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Minimum Detectable Change in Arterial Pulse Wave Conduction Time From Heart to Toe as a Function of the Number of Cardiac Pulses Included: A Prospective Noninterventional Study

Harvey N. Mayrovitz ¹

1. Medical Education, Nova Southeastern University Dr. Kiran C. Patel College of Allopathic Medicine, Davie, USA

Corresponding author: Harvey N. Mayrovitz, mayrovit@nova.edu

Abstract

Background and objective

Noninvasive assessments of arterial stiffness are used to evaluate a patient's vascular age and predict the risk of future cardiovascular events across various clinical conditions. These predictions are based on pulse wave velocity (PWV) measurements because PWV increases with increased arterial vessel stiffness. PWV is calculated from the measured pulse wave conduction time (PWCT) between two sites a known distance apart along an arterial pathway. Another application of PWV determinations is to assess an intervention's effect on vascular stiffness by measuring changes in PWV. For this purpose, an estimate of the minimum detectable change (MDC) in measured PWCT is needed, which itself depends on the number of pulses used (n) to estimate PWCT. The objective of this study was to provide initial quantitative estimates of the minimum detectable percentage change (MDC%) and its dependence on n.

Methods

Eight young adults with an age of 26.14 ± 0.83 years and a BMI of 23.20 ± 1.78 kg/m² participated after signing an institutional review board-approved consent form. With the subject supine, a photoplethysmographic (PPG) pulse was recorded from the great toe of one foot while an EKG was recorded continuously at 1000 samples/s for 40 minutes. For each sequential pulse pair, the PWCT was calculated as the measured time difference between the EKG R-wave peak and the PPG pulse arrival at the great toe, with pulse arrival determined by the maximum of the second derivative of the toe's PPG signal. This process produced N sequential PWCT values, where N depended on each subject's EKG RR interval over the 40-minute recording interval. For each subject's PWCT time series, an MDC% was determined for p-values of 0.05, 0.01, and 0.001. The MDC dependence on n was determined by calculating the MDCs for n values of 5, 10, 20, 40, 50, and 100. The MDC% was calculated using the equation $(t\text{-value} \times \sqrt{2} \times SD)$, where t-value is the two-sided Student's t-value for the n used, and SD is the standard deviation.

Results

The principal finding for the estimated MDC% was that MDC% for a given p-value decreased nonlinearly as the number of pulses (n) used to estimate MDC% increased. A key feature of this relationship was that, for any p-value, MDC% improves only slightly for sample sizes greater than 40-50 pulses. At a sample size of n = 50, the MDC% ranges from 5.8% to 10.0% for p-values of 0.05 and 0.001, respectively.

Conclusions

These findings offer initial guidance on the number of pulses to use when investigating a specific intervention's short-term effect on PWCT and, by extension, PWV estimates. Because the absolute values of the estimated MDC% come from a small group of healthy young adults, the determined MDC% are likely lower bounds for what might be observed in elderly patients with medical comorbidities or if the time between assessments is extensive. However, because the number of pulses needed to accurately estimate the MDC% was based on a large number of sequential PWCTs for each subject, the recommended 40-50 pulses should not be significantly affected, but further study of this relationship in elderly populations is warranted.

Categories: Cardiology

Keywords: arterial pulses, heart failure, hypertension, minimum detectable change, pulse conduction time, pulse wave velocity, pwv, stroke, vascular aging, vascular stiffness

Introduction

Noninvasive estimates of arterial stiffness are increasingly used to assess a patient's vascular age [1-3] and predict the risk of future cardiovascular events in patients with diabetes [4,5], cerebrovascular conditions [6],

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heart failure [7,8], hypertension [9,10], and other conditions. These predictions are best based on previously obtained direct pulse wave velocity (PWV) values determined in large populations that are then followed over months or years. In one method, the calculated PWV value is determined using the measured pulse wave conduction time (PWCT) and the estimated arterial pathway length over which the pulse is conducted. When not directly measured, an effective PWV (ePWV) is used as a surrogate, calculated from the patient's age and mean blood pressure (BP) [11], and used to predict a host of outcome conditions and relationships [12-15]. A higher arterial PWV is associated with decreased arterial compliance; thus, PWV is a key indicator of vascular stiffness.

Beyond using PWV data for prediction purposes, another application area concerns interventions that may reduce arterial stiffness, thereby theoretically improving morbidity or mortality outcomes. To assess an intervention's impact on these possibilities, it is important to have a prior estimate of the minimum detectable change (MDC) or difference that, at a specified statistical significance level, would represent a statistically successful outcome of the intervention [16,17]. Physiological processes and methodological issues create temporal variability in beat-to-beat arterial PWCT and consequently raise the fundamental question of how many beats to use when estimating PWV and how that number affects the MDC.

Various numbers of pulses have been empirically proposed and used, sometimes without direct consideration of the MDC. These range from 5 [18] to 8 [19] to 10 [20,21], to 50 or more consecutive beats [22]. A particular need for guidance on estimating the MDC arises when PWV values are assessed before and after an intervention or simply a time delay [23-26]. The question of how many beat-to-beat sequential pulses to be used has been previously investigated in the context of evaluating the MDC of heart-to-finger PWCT [27]. However, this arterial pathway excludes the arterial pulse transit through the aorta, a vessel of both fundamental and clinical significance in cardiovascular physiology. To address this knowledge gap, the present study aimed to develop an initial estimate of the MDC for heart-to-toe PWCT, a pathway that includes arterial pulse-wave passage through the aorta and peripheral vessels.

Materials And Methods

Subjects

This observational study used a convenience sample of eight young adult volunteers (four female and four male) who participated after signing a Nova Southeastern University Institutional Review Board-approved consent form (2019-598) approved on January 23, 2020. No sample size calculation was done because it was not considered applicable to the nature of this study. Entry requirements were (1) the ability and agreement to lie supine without significant movements for up to 60 minutes; (2) no history of cardiovascular or neurological conditions; (3) nonsmoker; (4) willingness to forgo caffeinated beverages on the day of the experiment; and (5) taking no prescribed medications. People with diabetes mellitus were excluded from participation. Age and BMI for this group (mean $\pm$ SD) were 26.14 ± 0.83 years and 23.20 ± 1.78 kg/m², with all subjects' BMI within the normal range.

Measurements

A photoplethysmographic (PPG) pulse was recorded from the great toe of the left foot using a matched infrared emitter and photodiode sensor (TSD200, Biopac Systems, Inc., Goleta, CA, USA) that was gently but securely secured to the toe with Velcro. The system uses an infrared excitation of 860 ± 60 nm and detects at 800 nm. Vascular volume pulses change electrical resistance, producing the PPG signal that, together with an EKG signal, was captured by an analog-to-digital converting system (model DI-720; DATAQ Instruments, Inc., Akron, OH, USA). Each channel was sampled at 1000 samples per second using Windaq recording and playback software (DATAQ Instruments, Inc.), and the output channels were displayed and recorded on a laptop computer. Figure 1 shows an example 60-second recording segment for a subject with a heart rate of approximately 60 bpm.

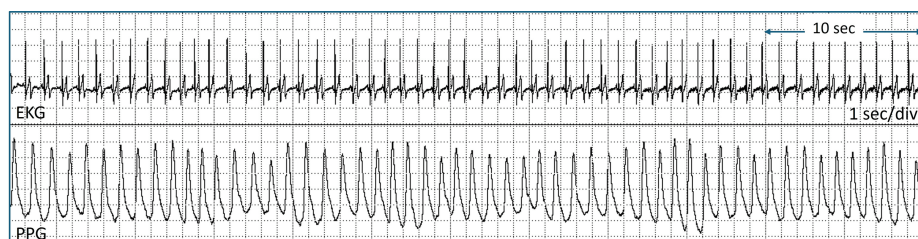


FIGURE 1: Illustrative data recording segment.

The EKG and the great toe PPG recordings are shown for an approximate 60-second segment. This time frame shows 55 pulses. This type of recording is done continuously for each subject for 40 minutes (2400 seconds). The vertical scales are not calibrated in this figure, whereas the horizontal scale is one second per division.

PPG, photoplethysmography

Protocol

Subjects took a supine position on a padded examination table. Before placing the EKG electrodes and PPG sensor, the approximate arterial pulse path length from the heart to the great toe was measured as the distance from the suprasternal notch to the bottom of the heel, plus the measured distance from the heel to the toe. EKG electrodes were placed to record a single-lead EKG (Lead I), and the PPG sensor was placed on the great toe of the left foot. Five minutes after placing the PPG sensor, data recording started, and room temperature and relative humidity were recorded. During recording, room lights were dimmed, and talking was prohibited. At the end of the 40-minute recording, room temperature and relative humidity were recorded again, and the subject's BP was measured in the left arm while they were supine using an automatic BP system (HEM-711, OMRON Healthcare, Inc., Sunrise, FL, USA).

Analysis

The PWCT was calculated as the measured time difference between the EKG R-wave peak and the PPG pulse arrival at the great toe, with pulse arrival determined by the maximum of the second derivative of the toe's PPG signal, as shown in Figure 2. The process used was to detect the recorded EKG's R-waves and determine the time delay between the peak of the R-wave and the peak of the PPG signal's second derivative using the Advanced CODAS Analysis Software (DATAQ Instruments, Inc.). For each pulse, the peak detection process was inspected and corrected if needed. The use of the second derivative as the marker for pulse arrival has been previously described [28,29].

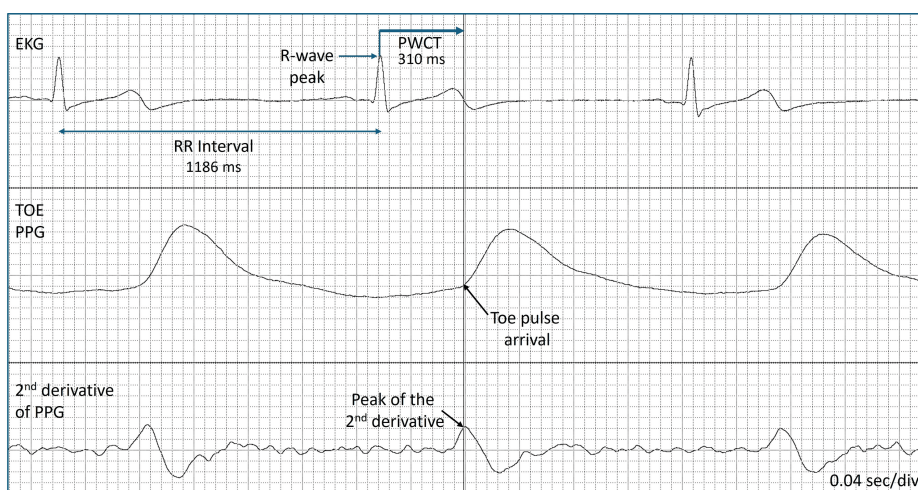


FIGURE 2: PWCT estimation.

The PWCT is defined here as the time difference between the peak of the EKG R-wave and the arrival of the toe pulse PPG signal. The arrival time coincides with the peak of the second derivative of the PPG signal. In this instance, the PWCT is shown as 310 ms, corresponding to an RR interval of 1186 ms. PWCT for all sequential pulses was determined.

PPG, photoplethysmography; PWCT, pulse wave conduction time

This process produced N sequential PWCT values, where N varied with the participant's average R-R interval over the 40-minute recording interval. A subject with a heart rate of 60 bpm produces $40 \times 60 = 2400$ sequential contiguous PWCTs. Figure 3 illustrates an example time series of contiguous PWCTs determined this way. This subject's heart rate was 63.1 bpm, resulting in 2349 contiguous PWCTs during the 40-minute measurement.

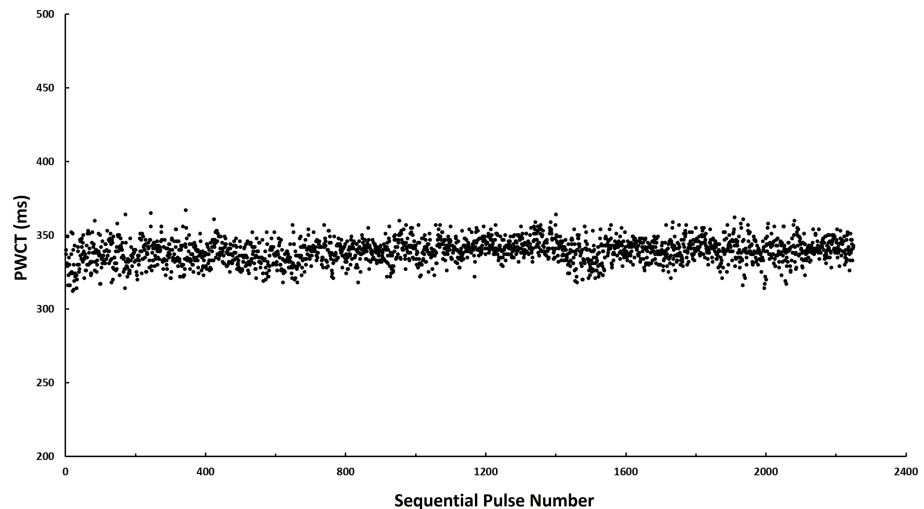


FIGURE 3: Example PWCT sequence.

This example PWCT sequence is for a subject with an average heart rate of 63.1 bpm, yielding 2349 contiguous PWCTs over the 40-minute measurement interval.

PWCT, pulse wave conduction time

An MDC was determined for each PWCT time series. The MDC was determined based on target p -values of 0.05, 0.01, and 0.001. The MDC dependence on the number of pulses used for the estimate (n) was calculated for n values of 5, 10, 20, 40, 50, and 100. For this calculation, the formula $t\text{-value} \times \sqrt{2} \times SD$ was used, in which the t -value is the two-sided Student's t -value for a sample size (number of PWCT used), and SD is its average standard deviation [27]. To estimate the MDC associated with an intervention, the analysis assumes equal sample sizes before and after an intervention or condition change. For example, if the sample size (n = number of sequential PWCT used) were 10, the t -value would be based on $N = 20$. Accordingly, the t -value and thus the MDC will depend on both n and the desired statistical significance level as represented by the p -value. Analyses were done with self-written code using Excel 365 (Microsoft Corporation, Redmond, WA, USA) combined with SPSS Statistics for Windows, version 16.0 (released 2007; SPSS Inc., Chicago, IL, USA) for any statistical comparisons.

Results

Participant parameters

Table 1 reports each participant's age, height, weight, BMI, BP, and heart rate. For the group as a whole, age and BMI were (mean $\pm$ SD) 26.14 ± 0.83 years, and BMI was 23.2 ± 1.78 kg/m². Systolic BP, diastolic BP, and heart rate at the end of the 40-minute supine lying interval were 121.2 ± 7.7 mmHg, 75.0 ± 4.4 mmHg, and 67.3 ± 10.2 bpm. These data indicate that the evaluated group was a young adult, a small sample with normal weight and BP. None of the quantitative parameters listed in Table 1 differed statistically between sexes ($p > 0.2$), as assessed using the nonparametric Mann-Whitney test.

Subject	Sex	Age (years)	Height (m)	Weight (kg)	BMI (kg/m²)	Systolic (mmHg)	Diastolic (mmHg)	HR (bpm)
1	M	25	1.73	66.96	22.45	127	76	69.9
2	F	26	1.7	66.96	23.29	121	75	58.5
3	M	26	1.63	66.07	25	122	78	75.7
4	F	26	1.65	53.57	19.65	107	68	82.5
5	M	26	1.73	71.43	23.94	120	70	55.1
6	M	26	1.66	62.5	22.7	134	82	70.3
7	F	28	1.78	80.36	25.42	117	76	54.3
8	F	26	1.69	66.84	23.21	121	75	65.1

TABLE 1: Demographic features of the participants.

Systolic and diastolic BPs were measured with the subject supine at the end of the measurement interval. HR is the average heart rate over the course of the entire 40-minute measurement interval.

BP, blood pressure

PWCT and RR intervals

Table 2 summarizes each subject’s PWCT, measured from the peak of the EKG R-wave to PPG pulse arrival at the great toe, along with the corresponding PWV and RR intervals, each reported as the mean ± SD over the entire 40-minute measurement interval. The overall group average of the 8 participants (mean ± SD) for PWCT was 338.9 ± 12.3, and the associated group average PWV was 4.64 ± 0.19 m/s. The overall average RR interval was 921.9 ± 139.7 ms. These values did not differ statistically between males and females (p > 0.4) as determined by the Mann-Whitney test. Room temperature and relative humidity were stable over the 40-minute measurement interval. Temperatures at the start and end were 25.6 ± 0.5 °C and 26.3 ± 0.5 °C, respectively, and relative humidity at the start and end was 42.4 ± 2.0% and 42.2 ± 2.0%, respectively.

Subject	Sex	PWCT (ms)	CV_PWCT (%)	RR (ms)	CV_RR (%)	Length (m)	PWV (m/s)
1	M	316.9 ± 11.6	3.66	858 ± 39	4.55	1.6	5.050
2	F	327.5 ± 12.2	3.73	1025 ± 45	4.39	1.448	4.421
3	M	346.3 ± 18.7	5.4	792 ± 21	2.65	1.562	4.511
4	F	338.3 ± 17.3	5.11	727 ± 33	4.54	1.535	4.539
5	M	347.2 ± 13.5	3.89	1091 ± 43	3.94	1.626	4.682
6	M	356.8 ± 10.3	2.89	854 ± 31	3.63	1.666	4.669
7	F	339.1 ± 8.0	2.36	1106 ± 44	3.98	1.56	4.600
8	F	338.9 ± 11.2	3.3	922 ± 37	3.97	1.571	4.636

TABLE 2: Individual subject pulse wave and RR features.

PWCT is the pulse wave conduction time ± SD, and CV_PWCT is its coefficient of variation across the entire 40-minute measuring interval. RR is the time difference between two consecutive EKG R-waves over the entire 40-minute measuring interval, and CV_RR is its coefficient of variation. Length is the measured path length from the suprasternal notch to the great toe where the pulse sensor is placed. PWV is the pulse wave velocity as determined from the measured length/PWCT.

PWCT, pulse wave conduction time

Minimum detectable percentage change estimates (MDC%)

Figure 4 summarizes the composite MDC% findings for each targeted p-value and sample size. For a given

sample size (number of sequential pulses sampled), the MDC% increases for smaller p-values. This is because when measuring a change, the amount of change required to statistically reject the null hypothesis of no change depends on the p-value chosen. The smaller the chosen p-value (e.g., 0.001 vs. 0.05), the larger the needed change and hence the larger the MDC%. However, for a given p-value, the MDC% decreases with increasing sample size. For the present group, MDC% ranged from 8.3% to 18.2% for a sample size of 5, and from 5.8% to 10.0% for a sample size of 50. Thus, the MDC percentage depends on both the sample size (n) and the selected statistical threshold (p-value). MDC% increases for smaller p-values and decreases for larger sample sizes.

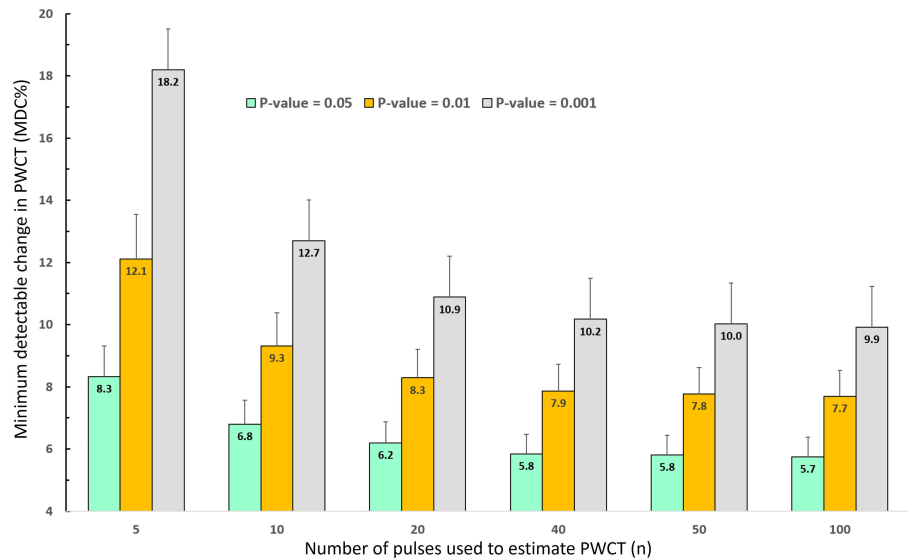


FIGURE 4: MDC distributions.

The MDC percentage (MDC%) depends on both the sample size (n) and the selected statistical threshold (p-value). MDC% increases for smaller p-values and decreases for larger sample sizes.

MDC, minimum detectable change; PWCT, pulse wave conduction time

Figure 5 shows how MDC% varies with the number of pulses used to estimate it for the three p-values evaluated.

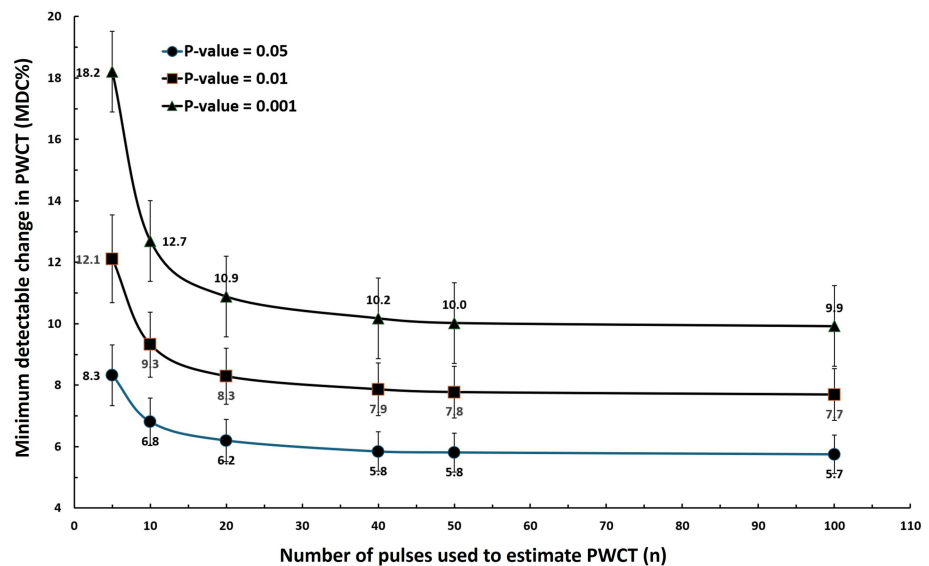


FIGURE 5: MDC estimates.

The figure shows the mean and standard deviation for the MDC% as a function of the number of pulses used to estimate the PWCT for three different p-values. The numbers above the data points are the MDC% values.

MDC, minimum detectable change; PWCT, pulse wave conduction time

Discussion

A key result of this study is a quantitative description of how the estimated arterial PWCT depends on the number of contiguous pulses used to assess it. Given the relatively long 40-minute evaluation sequence, the analysis used large numbers of measured PWCTs, which varied with heart rate and ranged from 2170 to 3301 PWCTs. This quantification yielded MDC% estimates representing a statistically significant change at p-values of 0.05, 0.01, and 0.001. These estimates may be useful to plan aspects of experiments or procedures in which short-term changes or differences in PWCT or PWV are of interest.

The main finding for the estimated MDC% under these conditions was that MDC% for a given p-value decreased nonlinearly as the number of pulses (n) included in the estimate increased. Figure 5 illustrates this composite feature, showing how MDC% varies with n for the three p-values evaluated. A key feature of this relationship is that, for any p-value, MDC% improves only slightly for sample sizes greater than 40-50 pulses. At a sample size of n = 50, the MDC% ranges from 5.8% to 10.0% for p-values of 0.05 and 0.001, respectively.

A few prior studies have examined arterial PWV variability in patients with various conditions. For example, in a 2020 study, Svačinová et al. investigated the effects of postural changes on PWV in patients with type 2 diabetes mellitus in comparison to healthy controls [30]. They reported that only in the diabetes group did positional change affect measured lower-extremity PWV variability. MDCs in PWV in post-stroke patients were assessed by Abreu et al., who reported MDC values in this group of patients [31]. The variability in PWV associated with hypertension was investigated by Kubalski and Hering using measurements taken four weeks apart and reported that, among patients, PWV was strongly related to the patient's BP, showing its importance when quantifying PWV measurement variability [32]. Wang et al. added to this concept by demonstrating the variability in PWV in patients with implanted pacemakers when the pacing frequency was varied [33]. PWV temporal variations that were quantified by their coefficient of variation were reported as 10.7% by Keehn et al. when assessed in a large number of hypertensive patients [34]. Test-retest measurements made twice 15 minutes apart in patients hospitalized with coronary artery disease by Grillo et al. reported coefficient of variations near 10% for PWV values assessed with different devices [35]. These values are in the range herein measured for the healthy population studied when sufficient pulses were used to estimate MDC%.

Limitations of findings

One important provision when using the absolute MDC% values is that they strictly apply to young, healthy adults whose sequential variations in PWCT are different from those that might be present in older individuals [36], or in people with specific cardiovascular conditions such as hypertension or heart failure [7].

A second consideration is that the estimated MDC% are based on measured conduction times from heart to

toe using the peak of the EKG R-wave as the zero point for timing. The PWCT (mean $\pm$ SD) was 338.9 ± 12.3 ms, with a calculated group-average PWV of 4.64 ± 0.19 m/s. However, this PWV is likely underestimated because of the time delay between the R-wave peak and aortic valve opening. High temporal resolution measurements in 12 healthy adults indicate that the valve starts opening approximately 40 ms from the R-wave peak, reaching its maximum opening rapidly after a delay of approximately 60 ms from the R-wave peak [37]. Accordingly, subtracting the mid-range value of 50 ms from the presently determined PWCT value yields an adjusted value of 298.9 ± 12.3 , with a PWV of 5.26 ± 0.23 m/s. These PWVs are consistent with those reported for healthy adults of the ages included in this study [38,39].

A third potential limitation is that the formulations were based on a single-session investigation of healthy young adults. Potential differences arise when standard PWV studies are done on elderly patients with preexisting cardiovascular conditions. In a particularly revealing study, elderly (75.7 ± 4.6 years), overweight (BMI 29.6 ± 4.0 kg/m²) patients with various morbidities were studied, focusing mainly on the reliability of PWV measurements between visits [40]. The authors calculated MDC for three PWV measurements using commercially available devices: carotid-to-femoral (cfPWV), brachial-to-ankle (baPWV), and femoral-to-ankle (faPWV). These measurements were made 40.3 ± 9.5 days apart. Their calculated absolute MDCs were 4.11 m/s, 3.71 m/s, and 3.01 m/s, respectively. Based on these data, the two-day average PWV for the three methods was 11.99, 17.42, and 10.63 m/s. From these data, the present author calculated MDC% values of 34.6%, 21.4%, and 28.6%, which are much greater than those obtained herein. Part of these large MDC% values may be attributable to aspects of their multicenter protocol; this highlights that the present findings are best applied when investigating the effect of shorter-term interventions. For that purpose, the present findings offer initial guidance on the number of pulses to use when investigating a specific intervention's effect on PWCT.

Conclusions

The present estimates offer initial guidance on the number of pulses to use when investigating a specific intervention's short-term effect on PWCT and, by extension, PWV estimates. Because the absolute values of the estimated MDC% come from a small group of healthy young adults, the determined MDC% are likely lower bounds for what might be observed in elderly patients with medical comorbidities or if the time between assessments is extensive. However, because the number of pulses needed to accurately estimate the MDC% was based on a large number of sequential PWCTs for each subject, the recommended 40-50 pulses should not be significantly affected, but further study of this relationship in elderly populations is warranted.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Harvey N. Mayrovitz

Acquisition, analysis, or interpretation of data: Harvey N. Mayrovitz

Drafting of the manuscript: Harvey N. Mayrovitz

Critical review of the manuscript for important intellectual content: Harvey N. Mayrovitz

Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Nova Southeastern University Institutional Review Board issued approval 2019-598. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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The individual subject data are available as listed in the paper. Further information regarding the data sequences is available from the author upon request and indication of intended use.

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