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Step Number and Aerobic Minute Exercise Prescription and Progression in Stroke: A Roadmap

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Abstract

Background: While higher therapeutic intensity improves motor recovery after stroke, translating findings from successful studies is challenging without clear exercise intensity targets. We show in the DOSE trial[1] more than double the steps and aerobic minutes within a session can be achieved compared with usual care and translates to improved long-term walking outcomes.

Objective: We modeled data from this successful higher intensity multi-site RCT to develop targets for prescribing and progressing exercise for varying levels of walking impairment after stroke.

Methods: In twenty-five individuals in inpatient rehabilitation, twenty sessions were monitored for a total of 500 one-hour physical therapy sessions. For the 500 sessions, step number and aerobic minute progression were modeled using linear mixed effects regression. Using formulas from the linear mixed effects regression, targets were calculated.

Results: The model for step number included session number and baseline walking speed, and for aerobic minutes, session number and age. For steps, there was an increase of 73 steps per session. With baseline walking speed, for every 0.1 m/s increase, a corresponding increase of 302 steps was predicted. For aerobic minutes, there was an increase of .56 minutes of aerobic activity (ie, 34 seconds) per session. For every year increase in age, a decrease of .39 minutes (ie, 23 seconds) was predicted.

Conclusions: Using data associated with better walking outcomes, we provide step number and aerobic minute targets that future studies can cross-validate. As walking speed and age are collected at admission, these models allow for uptake of routine measurement of therapeutic intensity.
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Keywords
Rehabilitation, gait, outcomes, stroke, exercise

Introduction

Frequency, intensity, time, and type, or the FITT principle, is a way to outline the components of exercise prescription. While interpretation of clinical trials require the components of FITT to be depicted to allow for successful implementation, Billinger et al (2015) report that exercise intensity is only described adequately in 59% of clinical trials.[2] Further, no studies outline data-driven prescription and progression of therapeutic exercise intensity after stroke. In the absence of specific exercise prescription guidelines, rehabilitation therapists provide low exercise doses, despite evidence that higher intensity exercise improves neural and functional recovery.[1,3]

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When general targets are given to research therapists, our recent study shows more than double the steps and aerobic minutes can be achieved vs usual care and translates to improved long-term walking outcomes.[1] Yet, safety concerns keep some therapists from delivering higher exercise intensity[4] since the subacute stroke period is a time of higher risk for cardiac complications.[5] A roadmap highlighting key parameters that impact safe prescription and progression targets based on these parameters would be a useful clinical tool. To address this gap, we modeled data from a successful higher intensity multi-site randomized clinical trial to develop formulas for prescribing and progressing exercise for varying walking impairment levels after stroke.[1]

Methods

These data are from the Determining Optimal Post-Stroke Exercise (DOSE) trial (2014–2018[1]) and involve post hoc analysis and modeling. Briefly, we undertook a protocol that progressively increased inpatients' step number and aerobic minutes with weight-bearing, walking-related activities, which resulted in clinical improvements in walking outcomes over usual care.[1] The protocol was developed with safety in mind, specifically requiring achieving a heart rate of 40% heart rate reserve, considered the lower bound for recommended training intensities to achieve aerobic benefits.[2] Additionally, it focused on completing a minimum of 30 minutes of activities that progressed in step number and aerobic minutes over the 20 sessions and was continuously monitored with a heart rate monitor and step counter. Assistive devices were permitted throughout the protocol. Protocol exercises included weight-bearing (ie, not sitting on a recumbent bike), walking-related activities which used standard equipment in typical stroke inpatient settings like parallel bars, overhead harness, and treadmill with and without body weight support. Each session's step number and aerobic minutes were recorded by the trained physical therapist, and weekly audits by the site research coordinator ensured the protocol was being delivered as designed. These data (each session's step number and aerobic minutes) are what was modeled in this secondary analysis. Intervention protocol details, progression guidelines, and algorithms can be found at https://neurorehab.med.ubc.ca/ and in the protocol paper.[6] Written informed consent was provided by each participant, and research ethics board approval was obtained from university and hospital institution review boards. The clinical trial consisted of 3 groups. Group 1 was usual care which consisted of 5 1-hour sessions per week. Group 2 was the DOSE1 intervention which replaced typical physical therapy for 5 1-hour sessions per week for 20 sessions. Group 3 was the DOSE2 group. For this group, in addition to the DOSE1 activity (typically morning), the DOSE2 group also received an extra, 1-hour exercise session, 5 days/week, for 4 weeks, which occurred later in the day (ie, typically from 4 to 5 PM daily), for a total of 40 sessions. The primary outcomes paper showed similar walking improvement at 1-year post-stroke for the DOSE1 and DOSE2 groups.[1] While the trial delivered 3 exercise intensities, the therapy time of the DOSE1 (Group 2) is consistent with that delivered in typical inpatient rehabilitation settings (1hr/day). Thus, this study focused on the exercise intensity progression in this group (n=25) over their inpatient stay.

Safety: As the protocol was generated with safety in mind, a heart rate of 40% heart rate reserve was used as it is considered the lower bound for recommended training intensities to achieve aerobic benefits.[2] During the clinical trial, all adverse events were recorded for all participants. A data safety monitoring board was made aware of all events, and all serious adverse events were reported in the primary outcomes manuscript.[1] Participants received 1:1 therapy at all times from a licensed physical therapist (±a rehabilitation assistant who was present when necessary for low level participants requiring 2-person assist). Additionally, the participant's HR was being constantly monitored by the watch, and therapists were instructed to mitigate any safety concerns immediately.

Measures: Age, sex, and days poststroke were collected. Baseline walking speed was the average of 2 trials of the 5 m walk test completed at the participant's preferred speed. The general targets therapists were given were to achieve by the end of 20 exercise sessions: >2000 walking steps per session (target derived from pilot data) and complete ≥30 consecutive aerobic minutes at an intensity ≥40% heart rate reserve, the minimum threshold to be considered moderate aerobic intensity.[2] A step counter on the non-paretic ankle (Fitbit One; Fitbit Inc, San Francisco, California) and wrist-based heart rate monitor (Mio Alpha; Mio Global, Vancouver, British Columbia) were worn during each of 20 sessions. The physical therapist used the step number and heart rate data to provide feedback to the participant and to progress the intervention over the 20 sessions. The Fitbit One can accurately measure steps during inpatient stroke rehabilitation physical therapy sessions.[7] The Mio Alpha has acceptable accuracy of heart rate with r=.929 (P <.01) compared with a Polar RS400 HR chest strap as the criterion measure.[8]

Statistics: The intent was to develop 2 parsimonious regression models, 1 for step number and 1 for aerobic minutes, that represented progression over 20 sessions. The following variables were tested as predictors with rationale added in brackets: age in years (associated with recovery and physical activity levels), baseline walking speed (related to impairment level), session number (needed to model progression of intensity through rehabilitation), sex (female sex associated with greater impairment and less physical activity), and days poststroke to study randomization (time after stroke). After exploring the data, a linear mixed effects model was chosen because there was nonindependence in the data due to repeated measures from participants being sampled within 6 rehabilitation units, and the aim required accounting for within- and across-individual variability. The intracluster correlation coefficient of rehabilitation unit across 6 Canadian

Table 1. Participant characteristics.

	Mean (SD) or Count
Sex (F/M)	9F/16M
Age (Years)	56.04 (11.41)
Days (from stroke to randomization)	26.88 (10.27)
Baseline gait speed (m/s)	.44 (.25)
Hemisphere affected (R/L)	15L/10R
Stroke type (H/I)	3H/22I
Pre-stroke disability	mRS 0 = 24; mRS 1 = 1

Days = days from stroke to randomization, F = female, H = hemorrhagic, I = ischemic, L = left, mRS = Modified Rankin Scale, M = male, R = right, SD = standard deviation.

stroke rehabilitation centers in the primary outcomes manuscript was low (<.01); therefore, a clustering factor of rehabilitation unit was not included. For modeling, the participant was the random effect and other factors were fixed effects. The crude relationship between the response variable and each predictor was examined in bivariable linear mixed effects models. Bivariable linear mixed effects can account for correlated observations like that in a repeated measures dataset, allows for estimation of predictor variables on outcomes, and the parameters are clear to interpret. For model building, the independent variable with the strongest bivariable relationship with the response variable was initially included in the model; independent fixed variables were added based on the strength of the bivariable relationship thereafter. Iterative models were tested with the likelihood ratio test until a new model was no longer statistically significantly different. Together, these requirements ensured the final model would explain a large amount of variance in the data and be more likely to be utilized by a front-line clinician. The predictor variable, walking speed, was centered to make interpretation of parameter estimates more straightforward. Analyses were conducted using R-Project for Statistical Computing.

Results

Participant characteristics are summarized in Table 1. As comfortable walking speed and impairment measures are related,[9] we used walking speed as a surrogate of impairment. Thus, using clinically meaningful functional ambulation categories, 13 participants walked at <0.4 m/s (household ambulation), 9 were between 0.4 m/s and 0.8 m/s (limited community ambulation), and 3 were >0.8 m/s (full community ambulation) at baseline.[10] The average baseline walking speed was .44 (.25) m/s, average completed steps were 2107 (1271), and average aerobic minutes 25.4 (15.6) over 20 sessions.

Safety: Here, we report all adverse events for participants in the DOSE1 arm of the study as these are the data that were modeled (n=25). Three participants in the DOSE1 group experienced adverse events.

1) For 1 participant, an open sore was observed on the right lateral side of the ankle which was attributed to an off-the-counter brace rubbing against the lateral malleolus during the intervention. A dressing was applied and the participant missed a few therapy sessions due to ankle swelling; however, the participant was able to complete the study.
2) A participant was transferring from a wheelchair to bed with RN supervision. The participant lost their balance during the transfer and fell into a wall, sustaining a minor abrasion to the left elbow with no other injuries sustained. A small dressing was applied to the abrasion. No physical therapy sessions were missed.
3) A participant got up from bed half asleep at 2am when they slipped off of the edge of the bed and fell onto the ground. The participant's head and knees hit the floor and bruising was observed around the knees, and headache/dizziness reported. The next day, the participant was unable to tolerate weight-bearing gait-related activities secondary to knee pain and headache/dizziness. After missing 1 therapy session, the participant was able to finish the study.

The data safety monitoring board determined that these events were minor. All of these events are within the scope of that observed during typical inpatient rehabilitation.

Models

The model for step number included session number and baseline walking speed (Table 2A). The model for aerobic minutes included session number and age (Table 2B). Sex or days poststroke did not significantly add to either model. For steps, there was an increase of 73 steps per session. With baseline walking speed, for every 0.1 m/s increase, a corresponding increase of 302 steps was predicted. For aerobic minutes, there was an increase of .56 minutes of aerobic activity (ie, 34 seconds) per session. For every year increase in age, a corresponding decrease of .39 minutes (ie, 23 seconds) was predicted.

Prediction Modeling

Table 3 provides predicted step number and aerobic minutes based on equations in Table 2 for sessions 1, 5, 10, 15, and 20. Session 1 was chosen to give clinicians a starting target for day 1 of therapy. Session 5, 10, 15, and 20 reflect the end of a 5-day workweek to give clinicians a target to reach by the end of each week. Even a patient that walks very slowly (eg, baseline walking speed 0.2 m/s and likely with one-person assistance) is predicted to reach the prescribed target of 2000 steps by 20 sessions, while a mildly impaired patient at baseline (eg, baseline walking speed at 0.8 m/s) will exceed 2000 steps on the first session. With age, less minutes are achieved with older age throughout rehabilitation. Yet, older

Table 2. A: Predictors of step number.

Predictors	*Estimates*	*CI*	*P*
(Intercept)	1349.56	1030.59–1668.53	**<.001**
Session number	73.19	63.70–82.68	**<.001**
Baseline walking speed	3023.46	1798.36–4248.56	**<.001**
Random effects: σ^2=367 727.57; $\tau_{00\ ID}$=579 519.44; ICC=.61; N_{ID}=25; observations=486; marginal R^2=.433; conditional R^2=.780			
Equation	Step number = 1349.56 + 73.19 (session number) + 3023.46 (baseline walking speed-.44)		
B: Predictors of aerobic minutes			
Predictors	Estimates	CI	*P*
(Intercept)	41.54	20.81–62.27	**<.001**
Session number	.56	.39–.73	**<.001**
Age in years	−.39	−.75 to −.03	**.034**
Random effects: σ^2=124.18; $\tau_{00\ ID}$=99.99; ICC=.45; N_{ID}=25; observations=493; marginal R^2=.117; conditional R^2=.511			
Equation	Minutes = 41.54 + .56 (session number) − .39 (age in years)		

Table 3. Targets for future studies to cross-validate.

*Baseline walking speed (m/s)**	*Session 1 Steps**	*Session 5 Steps**	*Session 10 Steps**	*Session 15 Steps**	*Session 20 Steps**
A: Baseline walking speed (m/s)					
0.2	701	994	1359	1725	2091
0.4	1305	1598	1964	2330	2696
0.6	1910	2203	2569	2935	3301
0.8	2515	2808	3174	3539	3905
1.0	3120	3412	3778	4144	4510
1.2	3724	4017	4383	4749	5115
B. Age (years)					
40	27	29	32	34	37
45	25	27	30	32	35
50	23	25	28	30	33
55	21	23	26	28	31
60	19	21	24	27	29
65	17	19	22	25	27
70	15	17	20	23	25

*Based on equation in Table 1A.
† Based on equation in Table 1B.

adults are predicted to progress the number of aerobic minutes over therapy.

Discussion

The model for step number included session number and baseline walking speed, and for aerobic minutes, session number and age in years. As the prescription and progression of patients poststroke with varying levels of walking impairment has never been addressed, the practical information provided in this study will help translate this research to front-line clinicians after future studies cross-validate the data (Table 3). A 65-year-old person walking at 0.4 m/s is predicted to achieve approximately 1305 steps and 17 aerobic minutes during the first session, with an increase to 2696 steps and 27 minutes by session 20. The models (Table 2) and targets (Table 3) generated with this study provide treatment prescription and progression targets that may be easy to use if they can be cross-validated. Clinically meaningful and lasting changes in walking endurance were achieved based on this higher dose of stepping practice,[1] suggesting these targets may be a threshold needed to obtain lasting changes in walking outcomes after stroke. Further,

improved walking outcomes and quality of life could be attained using these targets and a future study could test these targets in a new sample of individuals after stroke.

While slower comfortable walking speed is related to older age,[11] physical activity can impact this relationship[12] with even small increases of 100 steps per day improving walking speed.[11] Alternatively, faster comfortable walking speed is linked to higher physical activity levels.[13] While walking speed is partly explained by aerobic endurance in chronic stroke, walking outcomes can improve by focusing on increases to aerobic endurance.[14] Taken together, these studies suggest that walking speed and age may relate to changes in physical activity measures like step number or aerobic minutes during the subacute phase of recovery.

Because walking speed and age are routinely collected at admission, to translate these targets to front-line clinicians, sensors are needed to measure steps and heart rate. Given the plethora of inexpensive commercial options on the market, widespread uptake of routine measurement of therapeutic exercise intensity is possible and practical. Many sensors are already validated for use after stroke in individuals with slow walking steps.[7]

There are several limitations to implementation of higher levels of therapeutic intensity during inpatient rehabilitation, such as a patient fatigue level, and restrictions on a clinician's time. Clinicians need to address multiple treatment goals within a session beyond walking, such as upper extremity motor impairment. Additionally, there are regulatory constraints in many healthcare systems that limit the time a clinician has with a patient. Further, a limitation is the average age of our sample (56), which is younger than some rehabilitation facilities, so these targets could be further tested in older individuals. Three participants out of 25 experienced minor adverse events, and these events did not result in deviation from the study protocol beyond delaying physical therapy sessions; these individuals ended up participating in all 20 sessions of the protocol. However, the authors recommend that clinicians implementing these step numbers and aerobic minutes in their stroke patients continuously monitor HR as well as skin integrity if a brace is being used and ensure that any safety issues be alleviated immediately. While our sample size (n=25) was small, a large number of sessions (n=500) were assessed; results could be confirmed with a larger sample. Further, cross-validation was not performed with the models because this work is intended as a brief report to guide future research. While the results are clinically applicable, the authors recognize that the model needs to be validated on data that it was not trained on to be sure it is not overfitted and to quantify the predictive performance of the model.

Conclusions

Baseline walking speed and age can predict therapeutic target step number and aerobic minutes poststroke in inpatient rehabilitation.

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Supplemental Material

Supplemental material for this article is available online.

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