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The minimal clinically important difference for gait speed in significant unilateral vestibular hypofunction after vestibular rehabilitation

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ABSTRACT

Gait speed is a valid measure of both physical function and vestibular health. Vestibular rehabilitation is useful to improve gait speed for patients with vestibular hypofunction, yet there is little data to indicate how changes in gait speed reflect changes in patient-reported health outcomes. We determined the minimal clinically important difference in the gait speed of patients with unilateral vestibular hypofunction, mostly due to deafferentation surgery, as anchored to the Dizziness Handicap Index and the Activities Balance Confidence scale, validated using regression analysis, change difference, receiver-operator characteristic curve, and average change methods. After six weeks of vestibular rehabilitation, a change in gait speed from 0.20 to 0.34 m/s with 95% confidence was required for the patients to perceive a significant reduction in perception of dizziness and improved balance confidence.

1. Introduction

1.1. Gait speed and vestibular hypofunction

Gait speed is considered the sixth vital sign as it has been shown to predict morbidity and survival time (Studenski et al., 2011). Gait speed has also been suggested as a surrogate measure of vestibular dysfunction (Liu et al., 2017), which in turn is associated with a 12-fold increase in falls (Agrawal et al., 2009). Vestibular rehabilitation (VR) is considered the standard of care for treating deficits related to vestibular hypofunction and has been shown to improve postural instability and visual acuity during head rotation (Herdman et al., 2003, 2007; Hall et al., 2004; Schubert et al., 2008), but also to reduce perception of disability due to dizziness and reduce fall risk (Herdman et al., 1995; Hall et al., 2022).

The mechanism by which VR improves both the impairments and perception of dizziness is not fully understood though the processes of adaptation and habituation are certainly involved. Adaptation as applicable to VR implies a change in a physiologic response such as improved gain of the vestibulo-ocular reflex (Scherer et al., 2008; Schubert et al., 2008a) or an enhanced sensory reweighting such as increased reliance on vision (Lacour et al., 1997). It is thought that adaptation may involve the recalibration of existing physiological pathways, such as the corticospinal pathway involved in postural stability (Borel et al., 2002, 2004). In contrast, the process of habituation as applicable to VR implies a reduction of the intensity of a symptom (i.e. the sensation of dizziness) due to a repeat exposure to such motion provocation (Telian et al., 1990; Clendaniel 2010).

Vestibular sensation is critical for maintaining stability during the rapid head rotation common during gait (Raphan et al., 2001; St George and Fitzpatrick, 2011) and lesions to the peripheral vestibular end organ typically cause a “cautious” gait that is characterized by increased stride width, reduced ankle mobility, reduced gait speed, and reduced step length (Liu et al., 2017). In addition, patients with vestibular hypofunction spend more time while turning

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(Kim et al., 2021) as well as have smaller, fewer, and slower head turns than healthy controls (Paul et al., 2018). Patients with vestibular hypofunction have increased head-trunk coupling during large head turns, but not small head turns (Paul et al., 2018).

Recently, it has been reported that a patient's gait speed, stability, and variability are linearly related to the extent of vestibular asymmetry (Liu et al., 2017). Restoration of gait and posture is a major goal for clinicians treating patients with vestibular hypofunction, yet little normative data is available for clinicians to reference as a guide for knowing their patients have made a meaningful change in behavior. If gait speed is to be used as a measure of vestibular function, it must be determined what improvement in gait speed predicts a significant change in vestibular outcomes.

1.2. Minimal clinically important difference

An individual's quality of life should be an important primary outcome in human-subjects research. These measures are difficult to quantify and must be both valid and reliable (Guyatt et al., 1987, 2002). The minimal clinically important difference (MCID) is defined as the smallest change in a health-specific measure that is both perceived as beneficial by the individual and causes a change in healthcare strategy by the individual's healthcare team (Jaeschke et al., 1989). This definition therefore requires improvements perceived by both the clinician and the individual (Cook, 2008). Nine unique methods exist to determine the MCID, the method chosen depends on the type of data used for comparison (Beaton et al., 2001; Wells et al., 2001). These comparisons can be distribution-based, opinion/expert-based, or anchor-based (Lassere et al., 2001). Anchor-based methods use clinical or patient-reported measures to determine significant changes (Rai et al., 2015; Mouelhi et al., 2020).

For our research objective, the anchor-based method of MCID calculation is optimal since it compares change in a patient- or clinician-reported outcome to an objective change (Lydick and Epstein, 1993). This is referred to as the “within-patient” approach to anchor-based MCID (Juniper et al., 1994; Jaeschke et al., 1989; Copay et al., 2007). Common examples of patient-reported outcomes that have been used to calculate the MCID include the Global Rating of Change, Pain Disability Index, or Symptom Scale Interview (Mouelhi et al., 2020). In VR, common patient-reported outcomes include the Dizziness Handicap Inventory (DHI) and the Activity Balance Confidence (ABC) Scale. The DHI is a measure of the patient-perceived disability due to dizziness (Jacobson and Newman, 1990). It contains 25 questions and operates on a scale of even numbers with range of 0–100 (higher numbers indicate greater perception of disability) (Jacobson and Newman, 1990). The DHI is commonly grouped by severity – mild, moderate, and severe (Whitney et al., 2004). The DHI score significantly improves after VR (Cowand et al., 1998; Cohen and Kimball, 2003; Millar et al., 2020). The MCID for DHI in cases of vestibular dysfunction is 18 points, meaning that an increase in DHI of 18 points is the minimal improvement required for a significant change using a 95% confidence interval (Jacobson and Newman, 1990). Like the DHI's measure of patient-perceived disability, the ABC is a measure of patient-perceived confidence of balance doing various functional tasks (Powell and Myers, 1995). The ABC includes 16-questions that are scored ranging from 100% confidence to 0% confidence. Mean scores are tallied and interpreted as scores above 80% indicate high functioning, scores between 50% and 80% indicate moderate functioning, and scores below 50% indicate low functioning (Powell and Myers, 1995; Myers et al., 1998). The DHI is highly correlation with the ABC (Whitney et al., 1999). The MCID for the ABC ranges from 7 to 24% change score (Wellons et al., 2022).

1.3. Objectives and study design

The objective of this observational study is to determine the MCID in change of gait speed in patients with vestibular hypofunction mostly related to deafferentation, necessary for predicting an improvement in two patient reported outcomes (the DHI and the ABC). Four methods have been identified for calculating MCID using this type of anchor: Change Difference, Regression Analysis, Receiver Operator Curve, and Average Change (Mouelhi et al., 2020). In each of our three cohorts, we have recorded gait speed and DHI and/or ABC at both the onset and after six weeks following VR. To determine the required gait speed improvement, we calculated the MCID by each of the four methods using both the DHI and the ABC. A recent study calculated gait speed MCIDs in a heterogeneous group of patients with vestibular hypofunction in a rehabilitation setting to be 0.07–0.22 m/s (Wellons et al., 2022). We hypothesize that our calculated MCIDs will be in this range as well.

2. Methods

2.1. Participants and rehabilitation methods

Patients with vestibular hypofunction (n = 56) primarily due to surgical intervention for vestibular schwannoma (96%; n = 54) were recruited as part of three cohorts, all approved by their respective Institutional Review Board. The n = 2 patients with non-surgical unilateral vestibular hypofunction were confirmed via asymmetry greater than 25% on caloric test. The first cohort of patients were recruited from the Johns Hopkins University (JHU) School of Medicine as part of the Sensorimotor Assessment and Rehabilitation Apparatus (SARA) study (IRB: 00059430) (Schubert, 2017). The second cohort was recruited from Duke University (Clendaniel, 2010) and the third cohort was recruited from University of Utah (IRB: 00125069). In all cohorts, VR resembled those detailed by Millar et al. (2020) and patient data included gait speed, DHI, and ABC. Patients with major orthopedic or cardiovascular pathology were excluded.

2.2. MCID calculations

We fit DHI scores into three categories: 16–34 indicated mild handicap, 36–52 indicated moderate handicap, and 54 or greater indicated severe handicap in accordance with common clinical use (Stony Brook Medicine Southampton pdf). To calculate MCID, we used the four methods described above (Mouelhi et al., 2020). First, we calculated the difference in DHI, ABC, and gait speed between baseline and each time point. We treated the four ordinal impairment severities as discrete, quantitative variables, enabling us to perform linear regressions of the effect of change in gait speed on the change in impairment category for each time interval and measure (Table 1). We then created a dummy binary to contrast those who changed their category to those who did not. It has been reported that the MCID for the DHI is 18 points, thus we created an additional dummy binary to contrast those whose DHI changed by 18 points (Jacobson and Newman, 1990). All statistics were

Table 1
DHI and ABC Severity Categories. DHI scores can never be uneven. DHI – dizziness handicap inventory; ABC – activities-specific balance confidence scale.

Severity	DHI Range	ABC Range
None	0–14	100%
Mild	16–34	80% - 99%
Moderate	36–52	50%–79%
Severe	> 54	< 50%

conducted in STATA (College Station, Texas).

Regression Analysis was conducted using the change in gait speed against the change in severity category. The MCID was taken as the coefficient of the regression and interpreted as the minimal change in gait speed required to improve (or worsen) by one severity category. Change Difference and Average Change were compared by conducting a two-sided*t*-test of the change in gait speed by the binary of whether a participant changed severity categories or whether participant's DHI changed by 18 points. In the output of the *t*-test, the Change Difference MCID was taken as the difference between responders and non-responders while the Average Change MCID was taken simply as the value for responders. Because both values come from the same *t*-test, the p-values and degrees of freedom for the Change Difference and Average Change are the same.

Receiver Operator Curves (ROC) were calculated using the Non-Parametric ROC Curve feature in STATA. The binary of whether a participant changed severity or whether a participant's DHI changed by 18 points was used as the gold standard, to which the change in gait speed was compared. As calculated in this way, MCID was defined as the point with greatest percent correctly classified, which has the highest combined sensitivity and specificity and is the point closest to the top left of the curve (Mouelhi et al., 2020). Tests were considered sensitive if the sum of sensitivity and specificity was greater than one, and tests were considered significant if the 95% confidence interval for the area under the curve did not include the null value of 0.500.

3. Results

Our cohort was composed of three recruiting groups. At JHU, n = 42 patients with unilateral vestibular schwannoma tumor resection (26 left, 16 right) were recruited, aged 52.0 ± 13.0 years (Harris et al., 2009, 2019). The second cohort of patients (n = 7) were recruited from the Duke University Medical Center, aged 43.9 ± 14.5 years with unilateral vestibular hypofunction based on surgical history, abnormal caloric examinations (n = 5 with surgical deafferentation, n = 2 with vestibular neuritis). The third patient cohort (n = 7, unilateral vestibular deafferentation due to unilateral vestibular schwannoma tumor resection) were recruited from the University of Utah, aged 45 ± 15.2 years. Combined, patients received vestibular nerve resection surgery at a median of 77 days from diagnosis (mean 230 ± 486). VR was initiated at a median of 4 days from surgery (mean 11 ± 18), Table 2.

After six weeks of VR, we show that an improvement in gait speed from 0.08 to 0.32 m/s predicted a significant change in outcome as evaluated by the DHI while an improvement of 0.20–0.34 m/s predicted a significant change in outcome as evaluated by the ABC (Table 3). However, some of these values were not significant. Therefore, considering only significant values with a 95% level of confidence, the gait speed improvements were 0.23–0.32 m/s for the DHI and 0.20–0.34 m/s for the ABC. Gait speed was weakly, yet positively correlated with the DHI (Fig. 1, top; coefficient = 20.63, 95% CI: 1.55, 39.72; R^2 = 0.09, F(1, 37) = 4.80, p = 0.035) and the ABC (Fig. 1, bottom; coefficient = 27.53, 95% CI: 10.31, 44.76; R^2 = 0.27, F(1, 29) = 10.68, p = 0.003).

In order to determine MCID we first regressed change in gait speed with improvement in at least one severity level (i.e. moderate to mild, per Table 1) (Jayadevappa et al., 2012). Using the DHI, a gait speed change of 0.080 ± 0.112 m/s was necessary to show a change in an impairment (31/39), yet this change was not significant (F(1, 9) = 0.510, p = 0.492). Using the ABC, a gait speed change of 0.214 ± 0.136 m/s was necessary to change impairment category (20/31), which was similarly not significant (F(1, 20) = 2.510, p = 0.129).

Next, we calculated MCID by defining the Change Difference as the difference in gait speed change between those who improved at least one severity category (per Table 1) and those who did not. Using the DHI, at six weeks those who changed a severity category did show an improved gait speed by 0.127 ± 0.132 m/s, though this was not significant (F(1, 37) = 0.92, p = 0.344). When we determined MCID using a Change Difference of 18-point on the DHI, a gait speed of 0.234 ± 0.111 m/s was significant (t(1, 37) = -2.115, p = 0.041). Using the ABC, at six weeks those who changed classification had an MCID of improved gait speed by 0.325 ± 0.092 m/s, which was also significant (F(1, 29) = 12.57, p = 0.001).

Using ROC to demonstrate the sensitivity and specificity of using gait speed changes as a measure of change in at least one severity category at six weeks, the area under the curve (AUC) was 0.583 (95% CI: 0.376, 0.789) for the DHI (Fig. 2, top) with an MCID of 0.24 m/s (sensitivity: 58.1%, specificity: 75.0%, 61.5% correctly classified). For the ABC (Fig. 2, bottom), at six weeks the AUC was 0.846 (95% CI: 0.690, 1.000) with an MCID of 0.20 m/s (sensitivity: 85.0%, specificity: 90.9%, correctly classified: 83.9%). When considering a DHI change score of 18 points, at six weeks the AUC (Fig. 3) was 0.715 (95% CI: 0.553, 0.876) with an MCID of 0.24 m/s (sensitivity: 66.7%, specificity: 83.3%, 71.8% correctly classified).

The fourth MCID method used the Average Change in gait speed among those who improved by at least one severity level (per Table 1) on the DHI or ABC after six-weeks of VR. Using the DHI, those who improved one severity level had an improved gait speed of 0.271 ± 0.062 m/s, though this was not significant (t(37) = -0.959, p = 0.344). Using an 18-point DHI change score with MCID of gait speed by 0.317 ± 0.067 m/s was significant (t(37) = -2.115, p = 0.041). Using the ABC, those who improved their category had an MCID 0.337 ± 0.057 m/s, which was significant (t(29) = -3.547, p = 0.001).

4. Discussion

We conducted an observational, retrospective cohort study to determine the minimal clinically important difference in gait speed that corresponds with a significant improvement in the Dizziness Handicap Index or Activity Balance Confidence Scale in patients with unilateral vestibular hypofunction. Our results reveal that the magnitude of MCID varied somewhat depending on the significance of the model chosen to determine it.

An MCID is evaluated in three ways: statistical significance, clinical significance, and face validity. By definition (Jaeschke et al., 1989) and as applicable to our study, MCIDs are the difference in gait speed required to trigger a change in a patient's care trajectory. Our baseline mean and 1SD gait speed was 1.20 ± 0.28 m/s. Our

Table 2
Participant Characteristics of the Three Cohorts. DHI – dizziness handicap inventory; ABC – activities-specific balance confidence scale; SD-standard deviation. Characteristics of the three cohorts recruited are shown. The Duke cohort did not record ABC.

Cohort	Participants (n)	Age (mean ± SD)	Initial Gait Speed (m/s, mean ± SD)	Initial DHI (mean ± SD)	Initial ABC (mean ± SD)
Hopkins	42	52.0 ± 13.0	1.24 ± 0.27	41.9 ± 22.1	68.9 ± 18.8
Duke	7	43.9 ± 14.5	1.07 ± 0.12	55.7 ± 19.3	
Utah	7	45.0 ± 15.2	1.06 ± 0.40	66.9 ± 27.0	57.0 ± 28.2

Table 3
Summary of Minimal Clinically Important Differences. MCID values are shown for each method of calculation using the DHI and the ABC as mean (95% CI). *denotes significance at $\alpha = 0.5$. ROC analysis does not produce a 95% confidence interval. DHI – dizziness handicap inventory; ABC – activities-specific balance confidence scale.

	Six Week Change in Gait Speed (m/s)	
	DHI	ABC
Regression Analysis	0.08 (−0.17, 0.33)	0.21 (0.07, 0.50)
Change Difference	0.13 (−0.14, 0.40)	0.32* (0.14, 0.51)
Change Difference (18-point change)	0.23* (0.01, 0.46)	
Receiver-Operator Curve	0.24	0.20*
Receiver-Operator Curve (18-point change)	0.24*	
Average Change	0.27 (0.14, 0.40)	0.34* (0.22, 0.46)
Average Change (18-point change)	0.32* (0.18, 0.46)	

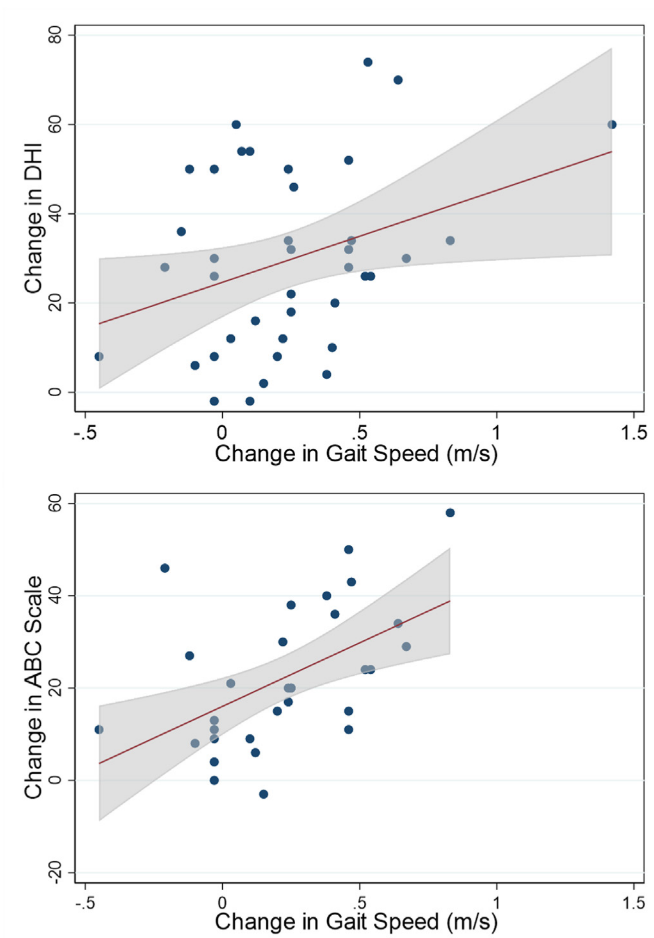

Fig. 1. Trendlines and Confidence Intervals in DHI and ABC Improvements
Scatterplots of gait speed changes at six weeks compared with changes in DHI (**top**, $R^2 = 0.11$) or ABC (**bottom**, $R^2 = 0.27$). These scatterplots were fitted with trendlines and 95% confidence intervals (shaded regions). Dizziness Handicap Inventory (DHI) and the Activity Balance Confidence (ABC) Scale.

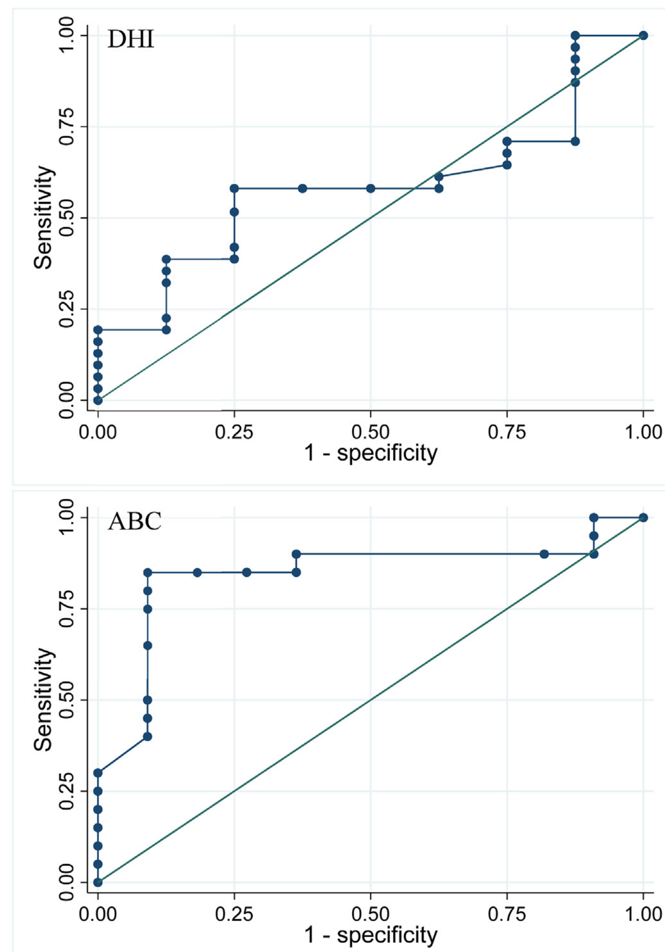

Fig. 2. Receiver-Operator Curves
Receiver-operator curves using change in gait speed as a continuous variable and improvement by at least one severity level in either the DHI or the ABC as a binary variable. Curves compared with changes in DHI (**top**) and ABC (**bottom**).

standard error of the mean was 0.04 m/s yet varied from 0.45 to 1.82 m/s. Practically, if we consider an MCID for gait speed of 0.1 m/s, then our fastest walker would only need to improve their gait speed by 5% to be considered significant. We believe this too small to be a valid representation of an objective improvement. In contrast, using an MCID of 0.29 m/s, which approximates the central tendencies of our statistically significant MCIDs, a patient with a baseline gait speed equal to our mean (1.20 m/s) must improve their gait speed by 25% to predict a significant change in vestibular outcomes. This is a large objective improvement predicting a large subjective improvement, which we believe represents good clinical significance with relevant face validity.

Comparing MCIDs calculated within our data, both Regression Analysis and Change Difference methods had poor internal consistency: the MCID calculated using Regression Analysis was statistically insignificant, and the two MCIDs calculated by the Change Difference method differed by almost 40%. Receiver Operator Curves had the best internal consistency, with two significant MCIDs falling within 0.04 m/s and the one insignificant MCID

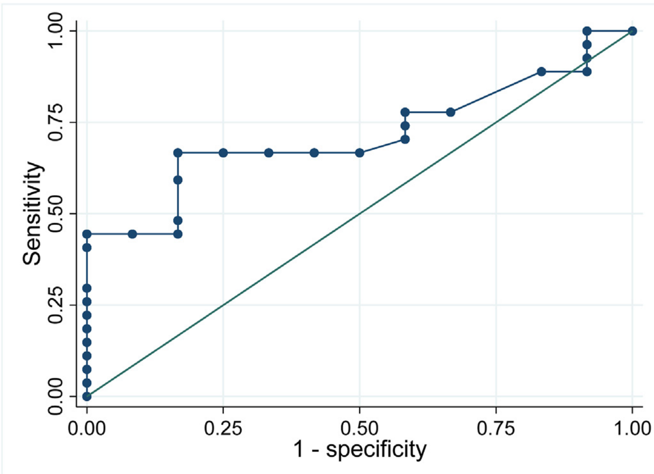

Fig. 3. Receiver Operator Curves for 18-Point Cut Point
Receiver-operator curves were created using change in gait speed as a continuous variable and improvement on the DHI by at least 18 points as a binary variable.

equaling one of the significant MCIDs. Using the Average Change method, the two significant MCIDs were within 0.02 m/s of one another, but the insignificant MCID was 0.05 m/s below the lower significant MCID. Average Change was the most liberal method of calculation. We therefore believe that, given our dataset, Receiver Operator Curves were the best method of calculating MCID. The Area Under the Curve for the ABC (0.846) exceeded 0.800, which is interpreted as having outstanding sensitivity and specificity (Mandrekar, 2010).

The ABC appeared a more consistent measure of change in gait speed than the DHI. Three of the four MCIDs methods using the ABC were significant, as compared to only three of the seven MCIDs calculated using the DHI, even though we had eight more patients with DHI data (39) than ABC data (31). MCIDs calculated using the DHI and both Regression Analysis (0.08 m/s) and Change Difference (0.13 m/s) were well outside the range of all other calculations. Perhaps this can be explained by the interpretation that the ABC scale better reflects constructs of motion and posture as opposed to the varied subscales of the DHI.

Our calculated MCID for gait speed are higher than those recently reported for patients with vestibular hypofunction that also completed VR (Wellons et al., 2022). Wellons et al. reported gait speed MCID ranging from 0.07 to 0.22 m/s (Wellons et al., 2022) with ROC values (0.6079) much lower than ours (0.846; 95% CI: 0.690, 1.000). One reason for the apparent discrepancy is the difference in sample between our studies. Our participants were of an overwhelming majority of surgical cases. The Wellons study include a broader inclusion of hypofunction pathologies. In addition, Wellons et al. anchored their MCIDs to the DHI perhaps presuming the DHI a better measure than the ABC. Our data reveal the MCIDs calculated using the ABC were more often significant than those considering the DHI.

Our reported MCID for gait speed in unilateral vestibular hypofunction is higher than those reported in other conditions: 0.1 m/s in hip fracture (Palombaro et al., 2006), 0.1 m/s in stroke (Perera et al., 2006), and 0.05–0.12 m/s in geriatric care (Pulignano et al., 2016). One explanation for our MCIDs being larger is our calculation of MCID using a clinically significant change in perception of severity in handicap, which again was well-powered as evidenced by the AUC values we report in our ROC analysis. A second reason for the apparently large MCID values we report is that neither the hip fracture (Palombaro et al., 2006) nor geriatric methods (Pulignano et al., 2016) used MCIDs with an anchor, relying instead on statistical significance. While statistical significance has great value, there is often no clinical meaning for the cut points. Anchoring to a clinical measure as opposed to a statistical measure gives a translational interpretation that seems more appropriate for reporting MCIDs in patients.

4.1. Limitations

Though we have calculated the MCID for gait speed in unilateral vestibular hypofunction, we have done so in a group of subjects with limited pathology (96% had surgical ablative procedures to the vestibular system), thus the MCID values (0.20–0.34 m/s) and the initial gait speeds (0.45–1.82 m/s) that we report varied considerably. However, we believe the combination of these three cohorts and our sample size improves generalizability to those rehabilitation providers treating patients with vestibular nerve section.

5. Conclusions

In patients with unilateral vestibular hypofunction primarily due to surgical tumor removal, we have shown that the minimal clinically important difference in gait speed predicting a change in perception of disability (DHI) and balance confidence (ABC) ranges from 0.20 to 0.34 m/s with a 95% confidence level, respectively. Receiver Operator Curve was the best method of calculating MCID, and the ABC was a more consistent measure of vestibular outcomes than the DHI.

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Declaration of competing interest

The authors report no conflicts of interest.

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