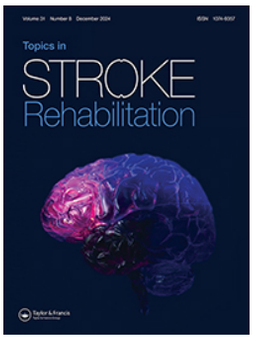

Topics in Stroke Rehabilitation

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The minimally clinically important difference in the 2-minute walk test for people in the subacute phase after a stroke

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ABSTRACT

Background: The 2-Minute Walk Test (2MWT) is a simple and reliable test used by clinicians to assess gait function in people with stroke (pwST). No studies established the minimal clinically important difference (MCID) of the 2MWT.

Objective: To determine the MCID of the 2MWT in subacute pwST using data from a longitudinal cohort study.

Methods: PwST within 180 days of stroke onset were recruited from the Italian National Health System (NHS) rehabilitation services across the country. Participants underwent physical therapy to improve balance and gait according to their specific needs. The 2MWT was used to assess gait performance at the beginning (T0) and after a minimum of 10 rehabilitation sessions (T1). The Global Perceived Effect (GPE), Activities-specific Balance Confidence Scale (ABC) and the ABC_gait were used to assess balance confidence and the perceived effect of the intervention at T1.

Results: 51 pwST (69 ± 12 years; 66.7% males) were included in the analysis. Statistically significant improvements were observed in 2MWT, ABC, and ABC_gait scores after rehabilitation using the Wilcoxon signed-rank test. Using an anchor-based approach the receiver operating characteristic (ROC) curves were calculated to establish the MCID. The MCID of the 2MWT was 31 meters with an Area under the curve (AUC) = 0.74 [0.60–0.89], a specificity of 71% and a sensitivity of 63%.

Conclusions: An improvement of 31 meters on the 2MWT can be considered clinically significant in subacute pwST undergoing rehabilitation. This study provides valuable insights for clinicians to assess walking performance in pwST and determine clinically meaningful changes post-rehabilitation.

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Stroke; rehabilitation; gait; minimal clinically important difference; patient outcome assessment

Introduction

Mobility and balance problems are commonly reported in people with stroke (pwST). Limited standing balance and reduced propulsive force in the paretic leg are common in this population, leading to a slow gait and increased risk of falls.[1] To improve mobility, a combination of balance, walking and aerobic exercise for at least 30 minutes to 1 hour, three to five times a week is recommended as part of a rehabilitation program.[2]

Several standardized outcome measures can be used during stroke rehabilitation to assess improvements in mobility.[3] A simple test suitable for assessing functional disability due to neurologic impairments is the 2-Minute Walk Test (2MWT), which is a valid measure to assess the walking performance of pwST over time.[4] The 2MWT showed adequate construct and concurrent validity in pwST[5] and can be used as a reliable alternative to longer walking

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tests (e.g. 6-minute walking test), saving time and effort.[4]

A recent systematic review on pwST[2] reported significant improvements in functional outcomes such as the 2MWT after rehabilitation, but these improvements do not always correspond to an increase in the subject's perceived meaningful change in walking function.[6] The measurement of perceived meaningful change is fundamental to assess rehabilitation progress and the minimal clinically important difference (MCID) represents the smallest amount of improvement considered worthwhile by a subject and is useful for meaningful interpretation of outcome's change scores following a clinical intervention.[7]

Currently, the MCID of the 2MWT has been investigated in people with chronic obstructive pulmonary disease (COPD), where an improvement of at least 5.5 meters following a pulmonary rehabilitation program has been identified as clinically meaningful.[8] No studies have measured what change in 2MWT corresponds to a clinically significant improvement in the subacute stroke population.

Given the importance of this outcome in measuring the impact of gait rehabilitation in pwST, this study aims to define the MCID of the 2MWT to determine the clinically meaningful improvement in walking performance in pwST in the subacute phase.

Materials and methods

Study design

Data were collected from a longitudinal prospective cohort study (trial registration number NCT04386863) exploring the content of rehabilitation in the neurological population in a multicentric network involving 6 hospitals and 3 rehabilitation centers all over Italy. Results from the study have been published in.[9] The study was approved by the local Ethics Committee (Number: Prot. n.27/2018/CE_FdG/FC/SA; Date: 22/06/2018) and was conducted under the Declaration of Helsinki. All participants signed an informed consent form. The manuscript conforms to the STROBE Guidelines for the reporting of observational studies.[10]

Participants

Eligibility criteria

Inclusion criteria: pwST (ischemic or hemorrhagic according to World Health Organization criteria,[11] time from stroke (onset) <180 days, admitted to the rehabilitation services of the Italian National Health System (NHS). Only pwST who shared the same rehabilitation goals (e.g. walking and balance improvement) and performed a minimum of 10 treatment sessions were included in this analysis. Exclusion criteria: age < 18 and inability to understand and perform the study protocol.

Experimental procedures

All participants underwent the rehabilitation sessions foreseen by the NHS and were clinically assessed before (T0) and after (T1) treatment. All the clinical evaluations have been performed by an experienced clinical researcher not involved in the rehabilitation sessions.

Intervention

Each participant has been included in a previous longitudinal cohort study exploring the content of neurological rehabilitation.[9] According to the results reported in the previous study,[9] subacute stroke sharing the same intervention goals (e.g. walking and balance improvements) were selected for the current analysis. The goals of the intervention were decided by the multidisciplinary rehabilitation team and were pursued by the physical therapist (PT) in charge of the treatment. The treatment included functional exercises to improve walking and balance, as well as strengthening exercises for the lower limb muscles. The level of intensity of the exercises and the duration of the whole intervention period varied among subjects based on their residual functional abilities and therapeutic needs. However, the minimum number of treatment sessions required to be included in the study was 10.

Assessment

Demographic characteristics were collected along with the overall disability measured by the

Modified Barthel Index (MBI).[12] Moreover, the following clinical outcome measures have been used to assess gait performance, balance confidence, and global perceived effect of the intervention:

2-minute walking test

The 2MWT is used to assess gait performance and functional capacity. Participants were instructed to walk as fast as possible over a 30 m walkway in 2 min and the total distance walked was recorded.[13] Normative 2MWT distances in healthy subjects varied from 150.3 m (women, 70 to 79 years) to 217.9 m (men, 20 to 29 years), and the distance for the minimal detectable change in healthy individuals was 42.5 m.[13,14]

Global perceived effect (GPE)

The GPE scale is used in both research and clinical practice for measuring participants' self-perceived condition after rehabilitation. The GPE scale asks the participants to rate, on a numerical scale from 1 (worse than ever) to 7 (very much improved), how much their condition has deteriorated or improved since some pre-defined time points.[15] The GPE is commonly used as an external criterion to test the measurement properties of other outcome measures.[16] In this article, the GPE has been used to measure the self-perceived effect of the rehabilitation for both participants (GPE_pwST) and physical therapists (GPE_PT).

Balance confidence: activities-specific balance confidence scale (ABC)

The ABC is a self-administered questionnaire that measures the self-perceived level of balance confidence while performing daily living activities.[17] All 16 items were scored from 0 (no confidence) to 100 (best confidence) and averaged to produce a total score ranging from 0 to 100, with higher scores indicating greater confidence.

Data analysis

A descriptive data analysis was carried out reporting the means (±1 standard deviation) and percentages. Based on recommendations from various papers[18,19] an anchor-based approach was chosen to establish an MCID of walking performance rather than the distribution-based methods.

The anchor-based approach was carried out using three different anchor tools: The GPE, the ABC scale and an abbreviated version of the ABC scale (i.e. the ABC_Gait). The ABC_gait is a subscore of the ABC scale containing only items investigating balance confidence during gait activities (Item 1: Walking around the house, Item 8: Walking outside the house to a car parked in the driveway, Item 10: Walking across a parking lot to the mall, Item 11: Walking up or down a ramp, Item 12: Walking in a crowded mall where people rapidly walk past).

Data have been checked for normality using the Kolmogorov-Smirnov test. Since data were not normally distributed, T0 to T1 changes were analyzed by the Wilcoxon signed-rank test and further analysis was performed using non-parametric tests. According to the anchor-based approach, we calculated the Spearman correlation between the 2MWT change score (2MWT_T1 - 2MWT_T0 = Δ 2MWT), GPE_pwST, GPE_PT, ABC change score (ABC_T1- ABC_T0 = Δ ABC_Gait) and ABC_Gait change score (ABC_Gait_T1 - ABC_Gait_T0 = Δ ABC_Gait). The threshold of 0.37 is recommended as a correlation value to define an acceptable association between an anchor and a scale change score.[20]

According to previous studies,[21] participants who reported more or less than a 10% change in the ABC scale or ABC_Gait were classified as improved (responders) and not improved (non-responders), respectively.[16] In addition, we performed a sensitivity analysis by also considering a 20% change in the responder classification. Based on this, receiver operating characteristic (ROC) curves were calculated to obtain cutoff values for the 2MWT change scores, taking into account the ratio of true positives to false positives in the classification of responders. To determine the cutoff value, the point on the curve least distant from the upper left corner of the ROC curve was selected, taking into account the point with sensitivity and specificity values closer to the optimal values (sensitivity = 1.00; specificity = 1.00). The area under the curve (AUC), which indicates the accuracy of the cutoff value, was calculated to assess the consistency of the results.

Table 1. Demographic and clinical characteristics of the sample.

Characteristic	pwST ($N = 51$)
Male (%)	34 (66.7%)
Age (years)	69 ± 12
Time from onset (days)	21 ± 18
MBI (T0) (score)	55.6 ± 21.4
2MWT (T0) (meters)	43 ± 43
2MWT (T1) (meters)	83 ± 41
ABC (T0) (score)	29.4 ± 24.2
ABC (T1) (score)	59 ± 24.8
ABC_Gait (T0) (score)	28.8 ± 27.9
ABC_Gait (T1) (score)	64.7 ± 25.8
GPE_pwST (score)	6 ± 1
GPE_PT (score)	6 ± 1

Values are reported as mean values ± standard deviations or (percentages). Abbreviations: people with stroke, pwST; Modified Barthel Index, MBI; 2-minute walk test, 2MWT; Activities Balance Confidence, ABC; Activities Balance Confidence Gait sub-score, ABC_Gait; Global Perceived Effect, GPE; physical therapist, PT.

Results

PwST (69 ± 12 years; 66.7% males) have been included in the analysis. Table 1 shows demographic and clinical characteristics of the sample.

We found statistically significant differences ($p < 0.01$) between 2MWT at T0 and T1, with a mean change score (Δ 2MWT) of 40 ± 34 meters. Similarly, the mean changes on the ABC scale (Δ ABC) are 29.7 ± 24.1 points ($p < 0.01$) with 39 pwST (76.5%) improved by more than 10% at T1. According to the sensitivity analysis, 27 pwST (52.9%) improved by more than 20%. The mean change in the ABC_Gait score (Δ ABC_Gait) after the intervention was statistically significant ($p < 0.01$) with a mean improvement of 35.9 ± 29.4 points.

Considering the ABC_Gait score at T1, 42 pwST (82.4%) improved by more than 10% while 30 pwST (58.8%) improved by more than 20% compared to the T0 assessment.

Finally, the GPE analysis revealed that 26 pwST (45.6%) reported a score greater than 6 on the GPE_pwST at T1, while on the GPE_PT a score greater than 6 has been reported 16 times out of 51 scales administered by PTs (31.4%).

Correlation analysis

The Spearman's correlation coefficient between the Δ 2MWT and the Δ ABC was 0.39 ($n = 51$, $p < 0.01$) while between the Δ 2MWT and the Δ ABC_Gait is 0.45 ($n = 51$, $p < 0.01$). Considering the GPE scale, the Spearman's correlation coefficient between the Δ 2MWT and the GPE_PT was 0.25 ($n = 51$, $p = 0.08$), while between the Δ 2MWT and the GPE_pwST was −0.03 ($n = 51$, $p = 0.86$).

Receiver operating characteristic curve

Optimal MCID cutoff points for the 2MWT, and AUC values [95% CI] were calculated using both the ABC and ABC_Gait, the two anchors that reported an acceptable association with the 2MWT.

Considering a 10% improvement in the ABC scale, the MCID of the 2MWT is 25.1 meters, AUC = 0.66 [0.48–0.84], specificity 58% and sensitivity 64%, Figure 1(a). Furthermore, considering a 10% improvement in the ABC_Gait, the MCID of the 2MWT is 13.5 meters, AUC = 0.71 [0.51–0.90], specificity 56% and sensitivity 90%, Figure 1(b).

Considering a 20% improvement in the ABC scale, the MCID of the 2MWT is 31 meters, AUC = 0.71 [0.56–0.85], specificity 67% and sensitivity 63%, Figure 1(c). In addition, considering a 20% improvement in the ABC_Gait, the MCID of the 2MWT is 31 meters, AUC = 0.74 [0.60–0.89], specificity 71% and sensitivity 63%, Figure 1(d).

Discussion

This paper is the first to investigate the smallest clinically significant improvement in the 2MWT during neurological rehabilitation in subacute pwST. We compared scores from this endurance test with different tools that measure improvement in the self-perceived level of balance confidence during daily activities. Our findings suggest that an improvement of 31 meters on the 2MWT can be considered clinically meaningful because it is associated with an improvement in self-perceived balance confidence.

To better understand our findings, it is important to note that the individuals in our study were subacute pwST with moderate to severe disabilities. This was evident in the baseline assessment, where our sample covered fewer meters compared to older adults living in long-term care facilities (77.5 ± 25.6 meters) or living in their own homes (150.4 ± 23.1 meters).[22] In this sample, we noticed a considerable improvement in walking ability at the time of discharge, which was probably due to a combination of spontaneous recovery that is

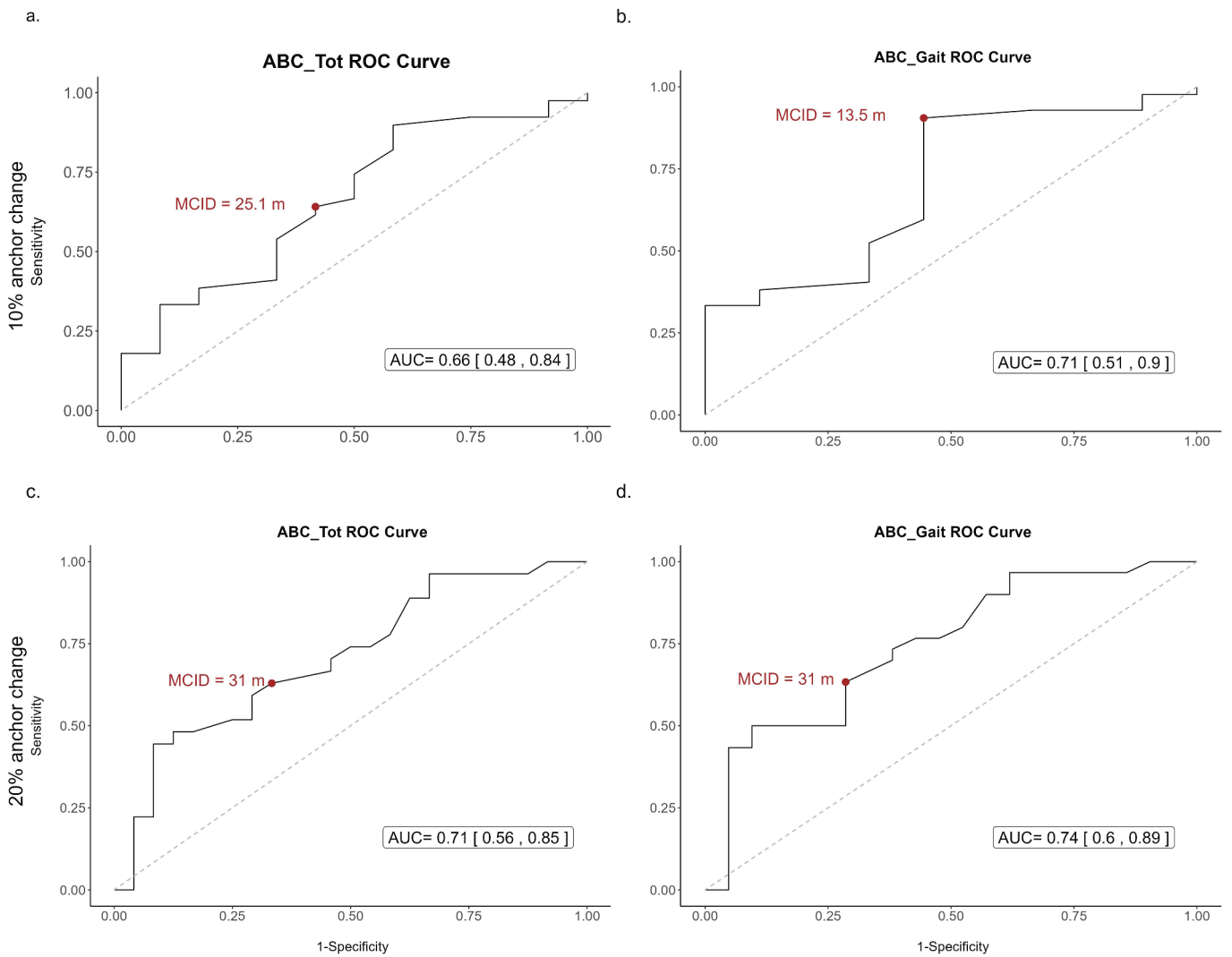

Figure 1. Receiver operating characteristic curve of 2MWT. a) 10% anchor change: ABC. b) 10% anchor change: ABC_Gait. c) 20% anchor change: ABC. d) 20% anchor change: ABC_Gait. 2-minute walk test, 2MWT; Activities Balance Confidence, ABC; Activities Balance Confidence Gait sub-score, ABC_Gait; receiver operating curve, ROC; minimal clincally important difference, MCID; area under the curve, AUC.

generally observed after subacute stroke and the rehabilitation treatments provided.[23] Noteworthy, the mean change score in the 2MWT was 40 ± 34 meters, and the average value for walking performance at the final assessment was 83 ± 41 meters. These results indicate that many of the study participants achieved a level of ambulation comparable to that of older adults residing in long-term care facilities.[22]

To achieve the 2MWT performance observed at the end of rehabilitation, it is necessary to have a gait speed that meets the thresholds found for community ambulation capacity. These gait speed thresholds have been found to be greater than 0.47 m/s or 0.8 m/s in the stroke population, depending on the study,[24–26] and correspond to a walking distance of more than 56.4 or 96 meters in 2 minutes. In our sample, 19 out of 51 participants achieved both the MCID at 2MWT and a 20% improvement in the ABC_Gait score, 16 of whom also achieved the gait speed threshold for community ambulation capacity.

Improvements in walking performance were linked to an increase in perceived confidence in dynamic balance during daily activities. As a result, we were able to calculate the MCID of the 2MWT. Based on the anchor-based approach, the ABC_Gait measure was found to be the most effective anchor measure for both 10% and 20% sensitivity analysis. The best MCID for 2MWT was determined to be 31 meters for 58.8% of the sample, which represents the optimal balance between sensitivity and specificity. Unfortunately, we cannot compare our results with those of other studies as this is the first study to assess the MCID on the 2MWT in pwST. However, our results are consistent with those of Fulk et al.[27] who reported that people between 2 and 6 months after stroke who experienced an improvement of 71 meters in the 6-minute walk test (6MWT) perceived a significant improvement in walking performance. The difference in meters between the two cutoff points may be due to subjects walking longer in 6MWT than in 2MWT. In the study of Fulk et al.[22] the modified Ranking Scale (mRS) was used as an external anchor measure. The mRS is an ordinal measure of overall disability with scores ranging from 0 (no symptoms) to 5 (severe disability) which are scored by a clinician. Participants who showed an improvement of 1 point or more on the mRS at the end were considered as improved. Interestingly, a 1-point improvement on the mRS scale is consistent with the 20% improvement we considered in our sensitivity analysis. However, instead of using an anchor based on the clinicians' assessment, we obtained more reliable results by using an anchor linked to the participants' perception of improvement, which is a closer estimate of the impact of changes on the activities of daily lives. In line with this, a recent systematic review by Zhang et al.[28] found that 99.12% of studies used subjective anchors, primarily because they are directly related to patient experience and are more likely to reflect clinically meaningful changes as perceived by patients.

According to the anchor-based approach, we tested different anchor measures and performed a sensitivity analysis to find the best classification capability. The majority of the sample showed clinically significant improvement in the ABC_Gait indicating relevant change in perceived balance confidence during walking activity. Indeed, the ABC_Gait showed the best correlation value (moderate correlation) with the 2MWT and, according to our sensitivity analysis, provided the best cutoff value for predicting whether a change in walking performance would be considered clinically significant or not. Acceptable cutoff values have been obtained also with the full ABC scale. Given its sensitivity to change and its good psychometric properties on pwST,[17,29] the ABC scale can also be considered a reliable anchor measure to determine the MCID value of the 2MWT. Indeed, the sensitivity analysis with a 20% cutoff showed the same MCID for the ABC and ABC_Gait, suggesting that this threshold may provide a more consistent cutoff for pwST. Our results confirm that individual motor abilities can be defined in terms of a relationship between the level of performance in a specific ability and the associated perception of difficulty, as suggested by Kopec JA et al.[30] In this sense, both the ABC and the ABC_Gait are suitable for measuring the perception of difficulty in balance-related activities, but it is evident that the ABC_Gait emerged as the best anchor probably due to the selection of items related to walking. On the other hand, both GPE_PT and GPE_pwST did not reach the

threshold required for the anchor-based approach.[20] The GPE_PT showed a low correlation with change in walking performance while the GPE_pwST showed no correlation. The lack of correlation of the GPE_pwST with change in walking performance may be a consequence of participants' altered perception of their balance and walking abilities without a reference to the walking abilities in the real-life context. Indeed, pwST could easily overestimate or underestimate their improvements when asked the general question "Do you feel you have improved your walking abilities?". Similarly, participants' improvement in walking performance assessed by PTs does not seem as reliable as more context-specific self-reported outcomes. This suggests that uncontextualized self-reported motor abilities do not appear to be a reliable tool when this type of assessment is not contextualized to specific activities of daily living, as is the case of the ABC scale.

Study limitations

Our study has some limitations. First of all, our sample is small and only included strokes in the subacute phase and our results can only be generalized to stroke populations with similar clinical characteristics. It might be useful to determine the MCIDs of the 2MWT in different clinical phases, for instance, the chronic phases of stroke. Indeed, different clinical phases could have different rehabilitation goals that should be specifically considered by physiotherapists or physicians.[31] Moreover, the sample size did not allow the analyses of cutoff consistency in subsets having different baseline characteristics. Finally, we did not perform a sample size/power analysis. However, the number of participants included in our study is in line with other publications calculating the MCID of the 2MWT and similar outcome measures for gait in people with neurological disease or undergoing pulmonary rehabilitation.[8,16]

Another limitation could be related to the outcome measure we used to implement the anchor-based approach. We could have used objective outcome measures instead of patient-reported outcomes as anchors. Objective anchors provide quantitative and reproducible data, are less influenced by individual biases, and should be favored when dealing with physiological parameters or when clear-cut standards exist. However, a recent systematic review[28] revealed that most studies use subjective anchors, particularly in clinical settings where function is assessed in people with severe disabilities. Indeed, in these clinical contexts, it may be challenging to obtain objective indicators, or the progress made by participants, while significant to them, may not yet meet the criteria for objective classification as functional or normal.

Considering the patient-reported outcomes employed as subjective anchor measures, although psychometric properties of the ABC scale have been demonstrated,[24] we used a shortened version of the ABC scale that has not been validated, and for which no literature data are available. However, by considering only the items related to walking, we can be more precise about the participants' perception of improvement in their walking ability. Finally, the ABC scale only measures confidence in balance without considering other impairments like fatigue, weakness, and spasticity that can affect walking. While dynamic balance disorders are quite common, it would be beneficial to compare cutoffs built on anchors assessing multiple domains.

In light of our results, we can suggest using the 2MWT as an alternative to the 6MWT to describe walking in pwST. Indeed, the 2MWT has been recommended by several expert panels for the assessment of walking performance in stroke, multiple sclerosis, Parkinson's disease, spinal cord injury and traumatic brain injury.[32] The advantages of the 2MWT over the 6MWT are that both tests assess the same domains, while the 2-minute walk test is less time-consuming, especially for more disabled people who are unable to walk for 6 minutes. Furthermore, the 6MWT and the 2MWT are highly correlated in the stroke population ($R^2 = 0.98$), suggesting that a shorter and more convenient test could replace the 6MWT, especially in a clinical setting where time often has to be managed optimally.[4]

Conclusion

This study used an anchor-based approach to establish a minimum clinically important

difference of 31 meters on the 2MWT test for subacute stroke subjects undergoing rehabilitation. The 2MWT test is a quick way to assess walking performance in this population, and this clinical cutoff may be useful for PTs and clinicians to determine when a significant change in the 2MWT test scores has been achieved after rehabilitation.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Author contributions

Conceptualization: T.B. and D.C.; methodology: T.B., F.G.M. M., F.M., A.T., S.M. and D.C.; data collection: T.B., F.G.M.M., S.S., F.M., C.A., S.B., M.G., F.G.M., E.P., M.P. and A.T.; data analysis: T.B., F.G.M.M. and DC; writing – original draft preparation: T.B. and F.G.M.M; writing – review and editing: S.S., F.M., C.A., S.B., M.G., F.G.M., E.P., M.P., A.T.; supervision: S.M. and D.C.; project administration: T.B, F.G.M. M. and D.C. All authors have read and agreed to the published version of the manuscript.

Abbreviations

2MWT; 2-Minute Walk Test,
6MWT; 6-Minute Walk Test,
ABC; Activities-specific Balance Confidence Scale,
AUC; Area under the curve,
GPE; Global Perceived Effect,
MBI; Modified Barthel Index,
MCID; minimal clinically important difference,
NHS; National Health System,
pwST; people with stroke,
PT; physical therapist,
ROC. Receiver operating characteristic curve,

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