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Maximal Fitness Testing in Sedentary Elderly at Substantial Risk of Disability: LIFE-P Study Experience

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Abstract

Background—The authors sought to evaluate the acceptability and feasibility of maximal fitness testing in sedentary older individuals at risk for mobility disability.

Methods—Maximal cycle-ergometer testing was performed at baseline and 6 and 12 months later in a subset of LIFE-P study participants at the Cooper Institute site. The mean age of the 20 participants (80% female) tested was 74.7 ± 3.4 years. The following criteria were used to determine whether participants achieved maximal effort: respiratory-exchange ratio (RER) ≥ 1.1 , heart rate within 10 beats/min of the maximal level predicted by age, and rating of perceived exertion (RPE) >17 .

Results—Participants' mean peak VO_2 was $12.1 (3.7) \text{ mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$. At baseline testing, only 20% of participants attained an RER ≥ 1.10 , only 35% achieved a peak heart rate within 10 beats of their age-predicted maximum, and 18% had an RPE of >17 . Subsequent testing at 6 and 12 months produced similar results.

Conclusions—In this pilot study of sedentary older persons at risk for mobility disability, very few participants were able to achieve maximal effort during graded cycle-ergometer testing.

With the well-documented aging of the American population, research evaluating interventions that promote maintenance of function and quality of life in older individuals is of great public health importance. Physical activity has been promoted as an intervention to enhance physical function and attenuate the comorbidities associated with the aging process. A hallmark means of assessing the success of aerobic-exercise interventions is maximal graded aerobic-exercise testing. Few studies, however, have evaluated the feasibility of maximal graded exercise testing in sedentary older adults who are at risk for disability, despite potential concerns related to the burden of chronic disease, participant tolerability, and quality of data.

The Lifestyle Interventions and Independence for Elders Pilot Study (LIFE-P) was a multicenter pilot study conducted to test feasibility and develop plans for a definitive,

randomized, single-blind, controlled trial to evaluate the efficacy of a physical activity intervention to reduce the incidence of major mobility disability in at-risk older adults (Rejeski et al., 2005). The goal of LIFE-P was to provide key benchmarks to inform the design and implementation of a definitive trial. In a pilot study to the LIFE-P trial, we sought to evaluate the acceptability and feasibility of maximal graded exercise testing in older individuals at risk for disability to determine whether this might be a viable outcome measure in future intervention trials in this population.

Methods

LIFE-P Study and Participants

The LIFE-P study was conducted at four field centers (The Cooper Institute, Dallas, TX; Stanford University, Palo Alto, CA; University of Pittsburgh, Pittsburgh, PA; and Wake Forest University, Winston-Salem, NC). The design and rationale of the LIFE-P study have been presented elsewhere (Rejeski et al., 2005). Briefly, sedentary older adults were randomized to participate in either a walking-based physical activity program or a “successful aging” health information and education program lasting from 12 to 18 months depending on the month of randomization. The eligibility criteria were aimed at identifying people age 70–89 years who were at high risk for mobility disability but who had not yet developed disability. High risk was defined as a score on the Short Physical Performance Battery (SPPB) less than 10. The SPPB includes assessments of balance, gait speed, and the ability to rise from a chair and stratifies people according to their disability risk on a 0–12 scale, with the risk of mobility disability rising sharply for scores less than 10 (Guralnik, Ferrucci, Simonsick, Salive, & Wallace, 1995).

Rationale for Maximal Graded Exercise Testing in Subgroup

Because LIFE-P was a pilot study, the steering committee decided that maximal graded exercise testing should be performed on a subset of participants to determine the need and feasibility of performing maximal graded exercise testing in the full-scale trial. The Cooper Institute site volunteered to take the lead on performing maximal graded exercise testing in a subset of participants. The primary substudy goals were to evaluate participant burden and acceptability of testing, determine staff burden, and determine whether potential changes in exercise in response to the physical activity training program could be adequately assessed even though improvement in maximal aerobic fitness was not a goal of the intervention.

Institutional-Review-Board Approval and Recruitment

The Cooper Institute institutional review board (IRB) was concerned about the risk:benefit ratio of the maximal fitness testing, both in terms of participant burden and safety, especially because fitness was not specified as a study outcome in LIFE-P. The IRB approved the maximal graded exercise testing protocol with two conditions: A physician must be in the room during testing, and testing should not be performed in very high-risk individuals such as those with diabetes or a previous history of cardiovascular disease.

Eligibility and Enrollment for Maximal Graded Exercise Testing

Eligibility for the exercise testing was based on clinical criteria for medical stability and on the IRB review of the risk:benefit ratio. Of the 103 people randomized at the Cooper Institute center, nearly half were ineligible, including those with diabetes ($n = 20$), previous cardiovascular disease ($n = 21$), or other limitations (primarily orthopedic) that made testing unsafe ($n = 9$). Many of these medically ineligible individuals met multiple exclusion criteria. Eligible individuals ($n = 53$) were informed of the opportunity to participate in the ancillary exercise testing only after all their baseline testing for the parent study was

completed and they had been randomized. This was done to ensure that the ancillary exercise testing did not interfere with recruitment or other baseline assessments of the parent study. The details of the fitness-testing pilot study were presented in a one-on-one session in a quiet, private room. Although it was emphasized that participation in the pilot study had no bearing or impact on participation in the parent study, individuals were passively encouraged to partake in the pilot study. Furthermore, individuals were informed that a small monetary incentive (\$20) would be provided at each fitness test. Of the eligible individuals, fewer than half were interested in performing the maximal graded exercise testing ($n = 24$). Of those 24, 4 declined the day of testing (2 because of musculoskeletal issues and 2 because of stories from friends about exercise testing).

Exercise Testing

Maximal graded exercise testing was performed at baseline, 6 months, and 12 months. During each test, participants were monitored at rest and throughout exercise using a 12-lead electrocardiogram system. All exercise tests were conducted using a Lode Excalibur Sport cycle ergometer (Groningen, Netherlands), an electronic, rate-independent ergometer, thereby allowing participants to self-select pedal rate without compromising data outcome. Participants were allowed to practice on the cycle ergometer before exercise testing, as well as familiarize themselves with the mouthpiece and nose clip. Exercise tests started at a low workload (15 W) and proceeded in 2-min stages until volitional fatigue was reached. Each subsequent stage after test initiation proceeded in 15-W increments. Participants were asked to keep a constant cycling cadence within the range of 50–80 rpm and were strongly encouraged throughout the test. We chose to use a cycle ergometer instead of a treadmill because of safety issues, reduced participant burden, and previous work demonstrating fitness testing with a cycle ergometer to be sensitive to change in response to low-intensity exercise training (Church, Earnest, Skinner, & Blair, 2007). Respiratory gases were measured using a Parvomedics True Max 2400 metabolic measurement cart, and gas-exchange variables (VO_2 , CO_2 production, ventilation, and respiratory-exchange ratio [RER]) were recorded every 15 s throughout the entire protocol. Ratings of perceived exertion (RPE) were obtained using the 20-point Borg scale during the last minute of each stage. As summarized in the most recent American of Sports Medicine (2006) guidelines for exercise testing and prescription, a variety of objective and subjective indicators can be used to assess maximal effort during graded exercise testing. Based on the available data and testing protocol we used the following criteria to assess whether participants achieved maximal effort: $\text{RER} \geq 1.1$, heart rate within 10 beats/min of the maximal level predicted by age, and $\text{RPE} > 17$.

Statistical Analysis

Group descriptive statistics were compared between LIFE-P participants who did and did not participate in exercise testing at the Cooper Institute site. Between-group differences were tested using analysis of variance with adjustment for gender. The mean $\text{VO}_{2\text{max}}$, maximum heart rate, RER, and RPE were calculated for the group at each testing time point. We calculated the percentage of participants that obtained an RER of ≥ 1.1 , came within 10 or fewer heartbeats of their predicted maximum heart rate ($220 - \text{age}$), and those that had an $\text{RER} > 17$ for each testing time point. All reported p values are two-sided. All analyses were performed using SAS version 9.0 (Cary, NC).

Results

The study population consisted of 16 women and 4 men (Table 1). Their mean age was 74.7 (3.4) years, and mean SPPB score was 7.6 (1.4). The participants who underwent exercise testing weighed less and had a smaller mean waist circumference and a faster mean 400-m

walking speed than the participants who did not undergo the exercise test ($p < .05$ for each in gender-adjusted analyses). Twenty participants were tested at baseline, 13 at the 6-month follow-up, and 15 at the 12-month follow-up. At both the 6-month and 12-month testing the staff went to great efforts to get participants back for testing. No adverse events were noted during the testing, and none of the tested participants dropped out of the parent study.

Table 2 provides the results of the exercise testing, among all participants and subsequently among only those who had test data at all three time points. Whether considered in relative or absolute terms, the peak VO_2 values were very low at each time point (American College of Sports Medicine, 2006). At baseline, for example, the mean absolute VO_2 was 0.9 (0.3) L/min and mean relative VO_2 was 12.1 (3.7) $\text{ml} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ among all tested participants. Values for the mean RER attained were also low at all three time points. At baseline, for example, the mean RER was 1.05 (0.07), suggesting that as a group maximal exercise effort was not achieved. Similarly, mean RPE at each testing point was low. For example, at baseline mean RPE was 16.2 (1.7) and at all three testing points mean RPE was <17 .

The number and percentage of participants meeting conventional benchmarks for maximal exercise effort are provided in Table 3. At each time point, relatively few participants (33–46% for all data) reached the predicted maximum heart rate. Similarly, relatively few (20–62%) achieved an $\text{RER} \geq 1.1$ across the three time points or achieved an $\text{RPE} >17$ (15.4–20%). Furthermore, there was great variability in terms of which individuals met the criteria for maximum across the testing time points. For example, only 3 of the 11 (27%) met the maximum heart-rate criteria, 2 of 11 (18%) met RER criteria, and none met RPE criteria at all three time points.

Discussion

The goal of this study was to evaluate the acceptability and feasibility of maximal graded exercise testing in sedentary older individuals at risk for disability. Almost half the potential participants had a high-risk medical condition that made the testing inadvisable, according to the local IRB. Of the eligible participants, fewer than half were interested in the testing. At each of the three time points, relatively few participants met accepted criteria for defining a successful maximal test, making the data difficult to interpret. The staff who performed the testing were highly experienced and found that despite strong verbal encouragement, pushing participants to maximal effort was quite challenging. This might be because of an age-related decrease in chronotropic function, as well as the anecdotal observation that participants often abruptly stopped the test for reasons other than cardio-pulmonary fatigue, such as knee pain or nonspecific complaints of discomfort. This is supported by the mean group SPPB of 7.6, which suggests that these were individuals at high risk for disability and that many were starting to develop functional limitations.

Other investigators have questioned the value of maximal testing in older adults to measure fitness because many older adults fall below the level of fitness that these tests were designed to assess (Gill, DiPietro, & Krumholz, 2000). Walking tests such as the 6-min walk or the long-distance or 400-m walk have been shown to correlate well with maximal testing in those who can do both (Enright et al., 2003; Meyerhardt et al., 2006; Simonsick, Fan, & Fleg, 2006). These prior studies also reported that many older adults and chronically ill people with congestive heart failure or chronic obstructive pulmonary disease fall below the level of walking speed that is needed for the slowest starting level of treadmill-based tests (Newman, Haggerty, Kritchevsky, Nevitt, & Simonsick, 2003; Peeters & Mets, 1996; Swerts, Mostert, & Wouters, 1990). Our experience confirms these prior observations and provides data on a specific subgroup that is at high risk for disability but able to walk the distance required for one of these modified tests.

Based on this experience, there are a number of reasons that we recommend that maximal graded exercise testing not be considered as a proxy outcome for trials in older adults at high risk for mobility disability. Given the low percentage of participants who achieved conventional benchmarks of maximal testing at any of the testing points, combined with the great individual variation in regard to achieving maximal effort over the testing points, the data are of little value for assessing change in maximal fitness. Although not specifically quantified for the purposes of this pilot study, the costs associated with the equipment, training, and staff time needed to conduct maximal graded exercise testing are substantial. Although some participants were initially excited about participating in the exercise testing, this enthusiasm waned with each subsequent testing. This not only poses a problem for the exercise-testing data but also, more important, could compromise the integrity of the whole study should participants drop out to avoid repeat maximal-exercise tests.

Our experience with maximal graded exercise testing should not dissuade investigators from using other forms of exercise or functional testing in older adults at high risk for disability, such as the 6-min walk, 400-m walk, or submaximal exercise testing (Enright et al., 2003; Meyerhardt et al., 2006; Simonsick et al., 2006). For example, the 400-m walk has low participant and researcher burden, is highly reproducible, and is predictive of mortality and mobility disability (Bittner et al., 1993; Newman et al., 2003; Simonsick, Montgomery, Newman, Bauer, & Harris, 2001).

Conclusion

In this pilot study of sedentary older adults at risk for mobility disability, we found that very few participants were able to achieve maximal effort during graded cycle-ergometer testing. These findings diminish the potential value of this type of testing for assessing changes in fitness in sedentary older adults.

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Table 1

Characteristics of Participants at Cooper Institute Field Site, *M (SD)*

	Participants tested <i>n</i> = 20	Participants not tested <i>n</i> = 83
Age, years	74.7 (3.4)	76.0 (4.5)
Female, %	80%	65%
Weight, kg	74.8 (11.5)	84.9 (17.2)*
Waist circumference, cm	93.4 (14.5)	101.0 (18.0)*
Systolic blood pressure, mmHg	132.2 (19.1)	130.8 (23.7)
Diastolic blood pressure, mm Hg	72.6 (9.29)	67.6 (13.3)
Short Physical Performance Battery score	7.6 (1.4)	7.6 (1.4)
400-m walk speed, m/s	1.03 (0.19)	0.93 (0.15)*

* *p* < .05 for between-group differences using gender-adjusted analyses.

Table 2

Exercise-Testing Data Across the Three Testing Time Points

Time	N	Absolute $\dot{V}O_{2\max}$ (L/min)	Relative $\dot{V}O_{2\max}$ ($\text{ml} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$)	Maximum heart rate	Respiratory-exchange ratio	Rating of perceived exertion
All available data						
baseline	20	0.9 (0.3)	12.1 (3.7)	125.7 (19.3)	1.05 (0.07)	16.2 (1.7) ^a
6 months	13	1.1 (0.3)	12.9 (5.1)	130.5 (13.8)	1.12 (0.07)	15.7 (1.9)
12 months	15	1.0 (0.3)	13.3 (3.3)	127.8 (15.6)	1.09 (0.07)	15.9 (2.2)
Participants tested at all 3 times						
baseline	11	1.0 (0.4)	12.9 (4.1)	127.5 (19.8)	1.08 (0.07)	16.4 (1.9) ^b
6 months	11	1.1 (0.3)	14.5 (3.5)	131.7 (11.7)	1.13 (0.06)	15.6 (2.0) ^b
12 months	11	1.1 (0.4)	13.7 (3.7)	128.5 (16.4)	1.11 (0.05)	15.2 (1.9) ^b

^a $n = 17$.

^b $n = 10$.

Table 3
Prevalence of Meeting Measures of Maximal Effort Across the Three Testing Points

Time	N	Max heart rate > age-predicted rate – 10	Respiratory-exchange ratio ≥ 1.1	Rating of perceived exertion > 17
All available data				
baseline	20	35%	20%	18% ^a
6 months	13	46%	62%	15%
12 months	15	33%	60%	20%
Participants tested at all 3 times				
baseline	11	45%	36%	30% ^b
6 months	11	55%	73%	10% ^b
12 months	11	36%	73%	20% ^b

^a n = 17.

^b n = 10.