extent in CAD patients^{13, 14}.

Field walk tests are objective measures that provide a means to monitor response to treatment³. The interpretation of functional changes can guide clinical management and can be primary endpoints in interventional or observational studies. It is thus important to determine whether a change in function is clinically relevant or not. One method to answer this question quantitatively is to determine the minimal clinically important difference (MCID) for the test used.

The Minimal Clinically Important Difference (MCID) is a concept defined as “the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patients management”¹⁵. The MCID is different from the Minimal Detectable Change, that indicates the amount of change required to exceed measurement variability^{16, 17}. Indeed, when interpreting clinical measures, it is important to consider that, even though small changes may be statistically significant, they may not be clinically relevant^{16, 18}. MCID values are therefore important to appreciate the clinical relevance of observed changes, at

both the individual and group levels. As individuals interpret “meaningful change” differently, depending on a multitude of factors (e.g. prior level of function, age, physical environment), the MCID is a dynamic and context-specific concept, and derivations of the MCID are usually estimated only for a specific population at a particular stage of recovery¹⁹. Because estimation of the MCID is a process evolving from multiple perspectives, it is important to estimate the MCID for key clinical outcome measures, such as walking ability in CAD patients. Indeed, walking is one of the most basic human motor activities and plays a key role in patients’ participation.

Numerous methods to derive the MCID have been described^{15, 16, 20-23}. They are usually divided into 2 categories: distribution-based and Anchor-based²¹.

Anchor-based methods involve comparing a patient’s change score with another measure of clinically relevant change²⁴. In this method, an external criterion of change is compared with another measure of change. An example of external criterion may be the change perceived by the patient or clinician^{16, 25}(e.g. self-perceived improvement in walking ability). The other measure of change used for comparison is usually an objective data, such as walking distance. Anchor based methods have the advantage of being more clearly understood because change are related to a clear clinical observation²⁶. This helps to determine that a change is considered important to the patient, physician or researcher, and even the health care authorities or society at large²⁷.

Distribution-based methods, such as the standard error of the measure (SEM)²⁸ and the effect size²⁹, are built on the statistical and psychometric properties of the measure in a population. Concurrent use of the two approaches is recommended to evaluate the effects of the methodology on the final value³⁰.

There is as yet no accepted threshold for clinically significant change in cardiac diseases in the 6MWT walked distance (6MWD)³¹, nor in the 200MFWT time (200MFWTT).

The aims of this study were (1) to prospectively determine the MCID for the 6MWD and the 200MFWTT in patients with CAD and (2) to determine if there was any difference between the MCID determined by patients and those assessed by their therapists.

METHODS

Participants

Patients who were referred to the cardiac rehabilitation department of Dijon University Hospital following an acute coronary syndrome were invited to participate. Patients were eligible if they had been admitted to an ambulatory cardiac rehabilitation program after percutaneous transluminal coronary angioplasty or coronary stenting, following an acute coronary syndrome. Only patients admitted within 2 months after the acute coronary syndrome, under optimal medical treatment according to the latest recommendations³² (i.e. β -blockers; Angiotensin converting enzyme inhibitors or Angiotensin receptor blockers, anti-platelet agents, statins) were included, with no restrictions regarding body mass index. All gave their written consent after being clearly advised about the protocol, which had been approved by the Institutional Ethics Committee and conformed to the principles outlined in the Declaration of Helsinki. Exclusion criteria were: residual myocardial ischemia or unstable angina; chronic heart failure, defined by (a) Framingham clinical criteria³³, (b) a left ventricular ejection fraction <45%, measured by echocardiography using the Simpson method; severe valve disease; diabetes; pulmonary hypertension); chronic respiratory

insufficiency; symptomatic lower limb artery disease; severe renal insufficiency; and any associated deficiency such as severe orthopaedic troubles limiting use of the lower limbs and that were more limiting to effort than the cardiac disease itself.

Protocol

All patients received an 8-week cardiac rehabilitation program that included two components:

- Personalised training tailored on the basis of the results of a stress test, performed on treadmill using the Bruce modified protocol³⁴, before entering the rehabilitation programme⁴¹, and individualized on the basis of preliminary physical activity habits, determined using the Dijon physical activity score questionnaire¹¹. The training intensity was prescribed at a target heart rate (HR) zone derived from the maximal HR at the end of the stress test. It was calculated using the Karvonen formula³⁵ as follows: training HR = rest HR + 75% (max HR – rest HR). During training sessions, Borg scale with level 6 to 20 was also used³⁶. The target was set between 13 and 15.

- Individual and group educational interventions based on the patient's risk factors³⁷.

The training program was in line with the latest recommendations in the field³⁷⁻³⁹, and consisted of one-and-a-half-hour sessions, 3 days a week over 8 weeks. Patients had to perform two 30-minute sessions of two different aerobic exercises (walking and bicycle or arm cycling) with a global warm up and cool down, and 20 minutes of circuit weight training adapted to each patient's capacities (solicited muscles groups were leg extensors and flexors, ankle dorsiflexors and plantar-flexors, elbow flexors and extensors, Latissimus dorsi).

Patients performed stress tests and walk tests as usual at the beginning and at the end of the rehabilitation program. The initial walk tests were performed 2 to 4 days after the ET. During

this interval, all patients performed a trial run of each walk test to familiarize them with the test and the path. They were repeated at the 6th and 12th training session. After each evaluation, and before giving the result of the test, the physiotherapist asked the patients the following question “Has there been any change in your walking ability since the last walking tests” ? The responses were made on a 9-level Likert scale, with a score of 0 indicating no change, positive scores indicating improvement, and negative scores indicating worsening walking ability. Change was scored as follows: (-4): much worse; (-3): worse; (-2): slightly worse, meaningful; (-1): very slightly worse, not meaningful; (0): Unchanged; (1): very slightly better, not meaningful; (2): slightly better, meaningful; (3) : better; (4): much better.

In order to study inter-observer agreement between the patient and his therapist, the same question was asked to the physiotherapist supervising the patient’s training, using the same 9-level scale. All ratings were completed before giving the result of the tests to ensure that both participants and clinicians were blinded to the performance, as recommended for the assessment of change in subjects in MCID studies ¹⁵.

During the walk-tests, patients wore a telemetric device (Teleguard, GE Medical Systems, Denmark). Blood pressure was measured before and immediately after each test in the left arm using a standard cuff mercury sphygmomanometer. Patients were also asked to rate their dyspnea on a Borg scale at the end of each test, and any clinical symptoms such as angina were recorded. Both walk tests were supervised by a physiotherapist blinded to the stress-test results and to the training group of the patient.

The 6MWT was performed on a 50-meter unobstructed path. The patients were instructed to walk at a self-selected pace from one end of the path to the other and back, in order to cover as much distance as they could during the allotted time. The time was called out every 2 minutes. Standard encouragement at 30-second intervals was provided. Slowing down and stopping to rest were permitted. At the end of 6 minutes, the total distance walked

in meters (m) was measured. These technical aspects are in line with the American Thoracic Society recommendations for the 6-minute walk test⁴⁰.

The 200-meter fast walk test consisted of walking twice up and down the 50-m long path in the hospital corridor as fast as possible, without running. Standard encouragement was provided at mid-distance. Slowing down and stopping to rest were permitted. The time taken to perform the test was measured in seconds^{7, 11}.

Statistical Analyses

Change in walking distance (for the 6MWD) and in time (for the) were expressed as an absolute distance or time, by subtracting the initial result from the discharge result.

For the anchor-based approach, patients were dichotomized based on their self assessment of clinical change. A cutoff of 2 (slightly better, meaningful) was used to identify patients who achieved an MCID (score ≥ 2) from those who did not (score <2). As previously described, the mean score change for the smallest meaningful change (*i.e.* ≥ 2) was taken as the MCID for both walk tests^{41, 42}. Then, the means of those subjects who achieved an MCID were compared with those who did not using a one-way ANOVA. The positive predictive value (PPV), negative predictive value (NPV), sensitivity and specificity for change in the 6MWD and in 200MFWTT were calculated and a Receiver Operating Characteristic (ROC) curve obtained. Given the objective of this work, *i.e.* to estimate the minimal improvement in the 6MWD or in the 200MFWTT that would lead the patient to be satisfied with his outcome, we chose to consider PPV and NPV rather than sensitivity and specificity to identify the MCID of these tests.

This analysis was repeated with patients dichotomized according to their physiotherapist's assessment of clinical change, in order to identify the MCID from the therapist's point of view. The same cutoff of 2 (slightly better, meaningful) was used to distinguish between patients who achieved an MCID and those who did not.

Concerning the distribution-based methods, we used the SEM to estimate the MCID. The SEM is defined as $\sigma_1 \times \sqrt{(1-r)}$, where σ_1 is the baseline standard deviation and r is the test-retest reliability. One SEM is supposed to be a close approximation of the MCID²⁸. The intraclass correlation coefficients used for test-retest reliability were calculated from data of a previous study⁷, and were set at 0.71 for the 6-MWT and 0.87 for the 200-MFWT.

Agreement between the ratings of patients and physiotherapists was studied using Cohen's κ correlation coefficient. Coefficients from 0 to 0.4 reflect a weak association, 0.4 - 0.75 a moderate association, and above 0.75 a strong association⁴³.

Improvement in maximal exercise capacity between patients achieving MCID and those who did not were compared using a Student t-test, and correlations between improvement in 6MWD and improvement in maximal exercise capacity were tested using Pearson correlation coefficient.

Data were recorded using Excel® software for Windows, and statistical analysis was performed using NCSS 2004® for Windows. The threshold for significance was set at $p < 0.05$.

Sample Size

As walk tests are usually performed only at the beginning of the rehabilitation program and at discharge, we could not calculate an estimated sample size based on the evolution of performance in tests repeated every 2 weeks. According to the latest studies concerning

MCID in the 6MWD in COPD and post-stroke functional measures^{41, 42, 44}, and anticipating a 10% dropout from the program, we initially planned to include 80 patients.

RESULTS

Participants

Eighty-one patients were recruited, and all of them completed the rehabilitation program. Two patients did not complete the 3rd evaluation (both had to stop training for 2 weeks for personal or family reasons). The demographic and anthropometric characteristics of the 81 included patients are described in table 1.

Walk tests and maximal exercise tests results

Overall, there was a mean improvement of 73.2 ± 56.5 meters in the 6MWD ($15.7 \pm 12.2\%$), and of 5 ± 17.7 seconds in the 200-MFWT time ($-5.3 \pm 10.8\%$) (figure 1). All of the walk tests were well tolerated both before and after rehabilitation, and were performed without being prematurely interrupted or stopped. No significant arrhythmias were observed on the telemetric device recordings. The mean rate of perceived exhaustion for the 6MWT and the 200MFWT were 14.9 ± 0.8 and 16 ± 0.9 before, and 14.6 ± 0.9 and 16.1 ± 1 after, respectively. All patients significantly improved maximal exercise capacity from 7.2 ± 1.7 METS at baseline to 9 ± 2.1 METs at the end of the training period (mean improvement $25 \pm 13.8\%$, $p < 0.01$), without significant change in the maximal heart rate (121.2 ± 13.8 and 126.4 ± 16 , respectively). There were no significant difference in the improvement of maximal exercise capacity between those patients who achieved MCID and those who did not between the 2nd and 3rd walk tests (mean improvement: $+ 26.4 \pm 10.2\%$ Vs $+ 24.7$

± 15.4%, respectively). Finally, improvement in 6MWD and in maximal exercise capacity, expressed in METs, were moderately correlated ($r= 0.59$, $p<0.05$)

Anchor-Based Estimation of the MCID

The distribution frequency of the change scores concerning walking ability, from the patients' point of view, between the initial and the 2nd evaluation, as well as between the 2nd and the 3rd, and the 3rd and the final evaluation, are shown in figure 2. The distribution was best balanced between the 2nd and 3rd evaluation. We thus considered that this period of the rehabilitation program (between the 6th and 12th training session) was the best suited for the calculation of the MCID, since during this period the assessments of the patients varied the most widely. Seventy-nine patients completed the 2nd and 3rd evaluation.

At this time, 40 patients rated themselves as ≥ 2 , while 39 reported little or no improvement, or even a worsening of perceived walking ability (score <2). The mean change in the 6MWD in those participants who classified themselves as improved was $+ 23.3 \pm 34.8$ meters, compared with $- 6.5 \pm 31$ meters in those who reported a small change or worsening (figure 3, A). The mean change in the 200MFWTT in those who classified themselves as improved was $- 1.4 \pm 6.8$ seconds, vs. $+ 0.1 \pm 4.8$ seconds in those who reported little or no change, or worsening. There was a significant difference between the 2 groups for the 6MWD ($p< 0.001$) whereas no significant difference was found for the 200MFWTT ($p=0.26$).

The PPV and NPV, sensitivity and specificity for the 6MWD and the 200MFWT using patients' rating of change are reported in table 2. Concerning the 6MWD, for an MCID between 21 and 27m, the PPV ranged between 0.8 and 0.9, and the NPV ranged between 0.63 and 0.66 (table 2, A). An MCID of 25 meters corresponded to a sensitivity of 0.55 and a specificity of 0.92, with an area under the curve (AUC) of 0.78 (95% CI: 0.65 –

0.86). Concerning the 200MFWT, for an MCID between -1 and -6 seconds, the PPV and NPV were poor, ranging from 0.45 to 0.47, and from 0.33 to 0.41, respectively (table 2, B). An MCID of -2 seconds corresponded to a sensitivity of 0.67 and a specificity of 0.14 (AUC : 0.4; 95% CI: 0.27 - 0.53) (Figure 4).

Concerning the physiotherapists' ratings, 58 patients were rated ≥ 2 and 21 rated < 2 . The mean change in the 6MWD in the patients classified as improved by the physiotherapist (≥ 2) was $+ 15.2 \pm 4.6$ meters, compared with $- 9.9 \pm 7.6$ meters in those who were classified as stable or worsened (< 2) (figure 3, B). The mean change in 200MFWTT in those judged as improved was $- 1.3 \pm 1.2$ seconds, vs. $+ 1.04 \pm 1$ seconds in those judged little improved or stable or worsened. There was a significant difference between the 2 groups for the 6MWD ($p < 0.01$) whereas no significant difference was found for the 200-MFWT performance ($p = 0.12$).

The PPV and NPV, sensitivity and specificity for the 6MWD and the 200MFWTT using physiotherapists' rating of change are reported in table 3. Concerning the 6MWD, for an MCID between 15 and 27m, the PPN ranged between 0.84 and 0.95, and the NPV ranged between 0.34 and 0.38. An MCID of 25 meters corresponded to a sensitivity of 0.41 and a specificity of 0.95 (AUC: 0.7; 95% CI: 0.55 –0.81). Concerning the 200MFWTT, for an MCID between -1 and -6 seconds, the PPN ranged between 0.68 and 0.71, and the NPV ranged between 0.11 and 0.2. An MCID of -2 seconds corresponded to a sensitivity of 0.67 and a specificity of 0.14, (AUC: 0.38; 95% CI :0.22 –0.5).

Cohen's κ correlation coefficient between patients' and physiotherapists' judgment was 0.17 for the 6-MWD and 0.29 for the 200-MFWTT, reflecting poor agreement.

When considering patients who rated themselves < 2 , 16 were considered stable or worsened by the physiotherapist (score < 2), and 23 were considered improved (score ≥ 2)

(table). There was no significant difference between patients classified <2 and those classified ≥ 2 by the physiotherapist for either the 6MWD or the 200MFWTT (table 4). Moreover, there was also no significant difference in the HR variation between the 2 evaluations for the 2 groups (table 4).

Distribution-Based Estimation of the MCID

When considering the patients' self assessment, the SEM for the 6MWD was 23 meters using the baseline standard deviation for the 6MWD and an intraclass correlation coefficient of 0.71. Concerning the 200MFWT, using an intraclass correlation coefficient of 0.87 the SEM for the 200MFWTT was - 4.2 seconds.

Using the same methodology with the physiotherapists' judgment, the SEM was 36 meters for the 6MWD and -5.5 seconds for the 20MFWT.

Overall, 76 out of 81 patients achieved an improvement of over 25 meters in the 6MWD. When considering the progression between the 2nd and 3rd evaluation, 23 had improved the 6MWD by over 25 meters, whereas 54 had improved by less than 25 meters. There was no difference in the initial 6MWD among patients who achieved the MCID (491 ± 55 meters) and those who did not (486 ± 56 meters).

DISCUSSION

We estimated the MCID for the 6MWD at approximately 25 meters among CAD patients who recently suffered an ACS and who had benefited from cardiac rehabilitation. This estimate was consistent, whatever the estimation method used (anchor-based or

distribution-based). Using the same methodology, we could not determine an MCID with satisfactory metrological qualities for the 200MFWTT.

To our knowledge, this is the first study to evaluate the MCID for walk tests among CAD patients. A previous study determined an MCID for the health status in patients with heart disease, but considered health-related quality of life scores, and used a different approach, based on a consensus reached by a panel of physicians ⁴⁵. Here, we used a patient anchor specific to functional walking capacity. Our work is thus complementary, as walking tests and quality of life questionnaires measure different constructs ⁴⁶. Indeed, changes in walking performance should not be used to infer changes in health-related quality of life, irrespective of whether the MCID is achieved.

The MCID of 25 meters for the 6MWD identified in this study is similar to that recently reported by Holland et al. among patients with diffuse parenchymal lung disease ⁴⁷ and COPD patients ⁴⁴. As in the latter study, we identified a threshold distance at which patients can identify clinical change using the ROC method, rather than using the average distance associated with clinical change in a group of patients. Using this cutoff, the positive predictive value was 0.9. This means that, when patients improve their 6MWD by 25 meters, there is a 90% chance that they will feel a real improvement in their walking performance. This was also associated with a specificity of 0.92, and a sensitivity of 0.55, meaning that when patients do perceive a clinical change, there is a 55% chance that their walking capacity has improved by more than 25 m.

Unlike the study of Holland et al. among COPD patients ⁴⁴, we did not find a difference in the absolute change in 6MWD depending on the baseline walking distance. This might be due to the difference in the sample, as our patients were younger, and showed a higher baseline performance with less variability. This could also be due to the different nature of the disease itself.

The majority of patients achieved the estimated MCID after rehabilitation (93%). We chose to estimate the MCID between the 6th and 12th session, in order to avoid a skewed distribution of perceived change scores (figure 1), and to minimize recall bias. Thus, at this time, only 36% had achieved the MCID. This means that we had patients with change scores greater than the calculated MCID values who considered their walking capacity unchanged or worsened. Conversely, other patients with change scores less than the calculated MCID considered their walking capacity improved ($\text{score} \geq 2$). Moreover, there was no difference in maximal exercise capacity improvement between patients achieving MCID for the 6MWD between the 2nd and 3rd evaluation and those who did not. This seems logical, as the 6MWT remains a submaximal walk tests, and as the correlation between improvement in 6MWD and maximal exercise capacity improvement was moderate, as previously reported ⁶. Our MCID values should thus be interpreted with caution, particularly when making judgments about individual patients, and exercise capacity assessment remains the gold standard for prognosis.

Studies of retrospective change have shown that subjects tend to judge their assessments of change based on their current condition, remembering backwards in time from that point rather than remembering their initial condition and working forward ⁴⁸. Thus, estimating perceived change every 6 to 8 sessions allowed us to minimize this bias, even though this methodology is not as strong as would be a prognostic study of predicted change.

The estimation of the MCID for the 6MWD was different when determined by the patient or the physiotherapist. Previous studies in other diseases concerning agreement between patients' and clinicians' ratings of change showed inconsistent results, ranging from poor ^{49, 50} to good ²⁶ agreement. Physicians may have a skewed perspective on functional change given the little time spent actually observing patients ⁵¹. However, one could think that other health professionals, such as physiotherapists, who are more familiar with the day-to-day functioning of patients, would have an estimation of clinical change closer to that of

patients. This was not the case in our study, as there was poor agreement between change assessed by patients and that assessed by physiotherapists (Cohen κ correlation coefficient = 0.17). For example, among patients who rated themselves <2 , 16 were considered stable or worsened by the physiotherapist (score < 2), and 23 were considered improved (score ≥ 2). However, there was no significant difference between these 2 groups for the 6MWD (table 4). Physiotherapists may take into account many subjective (general appearance of the patient, mood, other complaints, etc.) and objective data (total work on ergometers, HR during training sessions) in their judgment, related to their own experience and history. Some of these data were probably considered more important by the physiotherapist than by the patients in interpreting the perception of clinical change. However, in our study, there was no significant HR variation between the 2nd and the 3rd evaluation. This might not have affected the change perceived by the physiotherapist. Future studies may include regression analyses to identify the components of relevant clinical change for the therapist and the patient.

Our study failed to identify an MCID with satisfactory metrological qualities for the 200MFWT. The anchor-based method did not show a significant difference in means between patients rating <2 and those rating ≥ 2 . A 4.2-second improvement in the 200MFWTT was determined as the MCID when using the distribution method. However, this finding has to be interpreted very cautiously as the ROC method did not allow us to identify a threshold with sufficient metrological qualities for a time improvement at which patients can identify a clinical change. The 200MFWT test explores higher exercise intensities than does the 6MWT⁷. It could be harder for a patient to interpret his feelings during a test that is closer to his maximal capacity. Indeed, the 6MWT is submaximal moderate exercise, approximately corresponding to the first VT^{6, 52}. Thus, it might be easier for patients to have a better perception of their walking ability during this test, which may better reflect their daily activities than the 200MFWT, which is more like running to catch a bus, for example. The

200WFWT might be more useful as a tool to help design or assess high intensity rehabilitation programs, such as interval training.

The sensitivity and specificity of tests are often used to choose a cutoff for the significance of a clinical or biological variable. Here, we chose the PPV and NPV to identify a meaningful cutoff for the MCID. Indeed, we chose these metrologic properties to find answers to the question raised: will a patient who improves beyond the identified MCID perceive a clinical change? Based on our results, with a 25-meter cutoff, we can affirm that in this population, 90% of patients who improved their 6MWD by more than 25 meters perceived a meaningful clinical change in their walking ability. Conversely, among patients who improved by less than 25 meters, 66% did not perceive any change. The PPV is influenced by the prevalence of the studied parameter in the population considered. However, the anthropometric characteristics and baseline walk performance of our sample was quite similar to that of other studies in the field ^{7,9}.

By defining the threshold for clinically important change, we improve our ability to interpret the effects of cardiac rehabilitation programs in routine clinical practice as well as in randomized clinical trials that assess the effectiveness of interventions. Thus, an MCID reference improvement of 25 meters for the 6MWD could serve as an explicit therapeutic goal for rehabilitation or other therapeutic interventions that aim to improve walking ability and participation levels for CAD patients. Indeed, a valid MCID for 6MWD improvement is useful for the clinical interpretation of individual rehabilitation programs, but also the clinical significance of intervention studies that may find statistical improvements in 6MWD but may not achieve a clinically meaningful threshold. Moreover, sample size heavily influences the statistical significance of an improvement in performance in a clinical trial. The clinically interpretable effects of a training program on measurements of performance can be examined according to standards of meaningful change by comparing the proportion of treatment and

control groups who achieve change and calculating the number needed to treat ⁵³. Finally, sample size estimates are needed in the planning stage of research studies and should be based on the ability to detect clinically significant levels of change.

Study Limitations

Our study in one cardiac rehabilitation department comprised a relatively small sample of stable CAD patients and included very few women. Moreover, they all benefited from standardized care during the acute phase, which may vary from one cardiology acute care department to another. Thus, we cannot generalize our results to the whole population of CAD patients. Future studies with larger sample sizes including patients with different functional statuses are now needed to refine our estimates and to determine how MCID values are affected by time since the MI, by the severity and/or clinical features of the initial MI, and by the initial acute care procedure.

Even though we chose to assess the MCID at the period with the widest diversity in degrees of self-perceived change, very few patients (4) reported a decline in walking ability. This seems logical, given the well-known benefits of cardiac rehabilitation programs. Among these 4 patients, only one really had a lower 6MWD (-5 meters). We were therefore unable to assess whether the MCID for decline differed from the MCID for improvement, as has previously been reported ⁵⁴.

Finally, only a small number of physical therapists participated in the assessment of change, and all of these had specialized in cardiac rehabilitation. Future studies should include more physiotherapists from multiple settings.

CONCLUSIONS

Our study provides the first estimates of a minimal clinically important difference, approximately 25 meters, in performance at the 6-minute walk test in a CAD population. This result supports the use of the 6-MWT during cardiac rehabilitation programs in CAD patients after ACS , and will help practitioners and researchers interpret changes in the 6MWD in this population.

Acknowledgments: The authors would like to thank the whole rehabilitation team for their participation in this study. We would also like to thank Dr Dupeyron and Gelis for their unconditional 10-years support. The English was revised by Philip Bastable.

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