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Brief Report

What is a Clinically Meaningful Improvement in Leg-Extensor Power for Mobility-limited Older Adults?

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Abstract

Background: Muscle power is a key predictor of physical function in older adults; however, clinically meaningful improvements in leg-extensor muscle power have yet to be identified. The purpose of this study is to establish the minimal clinically important improvement (MCII) and substantial improvement (SI) for leg-extensor power and muscle contraction velocity in mobility-limited older adults.
Methods: Data were extracted from three randomized trials of leg-extensor muscle power training interventions (3- to 6-month duration). Measurements of leg-extensor power and velocity were obtained using dynamic bilateral leg press at 40% and 70% of the one-repetition maximum. Anchor-based MCIIs were calculated using selected items extracted from the Late Life Function and Disability Instrument. Standard error of measurement and effect size methods were used to calculate the distribution-based MCII.
Results: Data from 164 participants (mean age: 76.6 ± 5.6 years; Short Physical Performance Battery score: 7.8 ± 1.3) were used in this analysis. The respective MCII and SI estimates for 40% leg-extensor power were 18.3 (9%) and 30.5 (15%) W, and 23.1 (10%) and 41.6 (18%) W for 70% leg-extensor power. The respective MCII and SI estimates for 40% average velocity were 0.03(7%) and 0.08(18%) m/s, and 0.02(6%) and 0.05(15%) m/s for 70% average velocity.
Conclusions: This is the first study to establish a clinically meaningful improvement of leg-extensor power (9%–10%) and velocity (6%–7%) in mobility-limited older adults. These findings should be used to aid in the design and interpretation of clinical trials and interventions that target improvements in muscle power in this high-risk population.

Key Words: Physical performance—Muscle—Exercise—Power—Clinically important improvement

Older adults with mobility limitations (difficulty with ambulatory tasks such as walking and standing up from a chair) have higher rates of falls, fractures, institutionalization, and mortality (1). It has been established that leg-extensor power (Force × Velocity of the muscle contraction) is a critical determinant of physical function and mobility for older adults (2), as it declines earlier and more rapidly with age (3), and is more predictive of physical performance than muscle strength (4). Changes in leg-extensor power have been previously examined across a growing range of behavioral, translational, and pharmaceutical trials (2). However, the clinical meaningfulness of these changes remains uncertain, which limits the interpretation and understanding of results from previous intervention trials. Minimal clinically important improvements (MCIIs) will help provide the necessary context in studies examining muscle power by establishing estimates of improvements that are considered meaningful from the perspective of the patient (5). Furthermore, understanding the clinical meaning of improvements in muscle power will provide strong rationale for its use as an outcome measure in trials targeting this high-risk population.

The purpose of this study is to establish both MCII and substantial improvement (SI) estimates for leg-extensor power in older adults. In addition, we performed a subanalysis to determine the MCII for leg-extensor average contraction velocity, as these changes may be the key factor driving changes in muscle power (2).

Methods

Data Sources

We used data from three separate randomized trials, which have been previously described (6–8). In brief, all three studies enrolled older adults (65–94 years old at baseline) with objectively defined mobility limitations (Short Physical Performance Battery [SPPB] ≤ 9). Exclusion criteria included cognitive impairment, defined as a Mini-Mental State Examination score < 23 (9), unstable chronic disease, recent myocardial infarction or extremity fracture, and regular participation in structured physical activity, such as endurance or strength training, in the previous 6 months. Each study involved a lower extremity resistance training program (three sets of 10–12 repetitions, 2–3 times per week). All studies obtained institutional review board approval.

Measures

Assessment of Leg-extensor Power and Velocity

Leg-extensor power and velocity were collected using a Keiser A420 Pneumatic Leg Press (Leg Press A420, Keiser Corporation, Fresno, CA) at 40% and 70% of the one-repetition maximum, according to previously established and validated procedures (10). Power data were available from all studies, and velocity data were available from two of the three.

Anchor Measures

Selected items from Late-Life Disability Instrument (LLFDI) were used as anchors for this analysis (11). We selected four items a priori based on their excellent face validity, as we believe that each of these activities demand substantial leg-extensor power to complete (4). The items chosen were as follows: "How much difficulty do you have: (a) going up and down stairs inside, using a handrail? (b) walking a mile, taking rests as necessary? (c) running a short distance, such as to catch a bus? (d) stepping on and off a bus?" Responses were collected on a Likert scale from 1 to 5, where 5 indicates "None" and 1 indicates "Cannot Do". These data were available from all three studies.

Statistical Analysis

Distribution-based estimates

We used the standard error of measurement (SEM) and effect size methods to calculate MCII and SI estimates (5). The SEM method was calculated using $\sigma\sqrt{1-\gamma}$, where σ is the standard deviation of the outcome variable at baseline and γ is the test–retest reliability of the outcome measure (10,12). The test–retest reliability was obtained from a study in which leg-extensor power testing was conducted in a mobility-limited population of older adults (10). The SEM method will only provide one estimate, which is considered the MCII. The effect size is defined as $\delta = (\mu_{\text{follow-up}} - \mu_{\text{baseline}}) / \sigma_{\text{baseline}}$, where μ is the mean and σ is the standard deviation at baseline of each outcome measure. It has been previously established that effect sizes of 0.2 and 0.5 should be considered representative of small and moderately meaningful change. Using these effect sizes, we can estimate the MCII and SI as $0.2 \times \sigma_{\text{baseline}}$ and $0.5 \times \sigma_{\text{baseline}}$, respectively.

Anchor-based estimates

We calculated the individual percent change in leg-extensor power for each participant included in the analysis. We chose to use percent change rather than absolute values for two primary reasons: (a) this approach can be used to reduce the variability in the outcome variable while maintaining interpretability, and (b) the relative changes seen in leg-extensor power may be more translatable, as individuals with low power output at baseline may not require the same magnitude of change to be considered clinically meaningful as compared with an individual with higher power. We operationalized change over time in self-reported mobility into three levels: (a) no change, (b) minimal improvement (increase in LLFDI response by 1 point), and (c) SI (increase in LLFDI response by ≥ 2 points). The MCII was calculated as the difference in mean percent change in power for participants reporting minimal improvement and those who reported no change. SI was calculated as the difference in mean percent change in power for participants reporting SI and those who reported no change. This method was used to calculate the MCII and SI for 40% and 70% average power and velocity. SI calculations were not performed for average velocity, as too few participants reported "substantial improvement" to provide accurate estimates. The distribution of self-reported change can be found in Supplementary Tables 1 and 2.

All statistical analyses were performed using IBM SPSS Statistics 22.0 for Windows (IBM Corp, Armonk, NY).

Results

Baseline Characteristics

Detailed descriptions of the study protocols and results have been reported previously (6–8) and are summarized in Table 1.

Distribution-based Analysis

Results from effect size and SEM analysis are shown in Table 2. MCII estimates for leg-extensor power at 40% ranged from 15.6

Table 1. Subject Characteristics

Characteristic	Reid et al., 2008 (*n* = 57)	Reid et al., 2015 (*n* = 52)	Chale et al., 2013 (*n* = 55)
Age; mean ± *SD*	74.2 ± 6.9	77.8 ± 4.5	77.9 ± 4.1
Female; *n* (%)	31(54.4)	36(65.5)	33(60.0)
BMI; mean ± *SD*	28.7 ± 5.4	26.6 ± 3.3	27.1 ± 3.2
SPPB Score; mean (range)	7.7 (3–9)	8.0 (5–9)	7.7 (4–9)
Leg-extensor power; 40% (W)	230.2 ± 85.0	170.3 ± 77.8*	209.5 ± 104.8
Leg-extensor power; 70% (W)	245.4 ± 104.1	223.3 ± 104.0	225.4 ± 109.6
Average velocity; 40% (m/s)**	—	0.44 ± 0.15	0.43 ± 0.13
Average velocity; 70% (m/s)**	—	0.32 ± 0.10	0.31 ± 0.10

Notes: BMI = body mass index; SD = standard deviation; SPPB = Short Physical Performance Battery.

*Statistically significant difference between groups (*p* = .003).

**Average Velocity not available from Reid et al., 2008.

Table 2. Distribution-based Estimates (n = 164)

	Reid et al., 2008	Reid et al., 2015	Chale et al., 2013
	W (%)	W (%)	W (%)
Leg-extensor power 40%			
Effect size*			
Small improvement	17.0 (7.4)	15.6 (9.1)	21.0 (10.0)
Substantial improvement	42.5 (18.5)	38.9 (22.9)	52.4 (25.0)
SEM	22.49 (10.0)	20.6 (12.1)	27.7 (13.2)
Leg-extensor power 70%			
Effect size*			
Small improvement	20.8 (8.5)	20.8 (9.3)	21.9 (9.7)
Substantial improvement	52.0 (21.2)	52.0 (23.3)	54.8 (24.3)
SEM	27.5 (11.2)	27.5 (12.3)	29.0 (12.9)

Notes: SEM = standard error of measurement.
*Small improvement = 0.2; Substantial improvement = 0.5.

Table 3. Anchor-based Estimates of Meaningful Improvement

	Leg-extensor Power; 40% (%)	Leg-extensor Power; 70% (%)
Minimal improvement		
Going up and down a flight of stairs inside, using a handrail (n = 22)	6.7	14.3
Walking a mile, taking rests as necessary (n = 24)	7.4	6.8
Running a short distance, such as to catch a bus (n = 21)	−0.3	−7.4
Stepping on and off the bus (n = 24)	16.8	23.3
Mean	7.7	9.3
Substantial improvement		
Going up and down a flight of stairs inside, using a handrail (n = 6)	9.8	17.9
Walking a mile, taking rests as necessary (n = 5)	16.5	10.9
Running a short distance, such as to catch a bus (n = 10)	7.3	11.2
Stepping on and off the bus (n = 7)	7.0	13.2
Mean	10.1	13.3

Table 4. Estimates of Minimal and Substantial Improvement in Lower Extremity Power and Velocity

	Leg-extensor power 40%	Leg-extensor power 70%	Avg. Velocity 40%	Avg. Velocity 70%
	W (%)	W (%)	m/s (%)	m/s (%)
MCII	18.3 (9.0)	23.1 (10.0)	0.03 (7.0)	0.02 (6.0)
Substantial improvement	30.5 (15.0)	41.6 (18.0)	0.08 (18.0)	0.05 (15.0)

Note: MCII = minimal clinically important improvement.

to 27.7W (7.4% to 13.2%) and ranged from 20.8 to 29.0W (8.5 to 12.9%) for leg-extensor power at 70%. Distribution-based estimates for velocity can be found in Supplementary Table 3.

Anchor-based Analysis

Anchor-based MCII estimates for leg-extensor power at 40% and 70% were 7.7% (range −0.3% to 16.8%) and 9.3% (range −7.4% to 23.3%), respectively (Table 3). Anchor-based estimates for velocity can be found in Supplementary Table 4.

MCII Estimates

As there is no standard method of combining clinically meaningful estimates from multiple sources, we calculated the mean change in each variable across all four anchors and compared it with the corresponding distribution-based results to provide single estimates for MCII and SI (Table 4).

Discussion

This is the first study to provide clinically meaningful estimates for improvement of leg-extensor power and contraction velocity for mobility-limited older adults. Our analysis suggests that an approximate 9% and 10% improvement in leg-extensor power at 40% and 70%, respectively, should be considered clinically meaningful. Furthermore, we also calculated the threshold for SI, which is 15% and 18% for leg-extensor power at 40% and 70%, respectfully. These estimates are generally consistent across both anchor-based and distribution-based techniques. It should be noted that the estimates using the question, “How much difficulty do you have running a short distance, such as to catch a bus?” result in a negative change for minimal important improvement, though a positive change was revealed for SI. This may have been due to the fact that running to catch a bus requires a higher power output and may only be reflected in those who report a SI.

Leg-extensor power is recognized as a critical determinant of mobility for older adults (2). Muscle power declines earlier and more rapidly with age when compared with strength and is a stronger predictor of physical performance with advancing age in older persons (3,4). Multiple studies have examined leg-extensor power as a primary endpoint in mobility-limited older adults, many of which demonstrated substantial increases in physical function as well (2). For example, Reid and colleagues demonstrated an increase in leg-extensor power of 34%–40% by performing biweekly lower extremity exercises at either high or low external resistances. Concurrently, mean SPPB score increased by 1.3 to 1.8 units, a change considered clinically substantial (13). In a study examining the impact of dynamic exercises with weighted vests in mobility-limited older adults, the investigators reported approximately 10% increase in leg-extensor power, while also observing clinically meaningful changes in the SPPB (greater than 1 unit) (14). Taken together, these studies reveal that interventions that elicit clinically meaningful improvements in power may also produce substantial increases in physical function.

As leg-extensor power continues to be utilized as an outcome in geriatric research, there is a strong need to understand the clinical implications of the findings. The ability to conclude that observed improvements are not only statistically significant but also clinically meaningful makes data far more compelling, as there is direct applicability to the population that is being studied. For example, Perera and colleagues established a clinically meaningful change for various measures of mobility performance in older adults, including the SPPB (13). These estimates have provided many interventions a more meaningful comparator to evaluate changes in mobility, and the SPPB is often used as a primary outcome in interventions of older adults with mobility limitations (2,15).

This study has some limitations. First, consistent with other studies that calculate MCII, a large proportion of participants in this study indicated "no change" in self-reported function, which may have reduced the precision of the anchor-based estimates. Second, there is no defined magnitude between levels of change using the LLFDI, which makes the definition of minimal and substantial improvements somewhat arbitrary. However, we utilized both distribution- and anchor-based approaches, which provides both excellent face validity, as it reports change based on self-reported improvement in function and statistical precision (5). In addition, due to the relatively small sample size, these estimates should be considered preliminary and will require confirmation in larger study samples. Third, we chose to use individual percent change for the anchor-based analysis. Though this is not a typical method for calculating estimates of meaningful improvement, we believe that these results are relevant, as baseline levels of power can vary substantially in this mobility-limited population, particularly between men and women (16). We do acknowledge that it would be useful for future studies to provide absolute estimates, in addition to the relative estimates provided here. Furthermore, as this analysis only includes data from older adults with mobility limitations, these estimates may not be applicable to other subgroups of older adults, such as healthy older adults. Nevertheless, we believe that this study has strong clinical implications, as it was conducted using data from randomized intervention trials in which older adults with objectively measured limitations in mobility were enrolled. This is important, as this population is at high risk for future disability and is an appropriate target for interventions that aim to improve muscle power.

Conclusions

This is the first study to establish estimates of the MCII in leg-extensor power and muscle contraction velocity in mobility-limited older adults. The identification of a clinically meaningful threshold for improvements in muscle power provides further rationale for its use as an outcome for varied interventions, as well as context for results of previously completed trials. These estimates should be utilized when designing and interpreting interventions that target muscle power in this high-risk population.

Supplementary Material

Supplementary material can be found at: http://biomedgerontology.oxfordjournals.org/

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