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Comparison of manual and automated auscultatory blood pressure during graded exercise among people with type 2 diabetes

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Abstract

Manual measurement of blood pressure (BP) during exercise testing is the recommended standard. Automated measurement of BP is an alternative method used during clinical exercise testing, but there is little data comparing manual and automated BP in this setting. The aim of this study was to determine the concordance between manual and automated BP during a standard clinical treadmill exercise test. 416 participants (66 ± 5 years; 54% male) completed a Bruce treadmill exercise test at baseline or follow-up within a clinical trial of participants with type 2 diabetes mellitus. Manual and automated BP were measured simultaneously at each exercise test stage. Manual BP was measured by a technician blinded to automated BP values (Tango+, Suntech). Concordance between manual and automated BP was assessed using mean differences and intraclass correlations (ICC). Concordance between manual and automated BP across all exercise stages was excellent for systolic BP (overall mean difference: 3 ± 11 mm Hg, P = .598; ICC = 0.964 [95% CI 0.942-0.977] and pulse pressure (overall mean difference: 2 ± 14 mm Hg, P = .595; ICC = 0.934 [95% CI 0.899-0.956]). Concordance between manual and automated diastolic BP across all exercise stages was moderate-to-good (overall mean difference: 1 ± 9 mm Hg, P = .905; ICC = 0.784 [95% CI 0.672-0.858]). Automated BP using the Tango + device is concordant with manual BP during early stages of a standard clinical exercise test. Thus, this automated method may be a suitable alternative to manual measurement of BP during clinical exercise testing.

1 | INTRODUCTION

Clinical exercise testing is routinely indicated for the detection of coronary artery disease or to evaluate aerobic and functional exercise capacity.[1,2] International exercise testing guidelines recommend the monitoring of blood pressure (BP) during testing since abnormal exercise BP responses (eg, exercise hypertension and hypotension) may indicate increased cardiovascular disease risk and are used as clinical indications for terminating testing.[3-9] While manual measurement of BP is the recommended standard during exercise testing,[9] automated BP measurement is an alternative method routinely undertaken in clinical settings.[6,8,9] Despite this, there is a scarcity of data to indicate the relative concordance between manual and automated exercise BP in populations who would typically undertake clinical exercise testing (eg, those at increased cardiovascular disease risk, such as individuals with type 2 diabetes mellitus). Assessing the concordance between manual and automated exercise BP is of importance since substantial differences between

measurement methods could affect the ability to detect abnormal exercise BP responses. The aim of this study was to determine the concordance between manual and automated exercise BP during standard clinical exercise testing in a clinical population.

2 | METHODS

2.1 | Participants

Data for this study were drawn from an exercise-based clinical trial of participants with type 2 diabetes mellitus (http://www.anzctr.org.au; clinical trial ID: 12614000222640), the details of which have been previously reported.[10] Participants were included in the clinical trial, if they had diagnosed type 2 diabetes mellitus as defined within the American Diabetes Association guidelines,[11] were aged between 50 and 75 years, and willing to participate in a 6-month structured exercise program. Individuals with severe cardiovascular, orthopedic or respiratory conditions, and contraindications to exercise (according to the American College of Sports Medicine guidelines)[6] were excluded. Individuals were further excluded, if they had contraindications for magnetic resonance imaging, known dementia or central nervous system disorders (eg, intracranial tumor, multiple sclerosis, and Parkinson's disease) or if they were participating in ≥30 min/week of structured exercise. A total of 68 exercise tests with simultaneously measured manual and automated BP were available for analysis at either baseline (n = 37) or follow-up (n = 31). Participants who completed an exercise test at both baseline and follow-up were excluded (n = 23). In addition, participants who had an arm circumference outside the range of 27-40 cm (which was required for the cuff of the automated BP device) were excluded (n = 4), leaving a total of 41 participants included in this analysis. All participants provided written informed consent, and ethics approval was received from the Human Ethics Committee Tasmania Network (H0013664).

2.2 | Protocol

Participants attended the Menzies Institute for Medical Research clinic in a fasted state, having been asked to avoid smoking and caffeine within 3 hours of attendance. Participants had fasting blood taken, completed a medical assessment and questionnaire (including medical history), and had standardized anthropometry measured. Clinic BP was measured, and a graded exercise test was completed. Manual and automated auscultatory BP was measured simultaneously pre-exercise and at each stage of the exercise test.

2.3 | Exercise test

All participants completed a standard Bruce treadmill exercise testing protocol.[2] The initial exercise stage (exercise stage 1) involved walking on the treadmill at a speed of 2.7 km/hr with a 10% gradient. After 3 minutes, treadmill speed and gradient were increased with further increments every 3 minutes thereafter until the test was terminated. Criteria for termination were either upon volitional fatigue or when 85% of age-predicted maximal heart rate ((220 – age)/0.85) was attained, or if any medical indications arose, or upon participant request. Oxygen consumption was measured using breath-by-breath gas analysis (MasterScreen CPX, Vyaire Medical) during the exercise test. Peak oxygen capacity (VO_{2peak}) was defined as the oxygen consumption achieved when the exercise test was terminated.

2.4 | Exercise BP

The reference manual BP device used in this study was a digital display manual auscultatory sphygmomanometer (UM-101, A&D instruments), which has been validated according to international standards.[12,13] The manual BP device was attached to the cuff of an automated device (Tango+, Suntech Medical Instruments) by a t-connection in order to record simultaneous manual and automated auscultatory BP. The automated cuff was positioned with the microphone within the cuff placed over the left brachial artery before beginning the exercise test. A trained technician read the BP values from the auscultatory sphygmomanometer while placing a stethoscope over the brachial artery next to the microphone within the automated device cuff. The technician was blinded from all BP values recorded by the automated device, which operated with an automated deflation rate of 3-8 mm Hg/second. This process is illustrated in Figure S1. For all manual BP measurements, the 1st Korotkoff sound was taken as the systolic BP; while the 5th Korotkoff sound was taken as the diastolic BP. The automated method also measured BP by detection of Korotkoff sounds. A single

TABLE 1 Clinical characteristics of study participants (n = 41)

Variable	
Age (years)	66 ± 5
Sex (n, % male)	22 (53.7)
Height (cm)	167.1 ± 7.9
Weight (kg)	85 ± 13.3
Body mass index (kg/m^2)	30.4 ± 3.8
Waist circumference (cm)	105.0 ± 9.8
Hip circumference (cm)	106.5 ± 10.1
Waist-to-hip ratio	1.0 ± 0.08
Clinic systolic/diastolic blood pressure (mm Hg)	122 ± 12/77 ± 9
Arm circumference (cm)	34.0 ± 3.2
Insulin (mg/L)	22.8 ± 27.1
Fasting blood glucose (mmol/L; n = 37)	8.0 ± 2.7
HbA1c (%; n = 39)	6.8 ± 1.1
Maximal oxygen capacity ($\dot{V}O_{2peak}$; mL/kg/min)	22.3 ± 4.9
Type 2 diabetes mellitus history (year, n = 39)	12.3 ± 6.8
Self-reported Hypertension (n, %; n = 40)	28 (70.0)
Self-reported High cholesterol (n, %; n = 40)	26 (65)
Past myocardial infarction (n, %; n = 40)	2 (5.0)
Insulin therapy (n, %; n = 39)	7 (18.0)
Antihypertensive medication use (n, %; n = 40)	33 (82.5)

Note: Data presented as mean ± standard deviation for continuous variables or number (%) for categorical variables.

simultaneous manual and automated BP measure was taken as participants stood on the treadmill before the exercise test (pre-exercise) and at the second minute of each exercise stage (exercise stages 1 and 2). All BP measurements were taken with the participant's arm supported on the shoulder of the technician and according to recommendations.[8] Pulse pressure was calculated as the difference between systolic and diastolic BP. Concordance between manual and automated BP was assessed at pre-exercise, at each exercise stage and as the delta BP (change from pre-exercise to each exercise stage).

2.5 | Clinic BP

Clinic BP was measured using an automated device (Mobil-O-Graph, IEM, and GmbH) in a seated position according to guidelines.[7] Eight BP measures were taken over 15 minutes. The technician left the room after initiating the automated BP device, and all eight BP measures were completed with the participant unobserved. The average of all eight BP measurements formed the clinic BP reported in Table 1.

2.6 | Statistical analysis

Data were analyzed using SPSS software version 24 for Windows. Variable distributions were assessed using Shapiro-Wilk tests for normality. Agreement and variability between manual and automated BP were assessed using a combination of methods. Independent and single sample *t* tests were used to compare the mean difference between manual and automated BP for normally distributed data, and non-normally distributed variables were assessed using Mann-Whitney *U* tests. Bland-Altman plots were constructed to visualize the level of variability and bias between measures.[14] Average measures intraclass correlations (ICC; two-way mixed with absolute agreement) were calculated to assess the level of concordance between manual and automated BP with level of agreement assessed from the 95% confidence intervals of the ICC according to Koo and Li,[15] (<0.50 poor agreement, 0.50-0.75 moderate agreement, 0.75-0.90 good agreement, and >0.90 excellent agreement). Pearson correlations were also calculated to assess the relationship between measures and to determine any trends for systematic bias within Bland-Altman and linear correlation plots. The percentage of readings in which the difference between manual and automated BP was ≤5, ≤10, and ≤15 mm Hg was also calculated as per international standards for the accuracy validation of automated BP monitors.[16] Logistic regression models were used to calculate the specificity and sensitivity of automated systolic BP to classify exercise hypertension defined by manual systolic BP according to two systolic BP cut points (≥150 mm Hg and ≥175 mm Hg) that have been associated with increased cardiovascular disease risk.[17-20]

3 | RESULTS

3.1 | Clinical characteristics

Table 1 includes a summary of participant characteristics. The study population wase on average of middle-to-older age, predominately male with raised body mass index and waist-to-hip ratio, and low exercise capacity (based on $\dot{V}O_{2peak}$ achieved). Most participants self-reported a diagnosis of hypertension and were currently taking antihypertensive medication, but on average had controlled BP (clinic BP < 140/90 mm Hg). Most participants also self-reported having high cholesterol, while few participants reported having a previous myocardial infarction or being treated with insulin therapy.

3.2 | Comparison of manual and automated BP

A total of 90 manual and automated BP comparisons were available for analysis across all exercise stages, including 40 at pre-exercise, 33 at exercise stage 1, and 17 at exercise stage 2. Manual and automated BP comparisons available above exercise stage 2 were excluded from analysis due to low sample sizes (n = 1-5). Figure S2 provides the reasons underlying the decreasing numbers of comparisons available with each exercise test stage.

Manual and automated systolic BP had a small mean difference and moderate-to-excellent agreement based on the 95% confidence intervals of the ICC during pre-exercise, exercise stage 1, and exercise stage 2. (Table 2). Manual and automated diastolic BP had a small mean difference during all exercise test stages. Based on the 95% confidence intervals of the ICC, there was good-to-excellent agreement during pre-exercise, poor-to-good agreement during exercise stages 1 and 2 (Table 2). Manual and automated pulse pressure had a small mean difference during all exercise test stages, with moderate-to-excellent agreement based on the 95% confidence intervals of the ICC during pre-exercise, and exercise stages 1 and 2 (Table 2). Figure 1 presents the comparison between manual and automated systolic BP, diastolic BP and pulse pressure with each exercise stage using Bland-Altman and linear correlation plots. When combined across all exercise stages, manual and automated systolic BP and pulse pressure had small mean differences and excellent agreement based on the 95% confidence intervals of the ICC (Table 2, Figure 1A,B,E,F). Manual and automated diastolic BP had a small mean difference and moderate-to-good agreement (based on the 95% confidence intervals of the ICC) across all exercise stages combined (pre-exercise to exercise stage 2; Table 2, Figure 1C,D). Across all exercise stages combined, there was some evidence of systematic bias with automated diastolic BP (Pearson $r = .451$, $P < .001$; Table 2, Figure 1C) measures underestimating manual measures at low BP values and overestimating at high BP values. There was no evidence of systematic bias with systolic BP (Pearson $r = .114$, $P = .286$; Figure 1A) and pulse pressure (Pearson $r = -.035$, $P = .745$; Figure 1E) across all exercise stages combined. Results were consistent when pre-exercise comparisons were excluded (ie, exercise stages 1-2 only; Table 2), except there was evidence of systematic bias between manual and automated systolic BP (Pearson $r = .309$, $P = .029$) for underestimating manual BP at low values and overestimating at high BP values.

The mean difference between manual and automated delta systolic BP was small with moderate-to-excellent agreement based on

TABLE 2 Comparison between manual and automated auscultatory blood pressure at pre-exercise and different stages of a Bruce treadmill exercise test

Comparisons	Pre-exercise n = 40	Exercise stage 1 n = 33	Exercise stage 2 n = 17	All stages[a] n = 90	Exercise Stages only[b] n = 50
Systolic blood pressure (mm Hg)					
Automated	136 ± 15	175 ± 20	190 ± 30	160 ± 30	180 ± 25
Manual	133 ± 16	171 ± 18	187 ± 23	157 ± 29	177 ± 21
Mean difference	3 ± 8[c]	4 ± 12	2 ± 14	3 ± 11[c]	3 ± 12
ICC (95% confidence intervals)	0.92 (0.831-0.96)*	0.882 (0.760-0.942)*	0.933 (0.817-0.976)*	0.964 (0.941-0.977)*	0.915 (0.853-0.953)*
Diastolic blood pressure (mm Hg)					
Automated	72 ± 10	73 ± 13	77 ± 15	74 ± 13	75 ± 14
Manual	73 ± 9	73 ± 8	72 ± 10	73 ± 9	72 ± 9
Mean difference	−1 ± 7	1 ± 10[c]	6 ± 11 [c]	1 ± 9 [c]	2 ± 10[c]
ICC (95% confidence intervals)	0.848 (0.714-0.919)*	0.743 (0.478-0.873)*	0.774 (0.329-0.919)*	0.784 (0.672-0.858)*	0.751 (0.563-0.858)*
Pulse pressure (mm Hg)					
Automated	64 ± 16	101 ± 17	113 ± 26	87 ± 28	105 ± 21
Manual	59 ± 14	98 ± 18	115 ± 20	85 ± 29	104 ± 20
Mean difference	4 ± 11[c]	3 ± 15	-4 ± 17	2 ± 14	1 ± 16 [c]
ICC (95% confidence intervals)	0.827 (0.650-0.911)*	0.768 (0.536-0.885)*	0.845 (0.580-0.943)*	0.934 (0.899-0.956)*	0.826 (0.692-0.901)*

Note: Data represent mean ± standard deviation, unless specified. Mean difference corresponds to automated blood pressure minus manual blood pressure.
Abbreviation: ICC, intraclass correlation.
[a]Pre-exercise to exercise stage 2.
[b]Exercise stage 1 to stage 2 only (excluding pre-exercise).
[c]Comparison assessed using Mann-Whitney *U* test.
*$P < .001$.

the 95% confidence intervals of the ICC from pre-exercise to exercise stage 1. (Table S1). The mean difference between manual and automated delta diastolic BP was small with poor-to-good agreement from pre-exercise to exercise stage 1 and with poor-to-excellent agreement and from pre-exercise to exercise stage 2. The mean difference between manual and automated delta pulse pressure was small with poor-to-good agreement from pre-exercise to exercise stage 1 and poor-to-excellent agreement from pre-exercise to exercise stage 2.

The percentage of manual and automated systolic BP comparisons with mean differences ≤5 mm Hg, ≤10 mm Hg, and ≤15 mm Hg decreased with each exercise stage (Table S2). The percentage of manual and automated diastolic BP comparisons with mean differences ≤5 mm Hg were similar across each exercise stage, while manual and automated diastolic BP comparisons with a mean difference ≤10 mm Hg and ≤15 mm Hg decreased with each exercise stage (Table S2). The percentage of manual and automated pulse pressure comparisons with mean differences ≤5 mm Hg, ≤10 mm Hg, and ≤15 mm Hg decreased from pre-exercise to exercise stage 1 and persisted from exercise stage 1 to exercise stage 2 (Table S2).

Automated systolic BP had 97.7% sensitivity and 50.0% specificity for classifying exercise hypertension across exercise stages 1 and 2 defined by manual systolic BP as exercise systolic BP ≥ 150 mm Hg, and 80.8% sensitivity and 75.0% specificity when defined as exercise systolic BP ≥ 175 mm Hg.

4 | DISCUSSION

The principle finding of this study was that automated BP measured with the Tango + device was largely concordant with manual BP during early stages of a clinical treadmill exercise test involving a population of middle- to older-aged people with type 2 diabetes mellitus. Results also indicated little difference in the ability of automated BP to appropriately classify exercise hypertension compared with manual auscultation. Overall, these results suggest that automated measurement of BP with the Tango + BP device is appropriate to use during clinical exercise testing.

Six previous studies have explored the concordance between manual and automated measurement of BP during exercise.[21-26]

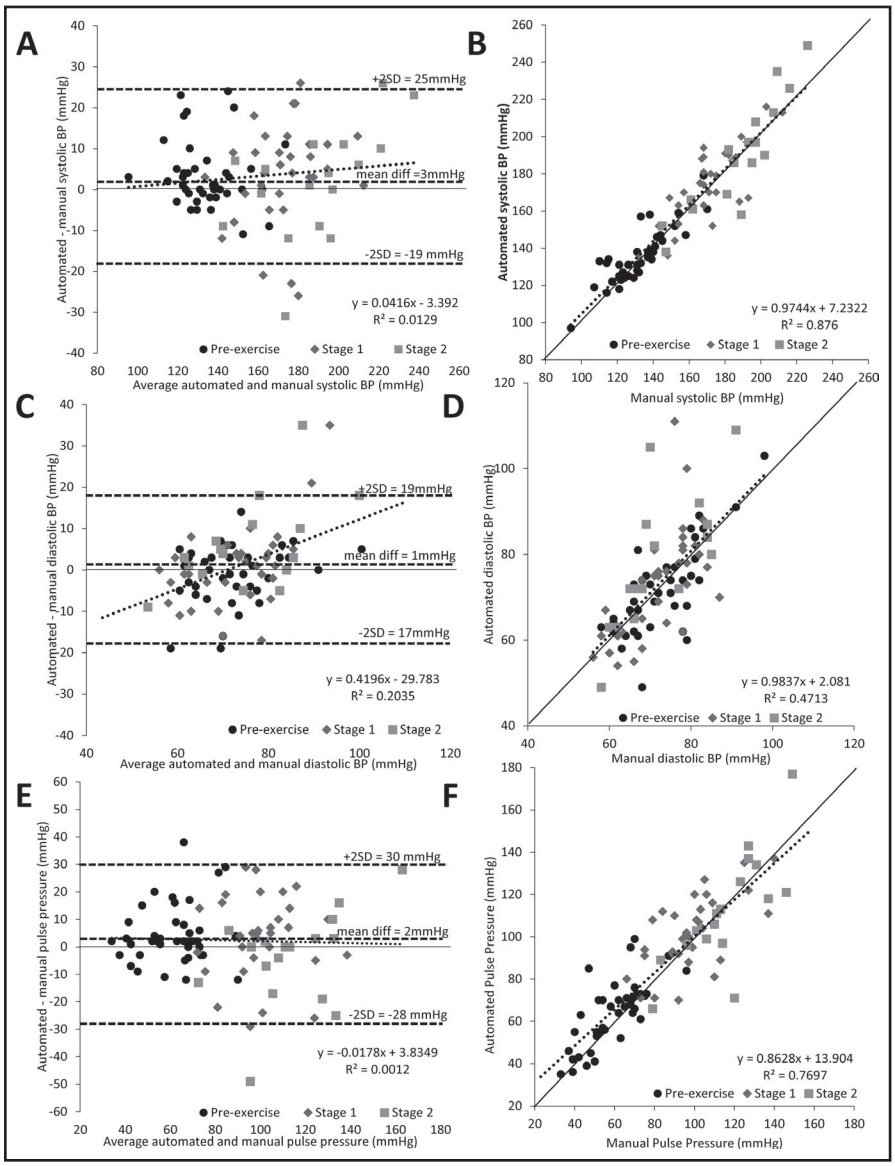

FIGURE 1 Comparison between manual and automated auscultatory blood pressure (BP) at different stages of a Bruce treadmill exercise test (n = 90). Bland-Altman analyses comparing the agreement and variability between manual and automated systolic BP (A), diastolic BP (C), and pulse pressure (E), along with correlations between manual and automated systolic BP (B), diastolic BP (D), and pulse pressure (F). The solid line is the line of identity, and the broken line is the linear trend line across all exercise stages (pre-exercise to exercise stage 2)

Cameron et al,[22] found automated BP to be concordant with manual BP in five healthy adults during supine cycling, utilizing the same automated BP device (Tango+) used in the current study. Our results are consistent with this, despite differences in the population and exercise protocol. Other studies have also indicated automated exercise BP (measured with a variety of devices) to be relatively concordant with manual BP during incremental treadmill exercise testing, especially at low-to-moderate exercise intensities.[21,23-26] Nonetheless, these studies have only included small sample sizes (n = 5-19 individuals) and "healthy" populations that would not typically undergo exercise testing within clinical settings.[21,24,25] Other studies, including Gracia-Gregory et al[23] also included a "healthy" population but had a larger sample size (n = 277), while Modesti et al included 16 participants with hypertension.[26] Our study extends on these studies in particular, and represents the first study to assess manual and automated exercise BP concordance in a population with type 2 diabetes mellitus during the early stages of a widely utilized clinical exercise testing protocol (Bruce treadmill).

In clinical practice, BP is often measured by an automated monitor during exercise testing. However, clinical exercise testing guidelines state a preference for manual BP measurement.[6,9] This is primarily due to the belief that automated BP devices may perform erratically during exercise, exacerbated during higher intensity exercise due to noise and movement artifacts.[6,8,9] Automated BP devices may also be unreliable during periods of elevated heart and respiratory rates.[27] On the other hand, accuracy of manual BP measurements may also be affected by noise and excessive patient movement, impairing technician ability to distinguish Korotkoff sounds, most notably the 4th and 5th Korotkoff sounds.[21,23,24,26] However, our results are consistent with observations from previous studies,[23,26] indicating at least some level of variability that could be attributable to noise and movement artifact.

Assessment of BP during exercise testing is of clinical importance since abnormal readings are among the criteria for terminating testing on safety grounds.[3-9] Moreover, abnormal exercise BP responses (such as exercise hypertension) during low-to-moderate exercise

intensity can indicate underlying raised BP missed by resting BP,[18,20] and increase the risk for the future development of hypertension,[28] cardiovascular morbidity and mortality.[29] Accurate measurement of exercise BP is likely to be of particular importance to individuals with type 2 diabetes mellitus since they carry a higher prevalence of exercise hypertension (reported as >50% in some studies).[30-32] Our results indicate that automated BP has high sensitivity and low specificity for classifying exercise hypertension defined from manual exercise systolic BP ≥ 150 mm Hg, with specificity increasing when exercise hypertension was classified using a threshold of exercise systolic BP ≥ 175 mm Hg. This suggests clinicians can have confidence that the Tango + device is suitable for identifying individuals with an abnormal BP response to light-to-moderate intensity exercise. These results also suggest confirmation of abnormal exercise BP initially measured by the Tango + device may not need to be subsequently confirmed by manual BP, as is the recommendation outlined in exercise testing guidelines.[6,9]

4.1 | Strengths and limitations

A strength of our study was the simultaneous measurement of manual and automated exercise BP on the same arm (rather than contralaterally), which eliminated any potential for inter-arm BP differences. However, our study population was exclusively those with type 2 diabetes mellitus. Consequently, our findings cannot be generalized to other clinical populations including those with cardiac arrhythmias where automated BP devices should be validated independently.[33] Our results are also limited by the small sample size and to the early stages of treadmill exercise testing only. However, people with type 2 diabetes mellitus are likely to only achieve exercise stages 1 or 2 due to early onset of fatigue and generally lower exercise/functional capacity.[34,35] It is possible that placement of the stethoscope in close proximity to the microphone within the automated device cuff may have impaired the quality of automated BP recordings, but the effects of this are unknown. It is also possible that the deflation rate of the automated BP device (which was set to operate automatically) could have affected the ability of the technician to accurately hear and record the Korotkoff sounds. However, the effect of deflation rate on measuring manual exercise BP is also likely minimal because manual and automated exercise BP was measured simultaneously on the same arm. Finally, it is worth noting that there is currently no standard procedure for the validation of BP devices during incremental exercise testing. The protocol followed for this study was also not in accordance with international standards for the accuracy validation of BP devices,[16] because these standards are set exclusively for resting conditions. Indeed, the measurement of exercise BP during incremental exercise testing is more nuanced due to the rapidly changing conditions (ie, increasing heart rate and intensity). While it was therefore not possible to perform repeat measures of BP, we followed the clinical directive of a single measure in the final minute of each test stage.[4,9] It is however possible that only having one technician measure exercise BP could have introduced some degree of bias to the results.

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CONFLICT OF INTEREST

Nothing to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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