ARTICLE

A new and specific automated blood pressure device for exercise stress testing

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Blood pressure (BP) measurement plays a critical role in cardiac stress testing and is most commonly assessed manually. The emphasis of social distancing during the COVID-19 pandemic has renewed the interest in and the need for an automated BP device for incremental exercise stress testing. We assessed the accuracy of a new automated blood pressure device specifically manufactured for cardiac stress testing. Thirty-five adults aged 35 ± 16 years were studied during an incremental stress test on the cycle ergometer. Three observers measured BP simultaneously, two listening to Korotkoff sounds using a dual-headed stethoscope and one using headphones to listen to sounds generated by an automated BP device. With increasing workload, systolic BP increased progressively without significant differences in BP readings between any observer compared with the automated monitor at any stage during exercise. Systolic BP obtained with the BP machine was strongly correlated with those obtained by the stethoscope observers ($r = 0.96$) and the observer with headphones ($r = 0.95$). Diastolic BP obtained with the BP machine was moderately and significantly associated with those obtained by the stethoscope observers ($r = 0.75$) and the observer with headphones ($r = 0.75$). The automated BP monitor specifically made for cardiac stress testing accurately measured both systolic and diastolic blood pressure during exercise.

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INTRODUCTION

Blood pressure (BP) is an essential measurement during exercise testing as it is a relative contraindication to terminate exercise [1]. Typically, manual BP measurements by a single technician are used during exercise testing in clinical settings. However, using a manual sphygmomanometer to measure BP during exercise has limitations as noise and motion artifact from the exerciser make these measurements difficult to take [2, 3]. This reduces the accuracy of BP measurements during exercise and could alter their clinical interpretation [4–9]. As many world organizations have expressed the importance of proper social distancing during the COVID-19 pandemic, the interest in an accurate and reliable automated BP monitor that can be used during exercise has been renewed.

A new automated BP monitor has recently been developed for the purpose of exercise stress testing. This monitor uses R-wave gating from an electrocardiogram paired with acoustic transduction via a microphone placed over the brachial artery within the BP cuff in order to measure BP. The purpose of the present study is to evaluate the accuracy of this new automated blood pressure device at rest, during exercise, and recovery. These automated measurements were compared to manual blood pressure measurements which served as the reference standard. We hypothesized that the measurements taken by the automated device would not be different from the reference measurements.

METHODS

Participants

A total of 35 apparently healthy adults (20 men and 15 women) varying widely in age (19–66 years) were studied (Table 1). Due to limitations placed during the COVID-19 pandemic, we were instructed by the Institutional Review Board to avoid recruiting hypertensive participants as they fell into the "high-risk" category for COVID-19. As such, the International Organization for Standardization (ISO) requirement that 10% of participants must have a resting BP ≥ 140 mmHg was not met. The health status of each participant was determined using a questionnaire. The 2020 PAR-Q + questionnaire was used to assess the safety of exercise. Informed consent was obtained from all participants before involvement in the study. This study was conducted in accordance with the Declaration of Helsinki, and all procedures were approved by the Institutional Review Board of The University of Texas at Austin.

Procedures

Participants came into the laboratory on two separate occasions separated by at least 2 days and at the same time of day. All participants refrained from caffeine on the day of the test, food intake >4 h prior to testing, and alcohol intake and strenuous exercise for >24 h prior to testing. Height and body weight were measured using an electronic balance scale (Seca #769, Vogel & Halke, Hamburg, Germany).

Upon entry into the laboratory, each participant was equipped with a 5-lead ECG, and the circumference of the upper arm was measured to ensure that a properly-sized blood pressure cuff was used. A new automated BP monitor (FBX-1000, Fukuda Denshi, Tokyo, Japan) specifically developed for exercise testing was evaluated during the study. Prior

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Table 1. Selected participant characteristics ($n = 35$).

Variable	Means (SD) or *n*
Male/Female	20/15
Age (years)	35 (16)
Height (cm)	173 (10)
Body Weight (kg)	72.8 (14.6)
Heart Rate at Rest (bpm)	69 (14)
Maximal Heart Rate (bpm)	183 (12)
Race	
White/Caucasian	19
Black/African American	2
Asian	13
Multiracial	1
Ethnicity	
Hispanic/Latino	2

to testing, an aneroid sphygmomanometer was calibrated using a pressure gauge and was found to be within ±2 mmHg. The automated BP monitor was calibrated against the aneroid sphygmomanometer and was within ±2 mmHg.

Each participant was then seated in an armchair with their back, elbows, and forearms supported. All participants were instructed to rest their feet flat on the ground. A BP cuff from the automated BP monitor was placed over the brachial artery of the designated arm, chosen at random. The opposite arm was used during the second day of testing. Following 10 min of seated rest, resting BP was simultaneously measured using three different methods: (1) by two experienced observers using a stethoscope with dual earpieces (one set for each observer) (reference), (2) by the Fukuda automated BP monitor, and (3) by an observer using headphones to listen to sounds generated by the microphone of the Fukuda BP monitor. The armrest of the chair was utilized so the measurement arm could remain relaxed and supported throughout the BP measurements. In addition, the height of the armrest allowed the BP cuff to be positioned at heart level. Participants were asked to keep their arm relaxed and not to tense their shoulder throughout the duration of the BP measurement. Each observer measured BP using the same method throughout the duration of the study and for each participant. The automated BP monitor was connected to a standard aneroid manometer using a Y-tube connector allowing each observer to be blinded to the BP readings of the automated monitor. The appearance of Korotkoff sounds (phase I) defined systolic BP and the disappearance of Korotkoff sounds (phase V) defined diastolic BP. Each observer was blinded to the BP measurements taken by each other. Heart rate was also obtained from the automated BP monitor.

An incremental exercise test was performed on a cycle ergometer (Excalibur, Lode B.V., Groningen, The Netherlands). Exercise began at 25 W and increased by 25 W every 2 min until a rating of perceived exertion (RPE) of 16 (Borg's original scale) or 80% of age-predicted maximal heart rate [10] was reached. BP was measured one minute into each exercise stage. The measurement arm of the participant was extended to the side so the BP cuff was positioned at heart level and supported by an observer to avoid excessive movement. All participants were asked to keep their arm relaxed during the BP measurement. Heart rate and RPE were measured within the final 15 s of each exercise stage. Immediately upon completion of exercise, the participant was quickly moved from the cycle ergometer and seated into an armchair with their back, elbow, and forearms supported. Heart rate and BP were measured every 2 min until BP returned to resting values ±5 mmHg.

Data analyses

Data analyses were performed using SPSS version 22 (IBM Corp., Armonk, NY). Shapiro–Wilk tests indicated a normal (Gaussian) distribution for all continuous variables. Differences between BP values obtained with the different methods were evaluated using two-factor analysis of variance (ANOVA) with repeated measures (BP methodologies × exercise stage). The LSD post-hoc analysis was used to determine specific differences between the groups. Pearson correlation analyses were conducted to observe relationships between the automated BP devices and the reference manual BP measurements. The Bland-Altman analyses of agreement were then conducted to observe the relative differences between two different methods. $P < 0.05$ was considered significant for all analyses. Sample size calculation was conducted using a power calculation software (G*Power 3.0.10, Dusseldorf, Germany) with power = 0.8, alpha level = 0.05, and effect size = 0.33.

RESULTS

Selected participant characteristics are shown in Table 1. The participants were relatively diverse in age, sex/gender, and racial distributions. Pearson correlation coefficients for the two observers using a stethoscope were 0.98 for systolic BP and 0.91 for diastolic BP. BP measurements between the two observers using a stethoscope were not significantly different at any stage. Due to the similarity in BP values, the measurements of the two stethoscope observers were averaged to provide one set of reference data in accordance with ISO guidelines. Systolic and diastolic BP at rest were not different between the reference, the automated BP monitor, and the observer using headphones (Fig. 1 and Table 2). Systolic BP showed gradual and significant increases throughout the incremental exercise protocol ($p < 0.05$, Fig. 1 and Table 2). Diastolic BP increased slightly and significantly during the incremental exercise protocol. There were no significant differences in systolic or diastolic BP between the methods at any individual stage during the incremental exercise protocol.

Systolic BP decreased progressively for the first 4 min of recovery (Fig. 1 and Table 3). Immediately after exercise, the automated BP monitor recorded a higher systolic and diastolic BP than the other two methods ($p < 0.05$, Fig. 1 and Table 2).

As shown in Fig. 2, systolic BP obtained with the reference was strongly associated with the Fukuda automated BP monitor ($p < 0.001$) as evidenced by a strong Pearson correlation coefficient of 0.96. Similar significant associations were obtained with diastolic BP although the strength of the association was slightly weaker at 0.75. These agreements are consistent with the Bland-Altman analysis. Comparable results were observed between the observer using headphones and the automated BP monitor (Supplemental Figs. 1 and 2). Systolic and diastolic BP with the reference showed significant associations with the observer listening via headphones as shown by strong Pearson correlation coefficients of 0.97 and 0.90 and Bland-Altman analysis.

During exercise, all participants obtained a heart rate at least 30% greater than their heart rate at rest. Heart rate increased progressively and significantly throughout the incremental exercise protocol ($p < 0.05$, Table 2). Heart rate significantly decreased throughout recovery from exercise ($p < 0.05$).

DISCUSSION

In the present study, the accuracy of a newly-developed automated BP device was compared with standard BP measurements at rest, during exercise, and recovery. The automated BP monitor accurately measured both systolic and diastolic BP at rest and during exercise. Both correlational analyses and Bland-Altman plots indicated that the BP obtained with the automated BP device were strongly associated with those obtained with the reference methods. The Fukuda automated BP device may be a suitable alternative to manual BP measurement especially when the proper social distance is needed.

Previous studies have assessed the accuracy of automated BP devices during exercise [2, 4, 11–14]. These studies produced highly mixed findings. In one of the earlier studies that evaluated four different BP monitors during cycle exercise at 100 W [14], the two BP devices (Colin 630 and Accutracker II BP monitors) were found to accurately measure BP at 100 W with minimal arm movement. However, it was stated that these devices would be unlikely to produce accurate and reliable measurement at higher intensities [14]. The other two devices (Del Mar P-IV and SpaceLabs 90202 BP devices) could not accurately measure BP

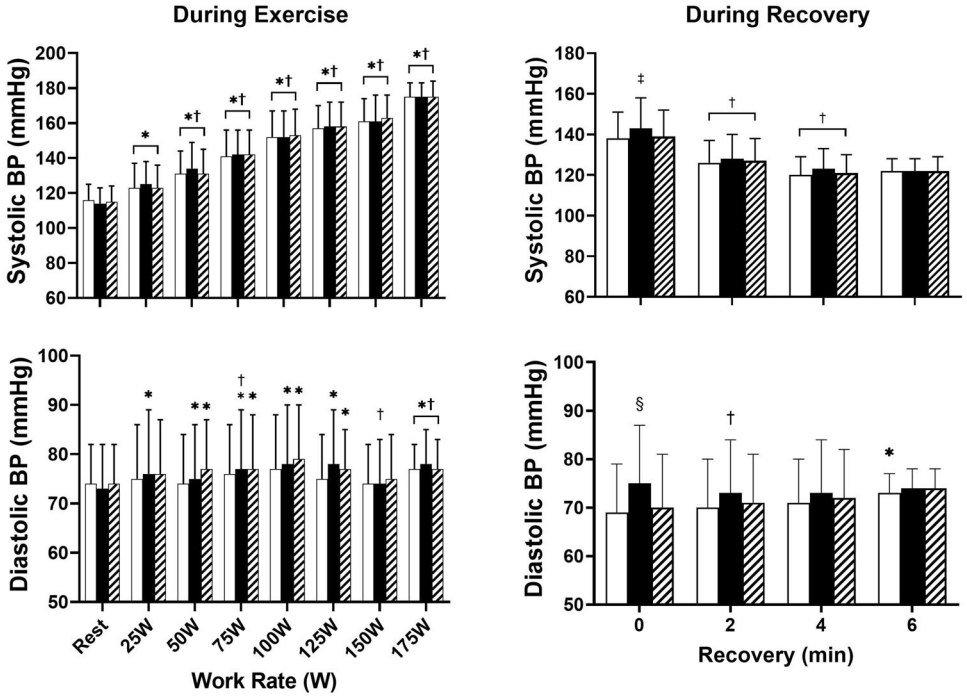

Fig. 1 Systolic and diastolic blood pressure (BP) at rest, during exercise (left panel) and recovery from exercise (right panel). Data are means (SD). $^{*}p < 0.05$ vs. Rest, $^{\dagger}p < 0.05$ vs. Immediately preceding stage, $^{\ddagger}p < 0.05$ vs. Reference, $^{\S}p < 0.05$ vs. All other methods at the same stage.

Table 2. Systolic (SBP) and diastolic blood pressure (DBP) measurements at rest and during incremental exercise.

Stage	Reference (A)		Fukuda monitor (B)		Fukuda monitor with headphones		B – A		Heart rate
	SBP	DBP	SBP	DBP	SBP	DBP	SBP	DBP	
Rest	116 (9)	74 (8)	114 (9)	73 (9)	115 (9)	74 (8)	−2 (5)	−1 (4)	69 (14)
25W	123 (14)*	75 (11)	125 (13)*	76 (13)*	123 (13)*	76 (11)	2 (6)	1 (7)	95 (14)*
50W	131 (13)*†	74 (10)	134 (15)*†	75 (11)*	131 (14)*†	77 (10)*	3 (7)	1 (6)	106 (18)*†
75W	141 (15)*†	76 (10)	142 (14)*†	77 (12)*†	142 (14)*†	77 (11)*	1 (5)	1 (6)	119 (20)*†
100W	152 (15)*†	77 (11)	152 (15)*†	78 (12)*	153 (15)*†	79 (11)*	0 (7)	1 (8)	129 (20)*†
125W	157 (13)*†	75 (9)	158 (14)*†	78 (11)*	158 (14)*†	77 (8)*	1 (6)	3 (8)	129 (14)*
150W	161 (13)*†	74 (8)	161 (15)*†	74 (9)†	163 (13)*†	75 (9)	0 (7)	0 (6)	134 (11)*†
175W	175 (8)*†	77 (5)*†	175 (8)*†	78 (7)*†	175 (9)*†	77 (6)*†	0 (5)	1 (7)	125 (7)*†

Data are means (SD).
$^{*}p < 0.05$ vs. Rest, $^{\dagger}p < 0.05$ vs. Immediately preceding stage.

Table 3. Systolic (SBP) and diastolic blood pressure (DBP) measurements during recovery from exercise.

Recovery (min)	Reference (A)		Fukuda monitor (B)		Fukuda monitor with headphones		B – A		Heart rate
	SBP	DBP	SBP	DBP	SBP	DBP	SBP	DBP	
0	138 (13)	69 (10)	143 (15)†	75 (12)‡	139 (13)	70 (11)	5 (7)	6 (10)	92 (17)
2	126 (11)*	70 (10)	128 (12)*	73 (11)*	127 (11)*	71 (10)	2 (7)	3 (7)	86 (15)*
4	120 (9)*	71 (9)	123 (10)*	73 (11)	121 (9)*	72 (10)	3 (7)	2 (5)	80 (11)*
6	122 (6)	73 (4)*	122 (6)	74 (4)	122 (7)	74 (4)	0 (5)	1 (3)	75 (7)*

Data are means (SD).
$^{*}p < 0.05$ vs. Immediately preceding stage, $^{\dagger}p < 0.05$ vs. Reference, $^{\ddagger}p < 0.05$ vs. All other methods at the same stage.

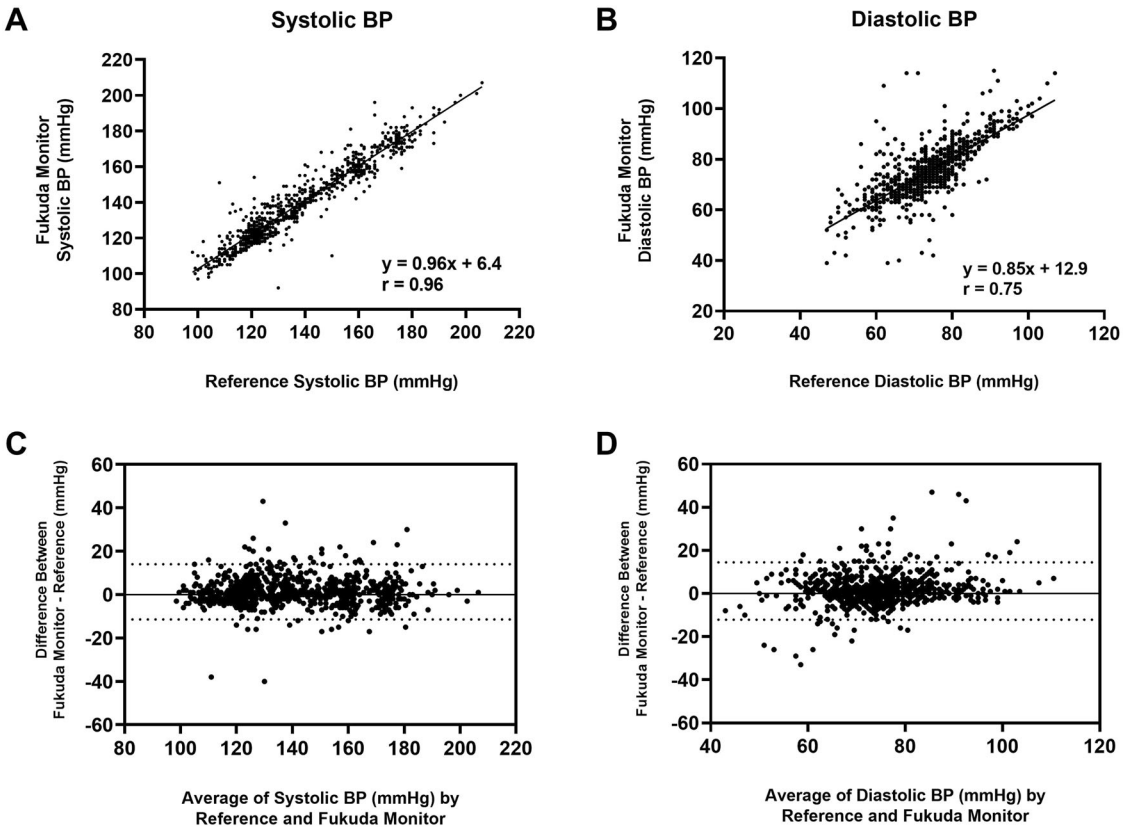

Fig. 2 Association of systolic and diastolic blood pressure (BP) between the Fukuda monitor and the reference (the observer using a stethoscope). Pearson correlation analysis of systolic and diastolic blood pressure are shown in (**A** and **B**). Bland-Altman analysis of agreement plots with mean difference ±2 standard deviations are shown in (**C** and **D**).

until the participant had completely stopped movement [14]. Colin later developed a new automated BP monitor (Colin 680) specifically for the purpose of exercise stress testing which was evaluated during high-intensity cycle and treadmill exercise [11]. The device produced significantly higher systolic BP during cycle ergometer and treadmill exercise compared with the reference (stethoscope) measurements. In contrast, in a follow-up study conducted by a different group [2], the monitor accurately measured systolic BP during low, moderate, and high-intensity cycle exercise but did not accurately measure diastolic BP at moderate and high-intensity exercise. The Colin BP monitor is no longer manufactured or sold in the market. The Tango M2 stress test monitor was also specifically developed for exercise stress testing [15]. Compared with manual BP measurements during incremental cycle exercise, the device produced reliable BP values with absolute BP differences within an acceptable clinical range [15]. Similar findings have been reported in individuals with diabetes [16] and other populations [17–21]. The present study found the newly-developed Fukuda automated BP monitor accurately measured both systolic and diastolic BP during exercise indicating that this is a suitable device which can be used during exercise stress testing.

It should be noted that the precise ISO guidelines were not followed strictly due to the design of our full experiment. We evaluated the Fukuda automated BP monitor as well as a new wristwatch that measures BP during incremental exercise. It was not feasible to measure brachial BP in both arms simultaneously as the arm with the wristwatch was required to be in a flexed position in order for the wristwatch to be positioned at heart level. The wristwatch was not able to accurately measure BP during exercise due to excessive movement artifact and was therefore removed from the paper. In addition, the use of the "same arm sequential" method of measuring BP as described in the ISO guidelines was not feasible during an incremental exercise protocol as BP tends to change even at the same exercise stage as exercise intensity progressed. Although ISO standard guidelines were constructed for resting BP and were not meant to be applied to exercise BP, the automated BP monitor has passed the validation criteria for non-invasive sphygmomanometers intended for use during exercise stress testing.

Overall, the automated brachial BP monitor accurately measured both systolic and diastolic BP at rest and during incremental cycle ergometer exercise. The accuracy and simplicity of this BP monitor make it a suitable option for use in laboratory and clinical settings and can aid proper social distancing in situations such as the COVID-19 pandemic.

SUMMARY

What is known about the topic

- Exercise stress testing is conducted to predict the risk of developing hypertension as well as diagnose and evaluate the treatment of cardiovascular disease. Manual blood pressure measurements during exercise are difficult to perform as motion and sound artifact from exercising participants often impede the ability of a technician to record accurate blood pressure.
- Blood pressure (BP) is a vital measurement during exercise stress testing as it is an indicator to terminate exercise.
- The onset of the COVID-19 pandemic has led international organizations to recommend social distancing to reduce the spread of the coronavirus.

What this study adds

- The validation of a new automated blood pressure device which was specifically developed for exercise stress testing and can be utilized in environments where social distancing is recommended.

DATA AVAILABILITY

The datasets generated and analyzed for the present study are available from the corresponding author upon reasonable request.

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AUTHOR CONTRIBUTIONS

NM, and HT designed the experiments, analyzed, and interpreted the data. NM, TW, and LC performed the data collection. NM wrote the initial draft of the paper and prepared figures. All authors edited, revised, and approved the final version of the paper.

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COMPETING INTERESTS

Fukuda Denshi provided the automated BP device evaluated in the present study.

ETHICS APPROVAL

This study was approved by Institutional Review Board at The University of Texas at Austin.

ADDITIONAL INFORMATION

Supplementary information The online version contains supplementary material available at https://doi.org/10.1038/s41371-022-00784-9.

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