Feasibility of the Physiological Cost Index as an Outcome Measure for the Assessment of Energy Expenditure During Walking

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ABSTRACT. IJzerman MJ, Nene AV. Feasibility of the Physiological Cost Index as an outcome measure for the assessment of energy expenditure during walking. Arch Phys Med Rehabil 2002;83:1777-82.

Objective: To determine if the Physiological Cost Index (PCI) can be recommended as an outcome measure in clinical trials.

Design: Three assessments were performed, 2 with shoes, 1 without. The difference between walking with shoes and walking barefoot was used to study the ability of the PCI to detect a change in the criterion standard.

Setting: A research department affiliated with a rehabilitation hospital in the Netherlands.

Participants: Twelve children with cerebral palsy.

Interventions: During the first and third assessments, the children walked with shoes. During the intermediate assessment, the children walked without shoes.

Main Outcome Measures: Breath-by-breath oxygen uptake, heart rate (HR), and walking speed were measured at a self-selected comfortable speed. Oxygen cost (EO_2) and the PCI were subsequently calculated offline. Feasibility judgments were made regarding the ability of the PCI to detect changes in a criterion standard and the statistical power of the outcome measure.

Results: Pearson correlation coefficients were .66 and .62 for $HR_{walking} - HR_{baseline}$ and $HR_{walking}$, respectively. The smallest detectable difference of the PCI and EO_2 were 69% and 32%, respectively. A difference of at least 69% or 32% should be found before one can conclude a difference with a certainty of 95%.

Conclusions: The reproducibility of the PCI and the ability to show small differences in EO_2 were moderate. Subtracting $HR_{baseline}$ when calculating the PCI is probably not useful because it only increased within-subject variability. With respect to statistical power of a new clinical trial, we recommend using EO_2 instead of the PCI.

Key Words: Cerebral palsy; Child; Disability evaluation; Energy metabolism; Heart rate; Locomotion; Orthotic devices; Oxygen consumption; Paraplegia; Rehabilitation; Spinal cord injuries; Walking.

MANY STUDIES ON THE efficacy of interventions for improvement of walking have used an oxygen uptake ($\dot{V}O_2$) recording in their measurement procedures. Preferably, the energy expenditure during walking is determined by measuring the $\dot{V}O_2$.[1] Because of the inconvenience in assessing the energy expenditure using $\dot{V}O_2$ measurements, various other low and intermediate technologies have been proposed.[2] Heart rate (HR) measurement is considered to be a low technology and is proposed to assess the energy expenditure during different tasks.[3,4] The use of heart rate monitoring to assess energy cost during walking probably originates from MacGregor, who introduced the Physiological Cost Index[5] (PCI).

At about the same time, a research group at the Orthotic Research & Locomotor Assessment Unit proposed a combined assessment of heart rate and walking speed.[6] The theoretical basis for the PCI is the relation that exists between heart rate and $\dot{V}O_2$ in healthy subjects up to submaximal workload.[7] The PCI is calculated by dividing the difference ($HR_{walking} - HR_{baseline}$) by walking speed. It thereby yields an outcome that is expressed in beats per meter. Consequently, the PCI is closely related to the oxygen cost (EO_2), which is expressed in milliliters of oxygen per meter.

Since its introduction, many have used the PCI as an outcome measure in healthy individuals and patients with pathologic conditions. The PCI was used in studies of rheumatoid arthritis,[8] healthy adolescents and adults,[9] healthy children,[10] paraplegic locomotion,[11-13] and cerebral palsy (CP).[14] Instead of the PCI, Rose et al[15,16] introduced the Energy Expenditure Index (EEI). The theoretical assumptions of this index are comparable to the PCI.

Obviously, convenience of the measurements is a major advantage of heart rate recordings. However, although the PCI is extensively used, it is not known what recommendations can be given pertaining to its use as an outcome measure in comparative trials. McCrory et al[3] have determined the variability in the relation between heart rate and oxygen consumption on 4 different occasions (2d of morning and afternoon sessions). They concluded that the heart rate–based energy expenditure estimates on the 4 occasions were the same for the whole group.[3] However, there were individual variations.

Bowen et al[17] studied the reproducibility of the PCI and EO_2 in children with CP. They concluded that EO_2 was more reproducible (avg variability, 13.2%) than the PCI (avg variability, 20.3%). IJzerman et al[18] have studied the reliability of the PCI and EO_2 in paraplegia and concluded that the PCI's reliability was less than the criterion standard. Nene[9] presented test-retest data in adolescents and adults and concluded that the PCI is reproducible.

Concerning validity, Bowen[17] calculated the correlation between the PCI and EO_2 in a study with CP children, and found a moderate correlation coefficient of .50. Rose[15] compared heart rate and $\dot{V}O_2$ during the last 10 seconds of a 2-minute walk at different speeds. They found an extremely high correlation ($r = .99$) between heart rate and $\dot{V}O_2$. Engsberg et al[19] concluded that vertical displacement of the pelvis, the PCI, and

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heart rate were adequate tools in the assessment of energy expenditure. IJzerman[18] studied the PCI in patients with spinal cord injury (SCI) and concluded that the ability of the PCI to detect changes (longitudinal validity) was good (r=.86).

The purpose of our study was to determine the feasibility of using the PCI as an outcome measure in clinical trials. In so doing, one is concerned whether repeated measurements in stable subjects and under similar conditions yield the same results and whether true differences caused by, for example, intervention, can be reliably detected.[20,21] This analytical approach appeared to yield valuable information on the same subject in a previous study[18] on mechanically supported paraplegic walking. In the present study, we performed a series of experiments to collect additional data in children with CP by using the same approach. On the basis of these data and a review of the literature, we intended to draw some general conclusions about the use of the PCI as an outcome measure.

METHODS

Participants

Twelve children with CP participated in this study. Exclusion criteria were cardiovascular abnormalities, breathing difficulties, and surgery during the previous year. Eight children had hemiplegia and 4 had diplegia. The children were able to walk both barefoot and with shoes on for at least 10 minutes, with or without the use of a walker. All of these children understood the instructions given to them. Written permission from their parents to participate in this study was obtained. The local medical ethics committee approved the protocol for the study.

Methodologic Issues and Study Design

Measurement properties required for an outcome measure are reproducibility, validity, and responsiveness.[20,21] Reproducibility (or repeatability) concerns whether a test consistently yields the same results when administered on several occasions to stable subjects. Validity is required to confirm that the test is actually measuring what it is supposed to measure. However, in determining the usefulness of an evaluative outcome measure, that is, an outcome measure that should detect changes, it is particularly important to determine its responsiveness.[20,22] Responsiveness, rather than validity and reproducibility, determines the power of a test to detect clinically important changes in a trial. Different articles have been published about the concept and calculation of responsiveness.

However, in our study, the approach of Husted et al[23] was followed. According to Husted,[23] responsiveness can be calculated without (internal responsiveness) and with (external responsiveness) an external criterion that determines a change. Internal responsiveness can be considered a power calculation, that is, the observed within-subject variability (noise) is related to a difference to be detected (signal). The signal then preferably represents a clinically relevant change. The most common statistic to calculate internal responsiveness is an effect size.[20] External responsiveness, on the other hand, reflects whether the observed changes in the new measure correspond with an external criterion (criterion standard). It can also be referred to as longitudinal construct validity.[22] The external responsiveness can be assessed by using either dichotomous statistics that discriminate between improvement or deterioration (eg, using receiver operator characteristics) or correlation coefficients for continuous data.

In our study, we chose a design in which 3 assessments were performed. Two assessments were made while walking with shoes on and 1 assessment while walking barefoot. Studying the difference between walking with shoes and barefoot is a convenient way to obtain a difference in the criterion standard that was expected to be clinically meaningful. This difference was estimated to be about 7% to 45%.[10] Moreover, because the children were accustomed to walking with shoes as well as in bare feet, we could compare 2 conditions that were familiar to them. The statistical power of the PCI to detect a difference in energy consumption was calculated by using the difference between the average of the 2 in-shoe trials and walking barefoot.

Measurements

Breath-by-breath measurement of $\dot{V}O_2$, carbon dioxide uptake, and ventilatory parameters were taken by using the PCI metabolic cart (Oxycon Alpha).[a] The heart rate was measured continuously by using a heart rate monitor.[b] The Oxycon Alpha is equipped with a small and flexible facemask that does not interfere with subjects' gait pattern. Two small lightweight gastubes connect the facemask to the analysis and processing unit.

A standardized measurement protocol was used to determine the different parameters. Baseline measurements of $\dot{V}O_2$ and heart rate were taken while the subject sat in a chair for at least 5 minutes to be confident of a steady state. The last 2 minutes of the baseline measurements were averaged and used for calculating the PCI. After the baseline measurements were completed, subjects were asked to stand up. Once the heart rate approached a stable level, subjects were asked to walk along a 160-m circular pathway at a comfortable walking speed. Heart rate and $\dot{V}O_2$ were measured for 8 minutes, assuming that a steady-state condition could be approached after about 4 minutes. The first 4-minute interval was used as a run-in period. Subsequently, the second 4-minute interval was used to calculate steady-state walking $\dot{V}O_2$ and heart rate. Walking distance was measured for the whole testing period and for the first and second 4-minute interval separately to facilitate calculation of the walking speed (v). Steady-state walking performance was also judged in real time by means of plateau levels of heart rate and expiratory volume. EO_2 and the PCI were calculated offline by using the steady-state values of heart rate and $\dot{V}O_2$ both during baseline and steady-state walking, using:

$$EO_2 = \dot{V}O_2/v \quad (1)$$

$$PCI = (HR_{walking} - HR_{baseline})/v \quad (2)$$

where v is the walking speed during steady state (m/min).

All measurements were performed at the same time of the day and under the same conditions. The children were asked to refrain from eating for at least 2 hours before arriving at the gait laboratory.

Data and Statistical Analysis

External responsiveness. External responsiveness was calculated for heart rate compared with $\dot{V}O_2$ (both per unit time) and the PCI compared with EO_2 (both per unit distance). Because both the PCI and EO_2 are calculated by dividing by the same denominator (walking speed), only the nominators were used in the calculations, that is, $HR_{walking} - HR_{baseline}$ and $\dot{V}O_2$, respectively. Pearson product-moment correlations were calculated for the differences between walking with and walking without shoes. A 95% confidence interval (CI) was calculated by using a Fisher z transformation.[24]

Internal responsiveness and reproducibility. Reproducibility is assessed by using intraclass correlation coefficients (ICCs). ICCs were calculated for all relevant outcome mea-

Table 1: Crude Data of the Walking Tests

	Day 1 $Shoes_1$	Day 2 Barefoot	Day 8 $Shoes_2$	Difference (95% CI) $Shoes_1 - Shoes_2$
HR_{rest} (beats/min)	93.7±16.4	94.5±12.9	92.9±12.4	0.8 (−5.9 to 7.6)
HR (beats/min)	133.7±19.9	131.6±21.4	138.0±21.4	−4.3 (−12.3 to 3.7)
PCI (beats/min)	.67±.3	.65±.4	.72±.3	−.05 (−.15 to .05)
$\dot{V}O_2$ (mL · kg^{-1} · min^{-1})	568*±187	618±187	644±247	−22.7* (−87.9 to 42.6)
EO_2 (mL · kg^{-1} · m^{-1})	9.38*±3.05	10.14±3.3	9.71±3.2	.29* (−.39 to .97)
Speed (m/min)	63.9±12.7	62.5±13.7	66.7±15.9	−2.8 (−6.6 to 0.9)

NOTE. Values are mean ± standard deviation. Except for HR_{rest}, all parameters represent values during steady-state walking. The difference between both tests with shoes is expressed by using a 95% CI (last column).
Abbreviations: $Shoes_1$, first walking trial with shoes; $Shoes_2$, second shoe trial.
* n=11.

sures by using a random-effects model. However, ICCs can be misleading because the between-subject variability is the variance of interest, whereas the within-subject variance is more relevant for detecting longitudinal changes.[18,20] The within-subject variability (standard error of measurement [SE_m]) is estimated by using the mean square error (MS_{error}) obtained from an analysis of variance. Subsequently, smallest detectable difference (SDD) can be calculated.[25] The SDD is the point at which the difference between 2 consecutive measurements exceeds the measurement error. In other words, the SDD can be interpreted as the difference that should be found to be 95% sure of a true difference.

$$SE_m = MS_{error} \quad (3)$$

$$SDD = 2.23 \cdot \sqrt{2} \cdot SE_m \quad (4)$$

Both the SE_m and the SDD are expressed in the unit of measurement of a variable. The SDD is also given as the relative difference with respect to the mean value determined during the first session.

Internal responsiveness was calculated by using effect sizes. Effect sizes were calculated for each of the outcome measures by using the mean difference between walking with shoes (average of trials 1, 3) and walking barefoot as signal (Δ). The noise was estimated by using the within-subject variability in the difference between walking barefoot and walking with shoes ($\sqrt{2}/MS_{error}$).

Effect size (Guyatt's responsiveness statistic[20])

$$= \frac{\Delta}{\sqrt{2 \cdot MS_{error}}} \quad (5)$$

where Δ is the difference to detect and $\sqrt{2} \cdot MS_{error}$ is the within-subject variability.

RESULTS

All subjects were able to walk at a comfortable speed with and without shoes for 8 minutes. During the first session, some children were anxious about wearing the facemask, but that improved during the second and the third sessions. All subjects were able to enter a steady state in approximately 4 minutes. The $\dot{V}O_2$ recording of 1 child during the first test was not reliable. We used the last recording (with shoes) as an estimate of walking with shoes instead.

Table 1 summarizes the crude data and shows mean values and standard deviations of each of the relevant parameters during the first, second, and third sessions, as well as differences between 2 consecutive assessments while walking with shoes.

External responsiveness. Two estimates of energy cost (ie, $HR_{walking} - HR_{baseline}$, $HR_{walking}$) were studied for the ability to detect changes in criterion standard ($\dot{V}O_2$). Figure 1 presents a scatterplot of the differences between walking with shoes and barefoot against the difference in $\dot{V}O_2$. Pearson correlation coefficients were .66 (95% CI, 0.15–.90) and .62 (95% CI, .08–.88) for ($HR_{walking} - HR_{baseline}$) and $HR_{walking}$, respectively.

Internal responsiveness and reproducibility. Differences between the first and third sessions (both with shoes) were estimated by using 95% CIs (table 1). We concluded that there was a systematic difference in the retest, which might be explained by a faster walking speed. The systematic difference was, however, not significant (table 1).

Table 2 shows the ICCs and the SDDs. The SDDs (%) of the PCI and EO_2 were large, and differences of more than 69% (PCI) and 32.4% (EO_2) should have ensured a true difference with a certainty of 95%. SDDs of walking speed and heart rate were approximately 29%.

In our study, we assumed that the difference between walking with shoes (averaged) and barefoot would exceed the measurement error and be clinically meaningful. By using this difference, the calculated effect size was about .22 and .26 for the EO_2 and the PCI, respectively (table 2). The sample sizes for a new hypothetical study that have to show these differences were estimated to be 210 and 168, respectively (table 2). However, these differences in the PCI and EO_2 between walking with shoes and barefoot were not the same (2.8% for EO_2, 6.4% for PCI). Assuming that a difference of 10% would be found in a new trial, it was estimated that the required sample

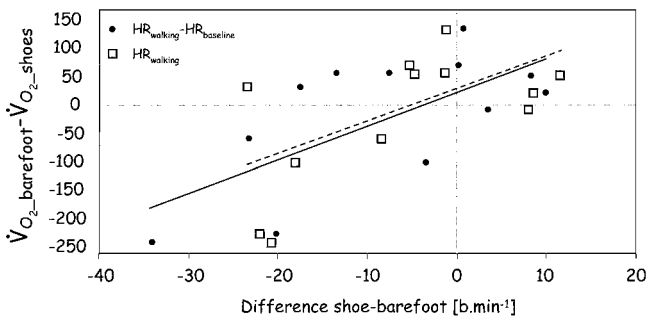

Fig 1. Ability of $HR_{walking} - HR_{rest}$ and $HR_{walking}$ to detect changes in the criterion standard (external responsiveness). The criterion standard is $\dot{V}O_2$ during steady-state walking. The change represents the difference between walking with and without shoes. Correlations are .66 (95% CI, .15–.90) and .62 (95% CI, .08–.88), respectively.

Table 2: Reproducibility (Both In-shoe Trials) and Power to Detect a Difference (Between Walking With Shoes and Barefoot)

	Reproducibility		Power to Detect a Difference				
	ICC	SDD (%)	Δ (%)	$\sqrt{2} \cdot MS_{error}$	Effect Size	N_{sample} Δ	N_{sample} 10%
HR_{rest} (beats/min)	.74	33.3 (35.5)	1.22 (1.0)	8.48		Irrelevant	
$HR_{walking}$ (beats/min)	.85	39.1 (29.3)	−4.30 (−3.1)	12.39	.34	89	9
PCI (beats/m)	.89	0.5 (69.3)	−0.05 (−6.4)	0.18	.26	168	70
$\dot{V}O_2$ (mL · kg^{-1} · min^{-1})	.91	319 (54.5)	−16.5* (−2.6)	118.27*	.14	539	36
EO_2 (mL · kg^{-1} · m^{-1})	.94	3.3 (32.6)	0.28* (2.8)	1.07*	.22	210	17
Speed (m/min)	.94	18.6 (29.1)	−2.80 (−4.2)	6.33	.44	53	10

NOTE. Effect sizes are calculated by using the difference between walking with shoes (average) and walking barefoot as a signal (Δ). This difference is also presented as a percentage. The sample size (paired data sets) required to detect this difference is estimated using the formula as published by Guyatt et al.[20] The sample size (N_{sample}) is calculated for the actual difference between walking barefoot and with shoes as well as a hypothetical difference of 10%.
* n=12 using $shoes_2$ data instead of mean ($shoe_1$, $shoe_2$) in 1 child.
† According to Guyatt[20]: $n_{subjects}=[(Z_\alpha+Z_\beta)\sigma/\Delta]^2$, where $\sigma=\sqrt{2} \cdot MS_{error}$ is the within-subject variability; Δ is the difference barefoot minus shoes as well as a hypothetical difference of 10% and $Z_{\alpha=.05}+Z_{\beta=.10}=3.24$.

size should be 17 and 70 for the EO_2 and the PCI, respectively. A difference of 10% in $HR_{walking}$ and walking speed could be detected with a sample size of about 10 subjects.

DISCUSSION

Although some articles have addressed the relation between heart rate and energy expenditure during walking, our study focused particularly on the feasibility of the PCI as an outcome measure in clinical trials. The PCI was considered feasible if the differences in energy requirements that have to be detected actually can be detected with sufficient statistical power. These topics are discussed later using our data, previously published data of a study in patients with SCI, and a literature overview.

For the analysis of external responsiveness, we studied 2 different heart rate–based measures, that is, $HR_{walking}$ and $HR_{walking}-HR_{baseline}$, the latter being the numerator in the equation for PCI. The correlation of both heart rate measures with the criterion standard was between .62 and .66. Although heart rate can be used to detect a change in the criterion standard, both correlations were moderate. Comparison of these findings with a study in SCI shows that the PCI may be more useful to detect changes in energy cost in SCI (fig 2). From both scatterplots (figs 1, 2), it can be concluded that the regression is linear and, despite the larger variability in CP, almost similar.

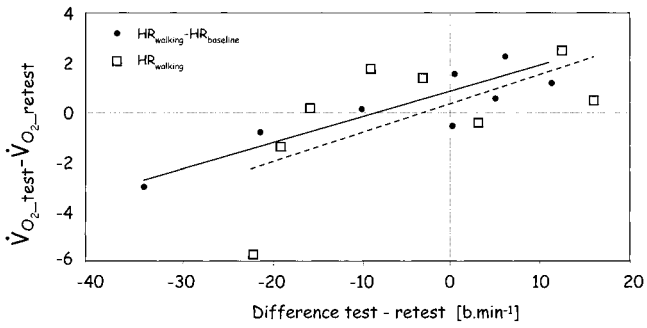

Fig 2. Ability of $HR_{walking}-HR_{rest}$ and $HR_{walking}$ to detect changes in the criterion standard (external responsiveness). The standard is $\dot{V}O_2$ during steady-state walking. The change represents the difference between test and retest. Correlations are .86 (95% CI, .39–.97) and .63 (95% CI, −.13 to .92) for $HR_{walking}-HR_{rest}$ and $HR_{walking}$, respectively. Data from a previous study.[18]

From a physiologic point of view, it was advocated to subtract the baseline heart rate from the steady-state walking heart rate to correct for differences between patients in aerobic capacity.[26] However, because most studies use the PCI as a within-subject comparison, there is no real need for this correction.[18] We therefore analyzed $HR_{walking}$ and $HR_{walking}-HR_{baseline}$ separately. As in the previous study, it can be concluded that there is no benefit in subtracting $HR_{baseline}$ from steady-state heart rate compared with $HR_{walking}$ alone.

Additionally, from a reproducibility point of view, it is preferable to use $HR_{walking}$. The SDD of $HR_{walking}$ is much better than the SDD of the PCI, and it may be concluded that subtracting $HR_{baseline}$ increases the within-subject variability and thus reduces the statistical power. Because the correlation with the criterion standard is not better, it may be concluded that the use of $HR_{walking}$ as an outcome measure is preferable, compared with the PCI.

The SDD of the PCI was 69.3%, whereas SDD of the EO_2 was 32.6%. It may be concluded that for statistical power, it is preferable to use EO_2 rather than the PCI.

One reason for the large within-subject variability in our study may be that the group of subjects consisted of CP children with hemiplegia or with diplegia. Rose et al[16] concluded that the EEI values for diplegic children were 3 times higher than those for hemiplegic children. Duffy et al[27] also described a significant difference in $\dot{V}O_2$ between children with hemiplegia and those with diplegia. According to Duffy,[27] children with diplegia consume more oxygen than other children because their abnormal equilibrium reactions impair their balance and ability to control their walking speed. In our study, we found no difference in $\dot{V}O_2$ between children with hemiplegia and with diplegia, but we did find that hemiplegic children walked faster than diplegic children. However, calculation of the SDD of the PCI and EO_2 in the subgroup of CP does not suggest a different conclusion.

The reproducibility results of this study agree with the results of others (table 3). Bowen et al[17] determined the variability of repeated measurement of the PCI and EO_2 in children with CP. They concluded that EO_2, with an average percentage of variability of 13.2%, is more reproducible than the PCI (20.3%). Butler et al[10] published raw test-retest data of the PCI in healthy children. Further analysis of their data yielded an SDD of 75% and 81% for walking with shoes and barefoot, respectively.[10] Boyd et al[2] studied reproducibility of the PCI and EO_2 in adults and children and calculated the "95% range

Table 3: Available Studies on Reproducibility and the Internal Responsiveness of the PCI

Study	Subjects	N	Analysis	Conclusion
Butler et al[10]	H children	10	Raw data published	SDD_{PCI}=81%* (barefoot) SDD_{PCI}=75%* (shoes)
Nene et al[11]	Paraplegia	4	Differences	No specific conclusion
Nene[9]	H adults	10	Raw data published	SDD_{PCI}=19%*
	H adolescents	10		SDD_{PCI}=24%*
Nene et al[14]	CP children	18	Raw data before and after surgery	SDD_{PCI}=130%*†
				Effect size: .70*
Bailey et al[28]	H students	15	PC	PC=.77–.86
Bowen et al[17]	CP children	5	% variability	CV_{EO2}=13.2%
	H children	5		CV_{PCI}=20.3%
IJzerman et al[18]	Paraplegia	10	SDD, ICC, effect size	PC=.63–.86
				SDD_{EO2}=33.7%
				SDD_{PCI}=41.8%
Boyd et al[2]	H adults	4	% variability	% V_{EO2}=18C/22A
	H children	5		%V_{PCI}=111C/169A
Present study	CP children	12	SDD, ICC, effect size	SDD_{EO2}=32%
				SDD_{PCI}=70%

Abbreviations: H, healthy; PC, Pearson correlation; CV, coefficient of variation; A, adults; C, children.
* After analyzing the raw data.
† Using within-subject variability in the difference before and after surgery.

for change," which is comparable to the SDD. They found a variability of approximately 110% for the PCI and approximately 20% for EO_2 (table 3). Probably the only study with satisfying reproducibility results for the PCI was conducted by Nene.[9] Analysis of Nene's data showed an SDD of approximately 20%.

Statistical power of the PCI to detect changes can be judged by using effect and sample sizes.[20] Effect sizes in our study were .22 for EO_2 and .26 for the PCI using the difference between walking with shoes and barefoot as a difference. However, the differences between walking with shoes and walking barefoot were not the same (2.8% for EO_2, −6.4% for the PCI; table 2). In addition, it appeared that the repeat test differed systematically from the first test while walking with shoes. This systematic difference was probably caused by unfamiliarity with the measurement procedures, that is, the children were anxious about wearing an oxygen mask and they walked faster during the second and third test. Because those problems probably will also be present in a clinical study, it should be recommended to include a pilot measurement before commencing the actual measurements.

For our study, one should be aware that the statistical calculations (eg, effect sizes and sample sizes) might be biased by this systematic difference. That is, if the signal (Δ) is biased by a systematic difference, it will also be reflected in the effect and sample size calculations. For this reason we decided to use the average of both in-shoes trials rather than either the first or second in-shoe trial separately. It can easily be seen from table 1 that the difference between walking barefoot and the second in-shoe trial was larger than the difference that we used to calculate the effect and sample sizes. It can thus be said that the presented data are conservative estimates and the required sample size to detect a difference between walking barefoot and with shoes is probably overestimated.

Analysis of the data of Butler et al[10] showed that the difference in the PCI between walking with shoes and walking barefoot was between 4% and 7%. Although the actual difference between walking barefoot and with shoes in our study also was between 4% and 7%, it might be questioned if this difference represents a clinically relevant difference. Therefore, a different approach can be used to calculate sample sizes.[25] Nene et al[14] published raw PCI data before and after multiple surgical procedures in 18 children with CP. Although the difference between walking with shoes and barefoot may be too small, the difference after surgery obviously should be considered a clinically relevant difference. Further analysis of their data showed that the mean difference in the PCI after surgery was approximately 35%.[14] Assuming that this difference could be shown in a new trial, the estimates of the effect size would be 1.08 and 2.32 for the PCI and EO_2, respectively. By using the same approach, we calculated sample sizes for a hypothetical study that has to show an arbitrarily chosen difference of 10% (table 2). The sample size required would be 70 and 17 for the PCI and EO_2, respectively.

CONCLUSIONS

From the present study and a review of the literature, we concluded that reproducibility of the PCI and the ability to show small differences in EO_2 is moderate. Subtracting $HR_{baseline}$ when calculating the PCI is probably not useful because it does not improve the ability to detect differences, whereas it increases the within-subject variability. The calculated effect sizes were small, in particular because most of the differences in clinical trials were between 0% and 20%. If these small differences need to be shown, it is preferable to use EO_2 as primary outcome measure. It appears that the use of the PCI in SCI is more justifiable than in CP. Based on our study, we recommend including a pilot measurement before starting a clinical trial.

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