Original Article

CLINICAL REHABILITATION

Clinical Rehabilitation
1–9

DOI: 10.1177/0269215520956338
journals.sagepub.com/home/cre
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Better balance: a randomised controlled trial of oculomotor and gaze stability exercises to reduce risk of falling after stroke

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Abstract

Objective: To assess the effect of a domiciliary program of oculomotor and gaze stability exercises on the incidence of falls and risk of fall in stroke survivors.

Design: Two-arm, non-blinded parallel randomized controlled trial.

Subjects: Stroke survivors older than 60 years, with positive Romberg test and autonomous gait after the stroke.

Setting: Physiotherapy outpatient clinic of a tertiary care hospital.

Interventions: Every participant accomplished the current rehabilitation program; the intervention group was randomly allocated into an additional three weeks intervention with a domiciliary program of oculomotor and gaze stability exercises.

Main measures: Primary outcome was the incidence of falls through the three weeks after the intervention started; in addition, the variation of the estimated risk for falling assessed by both Berg Balance Scale (four points) and Timed Up and Go Test (four seconds) was the secondary outcome.

Results: 79 patients were recruited and 68 completed the protocol (control group 35; intervention group 33). During the follow up, falls were registered in 4/35 participants in the control group and no event occurred in the intervention group ($P = 0.064$). The estimated risk for falling decreased in 11/35 control group participants and in 28/33 intervention group participants (RR 0.37; 95%CI 0.22–0.62; $P < 0.001$).

Conclusion: After three weeks of a domiciliary program of oculomotor and gaze stability exercises, the estimated risk of falling significantly diminished and no falls occurred among the intervention group. These findings encourage further exploration of this promising intervention.

Trial Registration: ClinicalTrials.gov Identifier: NCT02280980.

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Keywords
Balance, clinical trial, oculomotor and gaze stability exercises, risk for falls, stroke

Received: 5 May 2020; accepted: 15 August 2020

Introduction

The deficits after a stroke often include balance and gait impairments that lead to impaired function and, therefore, dependence.[1,2] Patients have a higher risk of falling, a great number of that falls occurring during gait.[3]

Balance control requires premotor processing, motor and sensory systems and sensorimotor integration; all these processes can be affected by stroke.[4]

The vestibular system detects movement of the head, maintaining the images stable in the fovea and postural control during head movement,[5] and contributes to adapt balance to environmental conditions[6] which is very important in walking activities.[5]

Vestibulo-ocular reflex is the first mechanism of gaze stability. The vestibulo-ocular reflex stabilizes gaze (eye position in space) during head movements, producing eye movements of equal speed and opposite direction to the movement of the head[7] to allow an adequate visual acuity. This mechanism is essential during gait.

Gaze stability exercises are already used, alone or with other vestibular rehabilitation strategies, in several conditions, decreasing the perception of disability (unilateral vestibular deficit),[8] improving postural stability (healthy young adults)[9] and balance (multiple sclerosis).[10]

The aim of this study assesses the effect of a domiciliary program of oculomotor and gaze stability exercises on the incidence of falls and on the risk of fall in stroke survivors.

Methods

This is a 2-arm, non-blinded, single-center, randomized controlled trial, registered in the ClinicalTrials.gov (NCT02280980). The study is reported following the guidance of the Consolidated Standards of Reporting Trials (CONSORT statement). This study complies with the Declaration of Helsinki and was approved by the Ethical Committee of Centro Hospitalar Universitário de Lisboa Central (Proc 140/2012). This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. The clinical trial had a recruitment period between July 2014 and May 2019. The Centro Hospitalar Universitário de Lisboa Central was responsible for oversight of study conduct and governance.

People older than 60 years, diagnosed with brain stroke, referred at discharge to the physiotherapy outpatient clinic of a tertiary care hospital (Hospital Curry Cabral - Centro Hospitalar Universitário de Lisboa Central) were screened for study eligibility.

The inclusion criteria were: stroke occurred 3 to 15 months before recruitment, verified impaired balance (positive Romberg test[11,12]), and ability to walk at least 3 meters by itself, with or without an assistive device.

The exclusion criteria were: balance impairment prior to the stroke, severe osteo-articular disease with inability to perform the proposed exercises, or previous performance of oculomotor or gaze stability exercises.

Eligible patients, according to inclusion and exclusion criteria, who accept to participate and gave written informed consent, were considered study participants.

All the participants were assessed in the first week of treatment (ambulatory physiotherapy) by either one of two trained physiotherapists. This assessment intended to identify balance problems, level of dependence and risk of fall; to collect demographic and clinic information (such as date of the stroke, brain topography, etiology, gait ability, number of falls after stroke, and present therapies). The instruments used were:

- Romberg test (used to identify balance problems), is a static balance test,[11] was performed on a stable surface, in which the individual stands with their feet together, first with eyes open and then with eyes closed; the test was repeated on an unstable surface (balance pad with 60 mm thick) under the same conditions. The test is positive if the individual moves a foot from the initial position or opens the eyes for 30 seconds test in each position.[12]

- The Motor Assessment Scale (used to identify level of dependence) is a performance-based scale to assess everyday motor function in stroke patients.[13] It consists of 8 items corresponding to different areas of motor function, each item is scored from 0 to 6, with a maximal of 48 points; the maximum score represents optimal performance.
- Berg Balance Scale[14] (to identify risk of fall) evaluates balance by assessing the performance on 14 functional tasks. The total score ranges from 0 to 56 points; 56 indicates the best balance. A score up to 45 is considered as risk of falling.[15] Berg Balance Scale is used in most studies and showed strong evidence of identifying balance disorders both in the acute and the chronic phases of stroke, in patients with low initial Berg Balance Scale score.[2]
- Timed Up and Go Test [16,17] (to identify risk of fall) is a simple test to assess mobility, requiring static and dynamic balance. It is usually used as an indicator for the risk of falling. Lower values indicate better motility[18] and, in the elderly, values higher than 14 seconds are considered predictive of falling.[16]

All participants received the current rehabilitation program. Based on the preintervention assessment, participants were randomly assigned either into the current program (control group) or into a supplemental domiciliary intervention program of oculomotor and gaze stability exercises (intervention group) through block randomization with stratification by age (60–69 years, 70–79 years and $\geqslant$ 80 years), functionality (using the score of the Motor Assessment Scale: major dependence – less than 16, moderate dependence – between 17 and 32, and minor dependence: over 33) and risk of fall (according to the predictive cut-off points for falling using Timed Up and Go Test[16] and Berg Balance Scale[15] – no risk of falling: Timed Up and Go Test $\leqslant$ 14 seconds and Berg Balance Scale $>$ 45, or with risk of falling: Timed Up and Go Test $>$ 14 and / or Berg Balance Scale $\leqslant$ 45).

The control group received the current institutional rehabilitation program provided for stroke patients[19,20]; the program was customized according to the identified problems and was based on the clinical reasoning, supported on the neurophysiology, motor control, biomechanics and motor learning theories.[19]

The intervention group received the current rehabilitation program and a supplemental domiciliary intervention based on oculomotor and gaze stability exercises (Online Appendix) executed twice a day for three weeks. The participants in the intervention group had one training session, to learn the exercises and to receive an explanatory leaflet and a logbook (to record compliance with the prescribed exercises). When the participants had difficulties in learning or performing the exercises by themselves, a caregiver was required to collaborate ensuring a correct and safe performance. The exercises were reviewed every week for compliance with the domiciliary program, to clarify doubts and to report difficulties or possible adverse effects.

Every participant was submitted to a postintervention assessment with the Berg Balance Scale and Timed Up and Go Test, three weeks after the intervention started, and was asked about the number of falls that occurred since recruitment. The participants in the intervention group were asked to return the logbook.

The primary outcome is the variation of the number of falls during follow up. The secondary outcome is the variation of the estimated risk of falling assessed by Berg Balance Scale and Timed Up and Go Test after three weeks of intervention: a minimum increase of 4 points on Berg Balance Scale or a decrease of four seconds on Timed Up and Go Test were considered clinically significant.[21,22]

The sample size was estimated in 33 participants in each group, considering the ability to identify (power 90% and confidence 90%) either a minimum increase of four points in Berg Balance Scale[21] or minimum decrease of four seconds in Timed Up and Go Test.[21,22] The estimated minimum sample size to detect four seconds of difference in the Timed Up and Go Test is 18 participants and for a difference of four points in Berg Balance Scale is 66 participants. The clinical trial had a recruitment period of 50 months when the defined sample size was reached.

The participants that interrupted the usual rehabilitation program for more than one week for any reason and those in the intervention group who were not able to learn the exercises of the domiciliary program or showed lack of adherence (less than 50% of the proposed plan) were identified and excluded from the per protocol analysis.

The characteristics of the participants were described and compared between the control group and the intervention group; Mann–Whitney test and Qui-square test or Fisher exact test were used, as adequate.

The per protocol analysis assessed the primary outcome by estimation of risk ratios for positive outcomes with 95% confidence intervals. Logistic regression models were used to explore factors that affect the success; variables that reached the established significance $P \leqslant 0.25$ in the univariable analysis were selected for multivariable analysis; odds ratios (OR) with 95% confidence intervals were estimated.

Complementary intention to treat analysis was planned if increased odds for non-adherence were identified for the control group and the intervention group. For the intention to treat analysis every patient would have been considered; those that did not comply and those that did not achieve success on the primary outcome were to be considered as failures. Data were analysed with SPSS 22.0 (SPSS for Windows, Rel. 22.0.1. 2013. SPSS Inc., Chicago, IL, USA) using descriptive statistics and statistical inference (univariable and bivariable), as per protocol.

Results

From 248 patients admitted for ambulatory physiotherapy after stroke, 166 were older than 60 years and were assessed for eligibility (Figure 1); 79 were recruited (39 in control group; 40 in intervention group). In the control group, 35 patients completed the protocol (89.7%), four were excluded from analysis because they interrupted the current rehabilitation program for more than one week. In the intervention group, seven patients were excluded from analysis, five interrupted the current rehabilitation program for more than one week and two had lack of adherence to the plan, 33 completed the protocol (82.5%). The compliance with either protocol was similar (p=0.378); no increased odds for non-adherence was identified (OR 0.54; 95%CI 0.14–2.01).

The baseline demographic and clinical characteristics for each group are presented on Table 1. There were no significant differences between the participants on the control group and the intervention group.

The outcome data were collected three weeks after baseline (Table 2). The number of events of falling during the intervention (primary outcome) registered in the control group was 4/35 (incidence rate 11.4%; 95%CI 4.54–25.95); no event was registered in the intervention group (incidence rate 0.0%; 95%CI 0.0–10.43); this borderline difference is not statistically significant (one-sided Fisher's exact test, $P = 0.064$).

The secondary outcome (the variation of the estimated risk of falling) assessed by Berg Balance Scale and Timed Up and Go Test after three weeks of intervention is presented in detail in Table 2. In 11/35 (31.4%) control group patients and in 28/33 (84.8%) intervention group patients (RR 0.37; 95%CI 0.22–0.62; $P < 0.001$) clinical significant changes were obtained in Berg Balance Scale and Timed Up and Go Test. All the female participants in the intervention group but 50% in the control group reached the combined secondary outcome.

The variables assessed by univariable analysis for association with the success of the secondary outcome are presented on Supplementary Table 1. The best fitted multiple logistic regression model, using the variables selected as described above, identified the intervention, female gender and previous Motor Assessment Scale as significantly affecting the odds for the success of the secondary outcome (Table 3). The previous risk of fall (as described above on randomization) was also identified as positively affecting the secondary outcome (not included in the multiple model due to collinearity with Motor Assessment Scale).

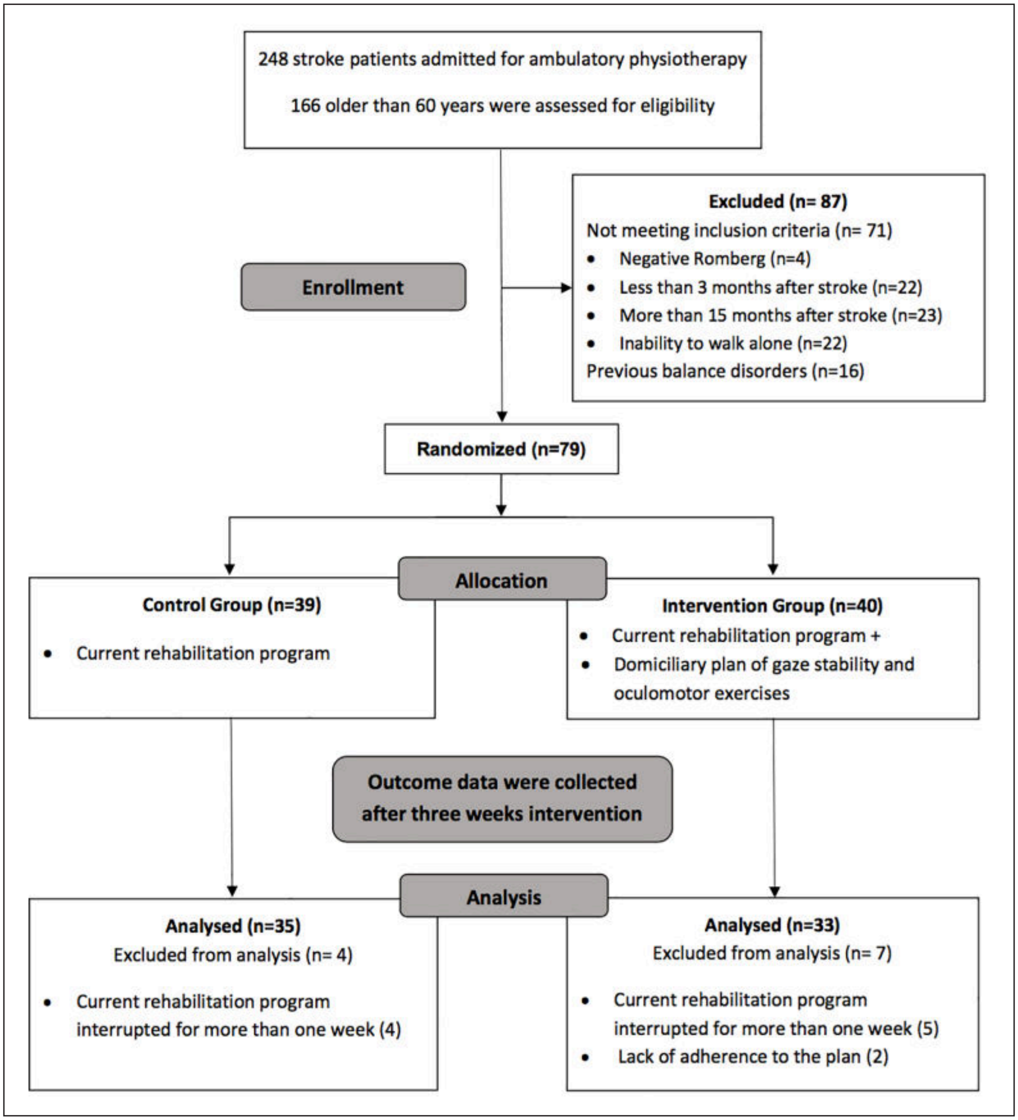

Figure 1. Randomized controlled trial flow diagram.

Complementary intention to treat analysis was not performed, as increased odds for non-adherence were not identified.

No adverse events were reported among the participants.

Discussion

The aim of this clinical trial was to assess the effect of a program of oculomotor and gaze stability exercises on the incidence of falls and on the risk of fall in senior patients after stroke. Through the 3 weeks of intervention, there was a significant difference in the assessment of the estimated risk of falling in the participants who performed the oculomotor and gaze exercises and there were no reported falls in the intervention group; these results give ground to explore this intervention through larger studies with longer follow-up.

Table 1. Demographic and clinical characteristics of the participants by group ($n = 68$).

Variable	Control group ($n = 35$)	Intervention group ($n = 33$)	*P*-value
Age (years), median (min–max)	73 (61–87)	73 (60–87)	0.902
Female gender, *n* (%)	12 (34.3)	10 (30.3)	0.726
First stroke, *n* (%)	29 (82.9)	30 (90.9)	0.478
Haemorrhagic stroke, *n* (%)	7 (20.0)	5 (15.2)	0.600
Time since stroke (days), median (min–max)	124 (92–372)	144 (90–414)	0.956
Patients using walking assistance devices, *n* (%)	9 (25.7)	9 (27.3)	0.884
Patients referring fall after stroke, *n* (%)	22 (62.9)	17 (51.5)	0.345
MAS (points), median (min–max)	35 (11–45)	34 (14–46)	0.792

MAS: Motor Assessment Scale; max: maximum; min: minimum.

Table 2. Reported occurrence of falls (primary outcome) and estimated risk of falling (secondary outcome) during the three weeks follow-up in the intervention and control groups. The estimated risk of falling is assessed by Berg Balance Scale ($\leqslant$ 45 points) and Timed Up and Go Test (>14 seconds); significant variation was considered as $\geqslant$ 4 points for Berg Balance Scale and $\geqslant$–4 seconds for Timed Up and Go Test. Statistic significance relate to comparison between the intervention and control groups.

Reported occurrence of falls, *n* (%)*	Control group ($n = 35$)		Intervention group ($n = 33$)	
	4 (11.4%)		0	
Estimated risk of falling	T1	T2	T1	T2
Berg Balance Scale (points), median (min; max)	36 (14–50)	38 (18–51)	38 (10–52)	44 (20–55)
Berg Balance Scale $\leqslant$ 45 points, *n* (%)	28 (80.0)	28 (80.0)	28 (84.8)	19 (57.6)
Δ Berg Balance Scale (points), median (min; max)§	2 (−2; 15)		6 (0; 16)	
Δ Berg Balance Scale $\geqslant$ 4 points, *n* (%)§	8 (22.9%)		27 (81.8%)	
Timed Up and Go Test (seconds), median (min; max)	18.87 (10.17–74.33)	18.35 (11.01–56.62)	19.43 (9.7-108.16)	16.41 (7.5–94.66)
Timed Up and Go Test > 14 seconds, *n* (%)	29 (82.9)	28 (80)	23 (69.7)	22 (66.7)
Δ Timed Up and Go Test (seconds), median (min; max)#	−0.54 (−20.9; 11.5)		−1.65 (−31.5; 4.2)	
Δ Timed Up and Go Test $\geqslant$ −4 seconds, *n* (%)#	3 (8.6%)		11 (33.3%)	
Combined secondary outcome, *n* (%)§	32 (91.4)	32 (91.4)	28 (84.8)	25 (75.8)

Δ: differential; max: maximum; min: minimum; T1: Initial assessment; T2: Final assessment; *$P = 0.064$; #$P < 0.05$; §$P < 0.001$.

Findings from this clinical trial demonstrate the feasibility of a short term, home program of oculomotor and gaze stability exercises and provide evidence supporting the effectiveness of this intervention as a complementary strategy for physiotherapy on decreasing the risk of falls after

Table 3. Results of multivariable logistic regression analysis for the variation of the estimated risk of falling assessed by Berg Balance Scale and Timed Up and Go Test during follow-up (secondary outcome). Significant variation was considered as $\geqslant$ 4 points for Berg Balance Scale and $\geqslant$–4 seconds for Timed Up and Go Test.

Variables	OR estimate (95% CI)	*P*-value
Stability exercise, intervention group	25.21 (5.58; 113.93)	<0.001
Female gender	4.34 (1.01; 18.71)	0.049
MAS (points)	0.90 (0.82; 0.98)	0.017

BBS: Berg Balance Scale; CI: Confidence Interval; MAS: Motor Assessment Scale; OR: Odds ratio; TUG: Timed Up and Go Test. *P*-values were obtained by logistic regression models'.

stroke in ambulatory older patients with impaired balance of recent onset. Results indicate that females, lower Motor Assessment Scale and higher risk of falling modify the effect of the intervention, leading to greater odds of improvement, thus allowing a more customized prognosis.

The strengths of this study are related to the use of validated, standard measuring instruments, well known and used in clinical practice, easy to apply with a short time of application and reduced cost; to the application of standardized rehabilitation protocols, the current rehabilitation program being carried out by a team of experienced physiotherapists and all the assessments, training for the exercises and their periodic review being carried out by either one of two physiotherapists, experts in this area, with deep knowledge of the used instruments and procedures; and to the involvement of caregivers to supervise the performance of the home program. The major limitation of this study is related to the ability of the study to detect actual falls, given by the relatively small number of participants and the very short follow-up (three weeks). Due to the absence falls reported in the intervention group, only surrogate estimates of the risk of falls, rather than the actual rate of falls, reached a statistically significant difference when assessing the effect of the intervention. Moreover, the planned complementary intention to treat analysis was not performed, due to the high compliance (80%–90%), because no increased odds for non-adherence between the control and the intervention groups were identified and due to the heterogeneity of the causes for non-compliance referred by the few (11) non-compliant patients. Another limitations or sources of possible bias are related with the lack of blinding; the heterogeneity of the sample (namely the etiology and the topography of the stroke, the presence of additional new and previous impairments, different stages and potential of recovery); the lack of power on the design to identify potential side effects and/or adverse events; the need to customize the rehabilitation program for the specific patient needs and the inexistence assessment of visual impairment. Just a small number of studies used gaze stability exercises as a differential intervention[23–26] and only one of these verified its effectiveness in post-stroke patients.[24] Mitsutake et al. measured postural stability and found a significant reduction in the speed of the pressure center in the orthostatic position (when performing head movements) with eyes open and eyes closed after gaze stability exercises.[24] Although both Mitsutake et al. and this clinical trial showed a significant improvement in the intervention group, the results cannot be straightforwardly compared due to methodological differences, namely in the assessment instruments. This clinical trial intended to identify the risk of falling, assessing balance and functional mobility, using tools that are easy to use and accessible in daily clinical practice.

It is accepted that, due to aging, the elderly has sensory and musculoskeletal changes and post-stroke patients have a higher risk of falling due to impairments in the sensory, motor, and high cerebral functions.[4] Regardless of location or etiology of stroke, there is usually a period of inactivity after stroke, with reduced mobility and fear of movement, which may affect the sensory integration. Stimulation of vestibulo-ocular reflex through gaze stability exercises can improve the integration of sensory afferences, contributing to the improvement of balance in post stroke patients.

The generalization of the findings is limited by the representativeness of the sample, recruited among patients referred for ambulatory physiotherapy in a tertiary hospital, where the characteristics of the patients may not match every older adult, victim of stroke. However, both the applicability of the home program in clinical practice and the replicability of the study seem to be extremely high, as it apparently can be carried out at home easily, safely and without adverse reactions and does not require supplementary resources or costs. Therefore, oculomotor and gaze stability exercises may be incorporated into any rehabilitation program with significant gains in improving balance and mobility.

The findings from this clinical trial point out issues that should be assessed in future studies. This trial needs to be replicated on a larger sample, for a longer time of follow-up, through wider age groups and using more-specific instruments, in order to identify potential side effects and/or adverse events, to verify the persistence of the effect over time and to determine if a longer intervention period should be considered.

Domiciliary oculomotor and gaze stability exercises are a promising approach as a complement in the physiotherapy intervention after stroke, whenever balance impairment is present. Given the high incidence of falls in these patients and their social and economic impact, this can be an efficient strategy to improve balance and reduce the risk for falls, restoring confidence and empowerment.

Clinical messages

- Oculomotor and gaze stability exercises improved balance, reflected both on the actual falls and the estimation of the risk of falling
- This study demonstrated the feasibility of domiciliary oculomotor and gaze stability exercises

Acknowledgements

The authors acknowledge the clinical and administrative staff of the Department of Physical Medicine and Rehabilitation at Hospital Curry Cabral (Centro Hospitalar Universitário de Lisboa Central) for their precious collaboration and are thankful to the patients and their relatives and caregivers for participating in the trial.

Authors' contributions

All authors participated in conception and design, acquisition of data, analysis and interpretation of data; made substantial contributions in drafting the article and revising it critically. The authors have given final approval of the version to be published and they confirm that there are no other persons who satisfied the criteria for authorship.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Protocol

Pimenta C, Correia A, Alves M, Virella D (2017) Effects of oculomotor and gaze stability exercises on balance after stroke: Clinical trial protocol. Porto Biomed. J. 2(3):76–80.

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Supplemental material

Supplemental material for this article is available online.

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