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Gait tests in multiple sclerosis: Reliability and cut-off values

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ABSTRACT

Background: Gait limitation is one of the most common disabilities in people with multiple sclerosis (MS). Several studies have used gait parameters to determine the effects of different therapies. However, few studies have determined their reproducibility, also the therapeutic effects could be overestimated.
Research question: To examine the reproducibility in gait measurements during short and long distances.
Methods: In this cross-sectional study we recruited a group of MS patients and compare it to a control group. The participants performed the following tests in a fixed order: a 25-foot walk at a comfortable speed, at a fast speed and during a dual task, a timed up-and-go test (TUG) and a six- minute walk test (6MWT). Two measurements were conducted a week apart. Systematic error was evaluated by the Student *t*-test, reliability by the intra-class correlation coefficients (ICC) and agreement by the minimum detectable change (MDC_{95}).
Results: A total of 58 people with MS and 19 healthy people were included. The absence of systematic error was only found for the fast speed condition. The reliability of the gait parameters had moderate to high ICC values (ICC > 0.7) except for the dual task cost (DTC) which was 0.45. The MDC_{95} was higher in people with MS compared to healthy people, and it was higher in people with MS for gait speeds in all conditions (> 34%). For the TUG and 6MWT, the MDC_{95} were 51.5% and 31.7% respectively. For people with MS the smallest MDC_{95} was found for the stance time for all conditions (6.8%), whereas the highest was found for the dual task cost (158.7%).
Significance: The MDC_{95} values were higher than the cut-off point based on the minimally important clinical difference (MICD) proposed in previous studies. Thus, the MDC_{95} should be used as a cut-off rather than MICD values.

1. Introduction

Gait limitation, defined as an activity limitation by the International Classification of Functioning Disability and Health, is one of the most common and disabling signs in people with multiple sclerosis (MS) [1,2], and 70% of them have reported gait limitations as the most serious problem [3].

Different parameters have been used to measure gait limitations in multiple sclerosis, including the timed 25-foot walk (T25FW), six-minute walk test (6MWT), spatio-temporal gait parameters measured with an instrumented walkway, or the timed up-and-go test (TUG) [4]. These different assessments can be performed using different conditions: a simple task, fast speed or dual task in which one gait is associated with a cognitive or other motor task [5].

Different approaches are possible for studying walking and changes in gait. The minimally important clinical difference (MICD) is one method and is defined as the smallest difference in an outcome of interest that is perceived as beneficial and non-trivial by patients and clinicians and can enhance patient management [6]. For people with MS, changes from baseline in the T25FW around 17.2%–20% are generally considered as clinically meaningful [7–12].

In order to determine meaningful clinical parameters as described above, it is also important to determine the amount of error in the evaluation procedures. To do so involves looking at reproducibility, an umbrella term that involves reliability and agreement [13]. Reliability is defined as the ability of a measurement to differentiate between participants, usually measured by intraclass correlation (ICC) tests. Agreement is defined as the ability of a measurement to assess to what extent scores or ratings are identical when the phenomenon studied does not change. Agreement is often measured by standard error of measurement (SEM) and minimum detectable change (MDC) [13,14]. Ideally, an MICD difference should be close to these reproducibility

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measurements to ensure that the phenomenon and any changes can be detected by the measurement method chosen by the evaluator.

With regard to MS, few studies have first focused on determining reproducibility and there are inconsistencies in the designs of these. First, the time between evaluations varied from one hour [15] to six months [16]. The relatively recent emergence of treatments with rapid action (14 days) on gait parameters in the MS population [17] required the study of reliability over an equivalent period. This has been done in one study [18], and in this study only 3 tests were used (T25WT fast condition, TUG and 6MWT. There is a striking absence of research reporting reproducibility for different gait parameters using dual tasks for patients with MS. To our knowledge only one study has used dual task assessment [15] and for a small number of gait parameters.

Considering the limitations of previous research, further reproducibility studies for gait measurements in patients with MS are necessary. Therefore, the aims of this study were to establish reproducibility in terms of reliability and agreement using ICC and MDC over a one- week period of time for different locomotion conditions in this population.

2. Methods

2.1. Study design

This cross-sectional study is derived from FAMPISEP (NCT02849782). Patients were recruited in Besancon (France) area between April 2014 and May 2016. They were evaluated two times one week apart before beginning drug treatment (Fampridine) [19] (Fig. 1).

2.2. Participants

The inclusion criteria were: (i) a multiple sclerosis diagnosis according to the modified McDonald criteria [20]; (ii) an Expanded Disability Status Scale (EDSS) status between 4.0 and 6.5; and (iii) the ability to walk for a period of six minutes. The exclusion criteria were: (i) worsening multiple sclerosis symptoms during the previous 60 days; and (ii) immunotherapy change in the previous 60 days. Healthy volunteers who were similar in terms of sex, age, height, weight and body mass index to the patient group participated in this study as a control group.

This protocol was governed by French legislation concerning interventional biomedical research and was submitted to the local ethics committee (#13/405). The study was approved by the French Health Products Safety Agency (#2013-A002305-56). Written informed consent was obtained from all participants of this study.

2.3. Measurements

Gait evaluation was carried out in a dedicated room at a controlled temperature (approximately 22 °C) using a 6.10 m GaitRite™ system (CIR Systems Inc) pressure sensitive walkway. Participants were asked to walk a 25-foot (7.62 m) distance which was delineated by two photocell barriers (Microgate Polifemo, Italy) [21]. They began and stopped walking two meters away from the 25-foot area. The GaitRite system was positioned in the middle of the barriers.

After appropriate instructions and familiarisation, participants were asked to perform three gait tasks: walking at a self-selected comfortable speed [22], walking at their maximum speed [23] and walking at a self-selected comfortable speed with a mental-tracking task [24], which was a dual-task recommended for people with MS [25]. The mental-tracking task consisted of serial subtractions of seven to be performed as accurately as possible [26]. As described in previous studies, the number seven was chosen because it did not involve auditory-pace synchronisation [27,28]. The cognitive function was evaluated by the symbol digit modalities tests (SDMT) [29].

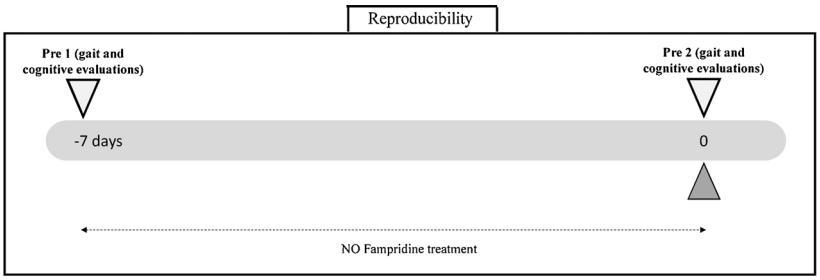
Ten gait cycles for each task were used for further analysis [30] and at least a five-minute rest period was allowed between tasks. Moreover, the dual task cost (%), which refers to the ratio between comfortable speed with a mental-tracking task and comfortable speed, was calculated for the dual task condition [31].

For the TUG test, a chair, 47 cm in height, with armrest and backrest was used. Participants were instructed to get up from the chair, walk three meters, turn around a cone and come back and sit down on the chair as quickly as possible, whilst ensuring their safety [32]. The TUG was performed twice. A third trial was performed if a difference of 10% was found between the first two trials. The mean value calculated from the two closest trials was used.

The 6MWT assessed the submaximal level of functional capacity. It was adapted from the recommendations of the American Thoracic Society [33]. The 6MWT instructions were read to the participants before each walk. Participants walked around a 24-meter circuit. They were allowed to have rests if necessary and words of encouragement were spoken every 30 s. The distance walked in 6 min was measured.

2.4. Procedure

Disability was ascertained using the Self-Report Expanded Disability Status Scale (SR-EDSS) [34]. The disease course was determined by the Lublin and Reingold classification [35]. The gait was evaluated (single evaluator) as described in the section above (2.2) on 2 occasions, with an interval of a week between each one. The evaluation was done on the same day of the week, but not systematically at the same time of day. All the measurements were administered in a fixed order (T25FW at three conditions, comfortable speed, fast speed and dual task; TUG; 6MWT). The use of a participant's assistive device was allowed and worn at each session. All the gait parameters were caring out with the GAITRite system (velocity, cadence, stride length, stride time, stance



Pre 1: first visit before fampridine treatment, Pre 2: second visit before fampridine treatment, Post 1: first visit after fampridine treatment, Post 2: second visit after fampridine treatment.
The only two first evaluations were used for this study.

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