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Are we supererestimating gait assessments of patients with idiopathic normal-pressure hydrocephalus?

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ABSTRACT

Introduction: Idiopathic normal pressure hydrocephalus (iNPH) is a syndrome characterized by a triad composed of cognitive alteration, urinary incontinence, and gait impairment associated with ventricular enlargement and normal cerebrospinal fluid pressure. Gait impairment is among the earliest symptoms; however, the reliability of the evaluation is not well-established and no consensus has been reaching regarding variables that should be analyzed and which parameters should be considered to accurately assess post-intervention improvement.
Research question: Are the degree of repeatability, standard error of measurement, and minimum detectable change considered to detect changes in gait variables in iNPH patients?
Methods: A total of 84 iNPH patients with a mean age of 77.1 (± 6.4) years were analyzed. Gait deviation index (GDI), speed, cadence, cycle time, stride length, single support, and first and second double support were chosen as the variables to be analyzed. Statistical analysis was performed by an independent evaluator, with gait repeatability assessed by the intraclass correlation coefficient (ICC) and the standard error of measure (SEM).
Results: ICC values were 0.76–0.85 with excellent repeatability, while SEM demonstrated that the variables with best repeatability were the GDI (mean, 4.94; 95% confidence interval (CI), 4.63–5.43), representing a 7.65% mean relative error of the measurement (mean, 0.05 m; 95% CI, 0.05–0.06), and stride length (mean 0.05 m; 95% CI, 0.05–0.06), with a 7.69% mean relative error.
Significance: We concluded that GDI and stride length were the variables with the best repeatability and lower variability in the gait of iNPH patients.

1. Introduction

Idiopathic normal pressure hydrocephalus (iNPH) is characterized by a triad of disturbances – including gait deviation, cognitive deterioration, and urinary incontinence – associated with ventricular enlargement but no elevated cerebrospinal fluid (CSF) pressure [1,2]. Gait impairment is the earliest symptom, characterized as hypokinetic [3], broad-based [4], feet rolled out, reduced speed and step length [5], in addition to difficulty initiating movement and instability while moving [6].

Because it is a primary feature, the diagnosis of gait dysfunction is fundamental, and the Tap Test (TT) is one of the most commonly used prognostic tests to determine whether the patient is responsive to CSF withdrawal (via lumbar puncture) [7–10] and estimate the likelihood of improvement after the implantation of a CSF system [11,12].

Although TT is widely used, there is no consensus on which parameters of gait should be analyzed. Chivukula et al. [13] used the dynamic gait index to assess gait improvement before and after CSF removal. Other studies analyzed velocity, stride length, and duration [14,15] as well as stride width and height [14]. Virhammar et al. [16] focused on the time and number of steps patients took on a 10-m track, while Wilkkesø et al. [17] compared the number of steps on an 18-m track, both pre- and post-TT. In turn, Williams et al. [18] analyzed the velocity, stride and stride length, cadence, and double support time before and after CSF.

Among the studies performed to date, some identified 5% [7,10,17,19] as the percentage of change needed to improve gait, while others identified 10% [5,16] and/or 20% [16,20]. However, none establishes the standard error of the measurement (SEM) or a plausible justification for the use of a particular variable and its percentage of change to consider patient improvement. Therefore, the aim of this study was to determine the degree of repeatability and the SEM of gait

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deviation index (GDI) as well as speed, cadence, cycle time and stride length, and double and single support during the analysis of patients with suspected iNPH.

2. Materials and methods

2.1. Participants

A retrospective analysis of the data collected between 2012 and 2016 from the Movement Analysis Laboratory (LEME-HIAE) was performed. The study involved 84 patients with a suspected iNPH diagnosis referred by neurologists based on the second edition of the Japanese iNPH guidelines [21].

Our sample included patients without visual and auditory deficits; who were capable of understanding simple commands; who were able to walk independently; who were able to walk barefoot; and who presented the triad of symptoms described in the medical records. Exclusion criteria were: patients < 60 years; uncontrolled infection, uncontrolled pre-existing medical conditions such as decompensated diabetes, hypertension, symptomatic pneumopathies or heart disease, orthopedic disorders; and use of orthoses. Inclusion and exclusion criteria was verified according to the laboratory findings, medical history, and medical records of each patient. The present study received approval from the ethics committee of the Hospital Israelita Albert Einstein under protocol number 775.998.

2.2. Procedure

All patients wore shorts and tops and were asked to walk barefoot on a trail measuring 1.5 m × 10 m at a self-selected speed. All gait analysis data were captured by 10 synchronized Vicon MX (Denver, CO, USA) cameras and Vicon Nexus 1.8.5 software.

2.3. Data processing and analysis

After the coordinates of the markers were captured, they were processed and saved in C3D format. Vicon Nexus 1.8.5 software was used to estimate the position of the articular centers and calculate the three-dimensional kinematics of the pelvis, hip, knee, and ankle joints, following the Plug-in-Gait® biomechanical model (Vicon®, 2002). Subsequently, a Woltring filter with a 2 mean square error (MSE) was applied to reduce noise produced by the movement cycle. The gait cycle was detect using the foot velocity algorithm [22]. Each patient participated in a single session that consisted of at least 10 trials. Six representative trials were randomly selected for analysis and were the same used in the gait laboratory report to calculate linear parameters and the GDI. Therefore, a total of 504 cycles were analyzed. GDI is based on the calculation of the distance between the patients' data and the mean of the reference data set in 15 kinematic gait characteristics [23], thus generating a more effective gait quality result [24]. The result of the index was 0–100 points, a value of 100 points or higher indicating the absence of a pathological gait [23]. This gait index is widely used in patients with cerebral palsy [25], Parkinson's disease [26,27], or stroke [28] as well as amputees [29].

The statistical analysis was performed by an independent evaluator, and the Shapiro-Wilk test was used to determine the distribution of the data. The gait repeatability of the subject group was verified by the intraclass correlation coefficient ($ICC_{2,1}$) [30]. To analyze the ICC results, the following criterion was used: poor = 0.00–0.39, weak = 0.40–0.59, good = 0.60–0.74, and excellent = 0.75–1.00 [31]. To quantify the magnitude of the changes in the gait variables studied, the minimum detectable change (MDC) was calculated using the 90% and 95% confidence levels (CIs) and the following formulas [30]:

$$MDC_{90} = 1.64 \times SEM \times \sqrt{2}$$

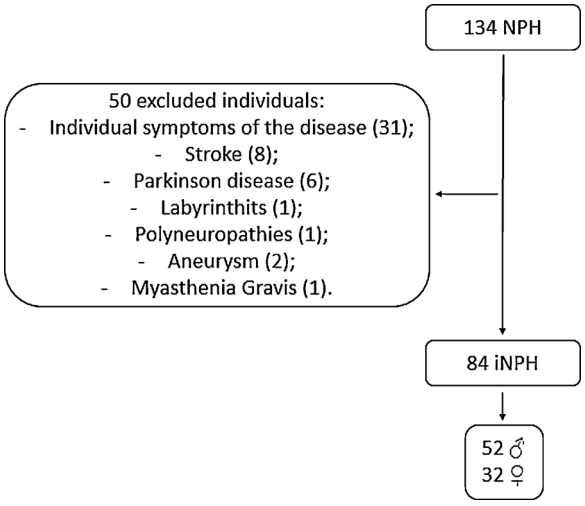

Fig. 1. Study flowchart.

$$MDC_{95} = 1.96 \times SEM \times \sqrt{2}$$

The SEM of each kinematic variable was calculated using the following formula [30]:

$$SEM = SD \times \sqrt{1} - ICC$$

3. Results

The flowchart of the study is shown in Fig. 1, while the demographic data are expressed in Table 1.

The mean, standard deviation, ICC, SEM and their respective CIs, and MDC_{90} and MDC_{95} are presented in Table 2.

Kinematic data presented excellent repeatability, with $ICC_{2,1}$ values of 0.76–0.95, and stride length presented the highest value at 0.95 (95% CI, 0.94–0.96). The second double support had the lowest value at 0.76 (95% CI, 0.76–0.79), but it was also found to be excellent (Fig. 2).

According to SEM, low values reflect greater reliability of the measurements since they best indicate their accuracy [32]. GDI had the highest reliability of all variables studied, with a SEM of 4.94 (95% CI, 4.63–5.43), which represents a 7.65% mean relative error of measurement (%SEM) and minimum detectable change values of 11.46 (MDC_{90}) and 13.69 (MDC_{95}). The second double support was the least reliable variable, with a SEM of 3.17% of the walking cycle (95% CI, 2.86–3.49); this value represents a 15.62% %SEM, and the values for minimum detectable change were 7.35 (MDC_{90}) and 8.79 (MDC_{95}).

4. Discussion

This study investigated the variables with lower variability and greater repeatability during a gait analysis session that consisted of 84 iNPH patients performing six gait cycles. The results demonstrated excellent repeatability and low variability, particularly for GDI and step length variables.

The criterion used to detect improvement in locomotor capacity

Table 1
Demographic data of the sample with the respective means ± standard deviation.

	Female N = 32	Male N = 52
Age (years)	77.31 ± 7.71	77.07 ± 5.60
Height (cm)	158.9 ± 6.13	169.8 ± 6.7
Body mass (kg)	67.5 ± 14	77.6 ± 10.7

Table 2
Repeatability, standard error of measurement and minimum detectable difference of gait variables: velocity, cadence, stride time, 1st and 2nd double support, single support, stride length and GDI of patients with iNPH.

	Mean (SD)	ICC (95% CI)	SEM (95% CI)	%SEM	MDC_{90}	MDC_{95}
Velocity (m/s)	0.52 (± 0.22)	0.94 (0.93–0.95)	0.05 (0.05–0.06)	10.25	0.12	0.15
Cadence (stride/min)	86.91 (± 17.04)	0.79 (0.75–0.83)	7.71 (6.98–8.45)	8.86	17.88	21.37
Stride time (s)	1.44 (± 0.39)	0.78 (0.74–0.82)	0.18 (0.16–0.20)	12.76	0.42	0.50
1 st Double Support (% gait cycle)	20.18 (± 6.58)	0.77 (0.72–0.81)	3.08 (2.79–3.38)	15.29	7.14	8.54
Single Support (% gait cycle)	29.77 (± 6.06)	0.83 (0.74–0.80)	2.46 (2.31–2.61)	8.27	5.71	6.82
1nd Double Support (% gait cycle)	20.33 (± 6.51)	0.76 (0.76–0.79)	3.17 (2.86–3.49)	15.62	7.35	8.79
Stride Length (m)	0.70 (± 0.25)	0.95 (0.94–0.96)	0.05 (0.05–0.06)	7.89	0.13	0.16
GDI	64.51 (± 12.93)	0.85 (0.83–0.87)	4.94 (4.63–5.43)	7.65	11.46	13.69

SD: standard deviation; ICC: intraclass correlation coefficient; CI: confidence interval; SEM: standard error of measurement; MDC: minimum detectable change; m/s: meters/second; min: minute; s: second; m: meter.

after an intervention remains a critical and controversial issue in the clinical practice of professionals treating iNPH patients. The variables most frequently found in the literature as parameters for detecting gait improvement in iNPH patients include speed [5,14,15,18], cadence [18], cycle time [5], stride length [14,15,18], double support [5], step width [14], base of support and height of step [14,18], time or number of steps to walk a certain distance [7,10,14–16], and stride time [14,15]. However, no consensus has been reached regarding both the best variable and the associated percentage to determine improvement after an intervention. Some studies argued that velocity should be greater than 5% [7,19] or 10% [5], and cadence greater than 5% [7,10,17,19], others claim that improvement would result from a positive association between the number of steps and the time needed to reach a given distance [16].

A number of studies used instrumented gait analysis and more robust data analysis methods to measure whether patients are responsive to the TT and shunt. However, the results are conflicting since the individual improvement in gait variables found pre- and post-TT are predictors of the response to surgery and is directly related to the screening of patients based on a specialized clinical assessment [18]. On the other hand, Agostini et al. [5] found no difference using a single score consisting of five linear variables and knee range of motion to calculate each patient's distance compared to the control group (Mahalanobis Distance). The researchers found that a combination of variables was more effective for detecting post-TT improvement.

Non-instrumented clinical tools have also been used in gait assessments of iNPH patients and have shown that values ≥ 7 in the dynamic gait index are sensitive and specific [13]. In the Timed Up and Go test, values > 16.5 s were also sensitive and specific for diagnosing patients with iNPH [31]. Regardless of whether or not instrumentation was used to evaluate the patient's gait, the studies mentioned above did not present repeatability and variability data, which may compromise their findings and their interpretation.

Once gait is considered critical in the diagnosis of suspected iNPH, the methods selected for gait evaluation should be associated with a small SEM value since it is crucial to ensure a small degree of measurement error when baseline assessment is performed. In this study, GDI and stride length presented excellent repeatability and similar % SEM values when gait cycles were evaluated. Therefore, if a patient presented a GDI of 64.51 on the first gait evaluation, our results indicate with 95% confidence that this patient's GDI is 50.82–78.2 or 2.77 times the SEM (4.94); similarly, if the stride length is 0.70 m, our results indicate with 95% confidence that this patient's stride length is 0.86–0.54 m.

We may extrapolate the results presented here and observe changes in gait velocity over time (pre- and post-TT or post-shunt). Our findings indicate that a change of 0.15 m/s or more in gait velocity is required in the assessments to ascertain with 95% confidence that an actual change

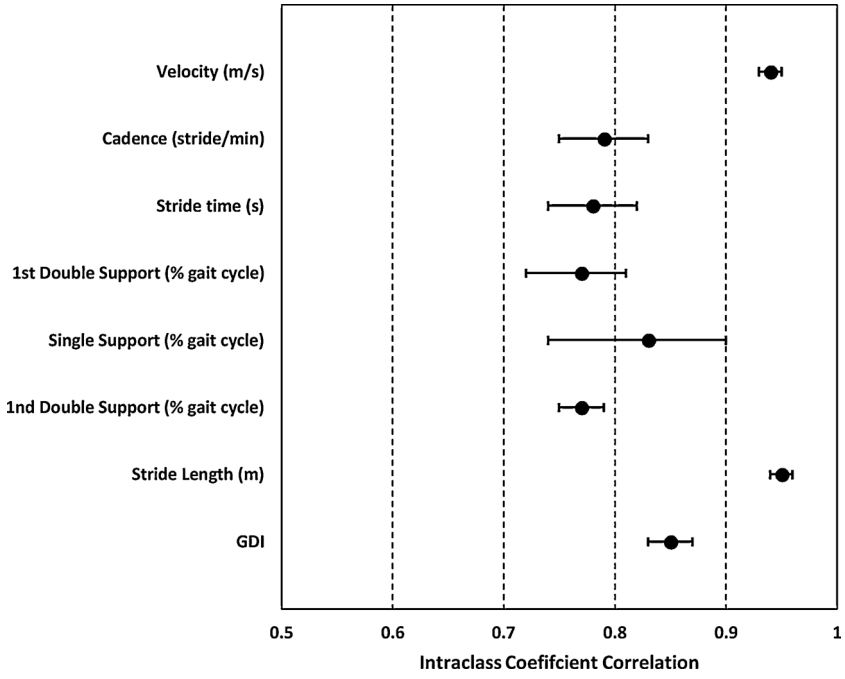

Fig. 2. Intraclass correlation coefficient (95% CI) of the tridimensional gait analysis.

occurred beyond the measurement error in iNPH patients. However, if we consider a 10% or even 20% increase in velocity, a patient walking at a speed of 0.52 m/s would have improved speed if his performance increased to 0.052 m/s and 0.104 m/s; however, this finding would have been underestimated and the diagnosis overestimated since SEM was not considered.

When we collect a series of measurements of the same clinical variable, we expect that these measures show some variability. This may be due to imperfection of the measuring instrument, specificity of the methodology used, or the fact that the property of the variable being measured may vary from one test to another or between patients. Understanding the amount of variability associated with a measurement may be very important in the clinical decision-making process. If we know that the variability of the measurement is low, we may have confidence in the measurement and thus use it as a variable at the moment of the intervention. On the other hand, the high variability of a measurement results in less confidence. Therefore, understanding the process requires acknowledging variability, such as the use of different methodologies or techniques, the days in which the measurements were taken, and the repetition of the same measurement [24].

Since patients normally perform the gait test on one day and the TT on the following day, further studies should carefully assess the reliability of the measurements and identify MDC values calculated from measurements performed at longer time intervals, such as days or weeks, as the results may differ from those that are calculated from repeated measurements performed during the same test session.

5. Conclusion

The variables presenting best repeatability and lower variability were GDI and stride length, respectively, but other variables could be used in iNPH patients that consider the SEM and MDC values. Our results suggest that professionals may be supererestimating gait assessment in iNPH patients.

Disclosure statement

None of the authors reports any conflict of interest.

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