Accuracy of a Newly-Introduced Oscillometric Device for the Estimation of Arterial Stiffness Indices in Patients on Peritoneal Dialysis: A Preliminary Validation Study

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The aim of the present study was to compare the aortic systolic blood pressure (aSBP), heart-rate-adjusted augmentation index (AIx_{75}), and pulse wave velocity (PWV) obtained using the Mobil-O-Graph (IEM, Stolberg, Germany) and SphygmoCor (AtCor, Sydney, Australia) devices in patients receiving peritoneal dialysis (PD).

After a 10-minute rest in the supine position, the Mobil-O-Graph and SphygmoCor devices were applied in randomized order in 27 consecutive PD patients. The agreement between the measurements produced by the Mobil-O-Graph and SphygmoCor devices was explored using Bland–Altman analysis.

The Mobil-O-Graph–derived aSBP, AIx_{75}, and PWV did not differ from the same measurements obtained with SphygmoCor (aSBP: 120.5 ± 18.2 mmHg vs. 124.4 ± 19.0 mmHg, p *= 0.438; AIx_{75}: 27.0% ± 12.4% vs. 24.5% ± 10.6%,* p *= 0.428; PWV: 9.5 ± 2.1 m/s vs. 10.1 ± 3.1 m/s,* p *= 0.397). The slight difference in the estimation of aSBP is possibly explained by the difference in brachial SBP used for the calibration of the devices (131.0 ± 20.6 mmHg vs. 134.5 ± 19.7 mmHg,* p *= 0.525). Mobil-O-Graph–derived measurements correlated strongly with paired measurements obtained with the SphygmoCor device. Bland–Altman plots showed no evidence of asymmetry and a wide range of agreement between the two devices.*

Our study shows acceptable agreement between Mobil-O-Graph and SphygmoCor in the estimation of arterial stiffness indices in PD patients. Accordingly, the Mobil-O-Graph device accurately performs aortic ambulatory blood pressure monitoring in this population.

Key words
Arterial stiffness, aortic pressure, Mobil-O-Graph, validation studies

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Introduction

Arterial stiffness increases with aging and is accelerated in various disease states (1,2), particularly in individuals with end-stage-renal-disease (ESRD) (3). The arteriosclerotic process mediates several hemodynamic alterations throughout the arterial tree. Stiffening of the aortic wall results in an augmentation of central aortic pressure during systole, a decrease in aortic pressure during diastole, and excessive pulsatile energy transmission from the macrocirculation to the microcirculation (1–3). Accordingly, arterial stiffening is proposed as a major pathogenic mechanism of isolated systolic hypertension, left ventricular (LV) hypertrophy and dysfunction, sub-endocardial hypoperfusion and aggravated microvascular damage (1–3). The huge burden of the foregoing complications in patients with ESRD is at least partly explained by the acceleration of arteriosclerosis and premature vascular aging in those patients. It is therefore

unsurprising that prospective cohort studies have consistently demonstrated that large-artery stiffness and aortic systolic pressure augmentation are both strong and independent predictors of all-cause and cardiovascular mortality in ESRD patients receiving either hemodialysis (HD) (4) or peritoneal dialysis (PD) (4,5).

Over past years, the validated and widely-applied method of applanation tonometry of peripheral arteries has been used by several commercially available devices to enable the noninvasive assessment of central aortic pressure and arterial stiffness indices in the office setting (2,6). The use of a newly-introduced, brachial cuff–based oscillometric device (Mobil-O-Graph: IEM, Stolberg, Germany) to noninvasively estimate those novel hemodynamic parameters under ambulatory conditions offers several advantages over the conventional ambulatory monitoring of brachial blood pressure (BP) (7–9). The Mobil-O-Graph oscillometric device was previously validated against invasive and noninvasive measurements and was shown to provide an accurate estimation of central aortic BP and pulse wave velocity (PWV) in healthy individuals and in patients with essential hypertension (7–9). However, the accuracy of this oscillometric technique in specific patient populations and in clinical settings of accelerated arterial stiffening, such as in patients with ESRD, is less well defined. The results of an earlier comparison study that tested the accuracy of oscillometric measurements against tonometric measurements of aortic systolic blood pressure (aSBP) and PWV obtained by the widely-applied SphygmoCor device (AtCor, Sydney, Australia) in patients receiving thrice-weekly HD represent the only currently available validation of the Mobil-O-Graph device in the ESRD population (10). However, the intermittent nature of renal replacement therapy, together with the excessive variability of BP during the intra- and interdialytic intervals represent only some of several differences between HD and PD (11,12), necessitating validation studies for the whole spectrum of ESRD.

The aim of the present study was to assess, for first time, the accuracy of the Mobil-O-Graph device in estimating central aortic BP and PWV in a cohort of stable PD patients, in comparison with static tonometric measurements obtained using the widely-applied SphygmoCor device as the reference standard.

Methods

A total of 27 consecutive stable patients on PD participated in this study. Patients were eligible if they had ESRD being treated with continuous ambulatory PD or automated PD, if they had been receiving renal replacement therapy for at least 3 months before study enrollment, and if they provided written informed consent. Exclusion criteria were the presence of peritonitis or any other active infection during the 4 weeks before study enrollment, the presence of chronic atrial fibrillation or any other arrhythmia, a body mass index exceeding 40 kg/m^2, an old functioning or nonfunctioning arteriovenous fistula in both arms that had been used as a dialysis access (patients previously treated with HD), and a history of malignancy or any other medical condition associated with very poor prognosis. All study procedures were carried out in accordance with the Declaration of Helsinki and its latest amendments, and all study participants provided written informed consent before study enrollment. The ethics committee of the School of Medicine, Aristotle University of Thessaloniki, approved the research protocol.

Study measurements were performed in the peritoneal dialysis unit, 1st Department of Medicine, AHEPA University Hospital, Thessaloniki, Greece. Study participants were asked to refrain from smoking, heavy exercise, and caffeine and alcohol consumption for at least 2 hours before their evaluation, according to international recommendations for noninvasive determination of arterial stiffness indices (2). Study assessments were performed by a single well-trained physician in a quiet room with stable air temperature (approximately 22°C) after the patient had been at rest for least 10 minutes in the supine position. Estimation of central aortic BP and PWV was performed by applying the Mobil-O-Graph and SphygmoCor devices in a randomized order.

Radial artery applanation tonometry with a high-fidelity pencil-type SPT-301 probe interfaced with a computer running the SphygmoCor software was performed to estimate central hemodynamic indices. The SphygmoCor software uses mathematical transformation of the radial pulse waveform (generalized transfer function) to regenerate the aortic pulse waveform (2,6). The aortic pulse waveform was calibrated by inserting the brachial systolic BP (bSBP) and brachial diastolic BP (bDBP) recorded immediately before the SphygmoCor measurement. The augmentation pressure was defined as the difference in aortic

pressures between the second and first systolic peaks. The augmentation index (AIx) was calculated as the ratio of the augmentation pressure to the aortic pulse pressure (aPP) and is expressed as a percentage. The heart-rate-adjusted AIx (AIx_{75}) was estimated by adjusting the AIx at an inverse rate of 4.8% for each 10 beats-per-minute increase in heart rate (2,6). The aortic PWV was determined by performing applanation tonometry at the carotid and femoral arteries with the SPT-301 tonometer. Pulse waveforms were referenced to a concurrently recorded electrocardiogram, and pulse wave transit time between the subsequent recording sites was calculated using the foot-to-foot time difference between the carotid and femoral waveforms. Body surface distances from the suprasternal notch to the carotid recording site (distance A) and from the suprasternal notch to the femoral recording site (distance B) were measured, and the pulse wave travel distance was calculated by subtracting distance B from distance A. The aortic PWV was estimated as the pulse wave travel distance divided by the transit time. We measured PWV over 10 consecutive heartbeats to cover a complete respiratory cycle (2,6). The first valid tonometric measurement was used in the statistical analysis.

The Mobil-O-Graph is a commercially available brachial-cuff-based oscillometric device. Its BP detection unit has been validated in accordance with the British Hypertension Society and European Society of Hypertension international protocols (13). The device performs a brachial oscillometric BP measurement and, immediately afterward, records the brachial pulse waveforms (8,14). The recordings are obtained at the diastolic phase for approximately 10 s, using a conventional brachial cuff for adults (available in two sizes: 24 – 34 cm and 32 – 42 cm) and a high-fidelity pressure sensor (MPX5050: Freescale, Tempe, AZ, U.S.A.). For calibration of the brachial pulse waveforms, we used the oscillometric bSBP and bDBP and identical calibration methods to compare the Mobil-O-Graph and SphygmoCor device estimations of central aortic pressures. The aortic pulse waveform is generated using the ARCSolver algorithm with generalized transfer function. The software of the Mobil-O-Graph device (HMS version 4.5) performs wave separation analysis by decomposing the aortic pulse waveform into forward- and backward-traveling pulse waves with the use of a physiologic aortic flow waveform (15). The Mobil-O-Graph–derived PWV is an indirect estimate of large-artery stiffness based on mathematical models incorporating several parameters derived from pulse wave analysis and wave-separation analysis, as previously published (8,14). The first valid oscillometric measurement was used in the analysis.

Statistical analyses were performed using IBM SPSS Statistics (version 23.0 for Windows XP: IBM, Armonk, NY, U.S.A.). Continuous variables are expressed as mean ± standard deviation, and categorical variables, as absolute frequencies and percentages. All continuous variables were checked for normality using the Kolmogorov–Smirnov test. Comparisons between the SphygmoCor and Mobil-O-Graph devices were performed using unpaired *t*-tests or Mann–Whitney *U*-tests. as appropriate according to the normality of the distribution of each variable. To assess the strength of the association between measurements obtained with the Mobil-O-Graph and the SphygmoCor, we used the Pearson product formula to calculate bivariate correlation coefficients *(r)*. Bland–Altman analysis was performed to explore the agreement between the tonometric and oscillometric measurements of aSBP, AIx_{75}, and PWV. A two-tailed p value less than 0.05 was considered statistically significant.

Results

Table I presents the demographic and routine biochemical characteristics of the study participants. The group included 19 men and 8 women with a mean age of 62.5 ± 15.6 years who had been receiving PD therapy for an average of 35.7 ± 21.8 months. Of the 27 participants, 19 were receiving automated PD; the remaining 8 patients were receiving continuous ambulatory PD. With respect to the primary cause of ESRD, 11 of the 27 patients had diabetic nephropathy, 4 had hypertensive nephrosclerosis, 3 had polycystic kidney disease, 1 had chronic glomerulonephritis, and 1 had obstructive nephropathy. In 7 patients, the primary cause of renal failure was unknown.

As shown in Table II, the SphygmoCor-derived aSBP, aortic DBP, and aPP were numerically higher, but not significantly different from the measurements obtained with the Mobil-O-Graph device (aSBP: 124.4 ± 19.0 mmHg vs. 120.5 ± 18.2 mmHg, $p = 0.438$; aortic DBP: 85.1 ± 12.6 mmHg vs. 84.6 ± 14.2 mmHg, $p = 0.888$; aPP: 39.1 ± 12.8 mmHg vs. 35.9 ± 10.0 mmHg, $p = 0.302$). The differences between the SphygmoCor and Mobil-O-Graph devices in central hemodynamic parameters were similar in extent to the differences

TABLE I Baseline characteristics of the 27 study participants

Characteristic	*Value*
Mean age (years)	62.5±15.6
Sex (men/women)	19/8
Mean physical parameters	
Weight (kg)	75.8±17.6
Height (cm)	168.9±9.5
BMI (kg/m^2)	26.3±4.4
Mean dialysis vintage (months)	35.7±21.8
Dialysis modality (CAPD/APD)	8/19
Primary cause of ESRD [*n* (%)]	
Diabetes	11 (41)
Hypertension	4 (15)
Polycystic kidney disease	3 (11)
Glomerulonephritis	1 (4)
Obstructive kidney disease	1 (4)
Unknown	7 (25)
Mean laboratory values	
Hematocrit (%)	35.2±5.5
Hemoglobin (g/dL)	11.8±1.8
Serum urea (mg/dL)	113.6±30.3
Serum creatinine (mg/dL)	8.2±4.9
Total protein (g/dL)	6.5±0.58
Serum albumin (g/dL)	3.7±0.38
Total cholesterol (mg/dL)	146.3±39.7
LDL cholesterol (mg/dL)	72.6±28.4
HDL cholesterol (mg/dL)	40.2±15.0
Triglycerides (mg/dL)	168.0±88.9

BMI = body mass index; CAPD = continuous ambulatory peritoneal dialysis; APD = automated peritoneal dialysis; ESRD = end-stage renal disease; LDL = low-density lipoprotein; HDL = high-density lipoprotein.

between the bSBPs and bDBPs used to calibrate the aortic pulse waveforms (bSBP: 134.5 ± 9.7 mmHg vs. 131.0 ± 20.7 mmHg, $p = 0.525$; bDBP: 85.1 ± 12.4 mmHg vs. 84.6 ± 14.3 mmHg, $p = 0.880$). Correlation analysis showed a strong positive association between the SphygmoCor-derived and Mobil-O-Graph–derived aSBP [$r = 0.889$, $p < 0.001$, Figure 1(A)]. The Bland–Altman plots depicted in Figure 1(B) show acceptable agreement for the estimation of aSBP between the two devices (mean difference: 3.96 mmHg; 95% limits of agreement: –13.3 mmHg to 21.2 mmHg), without evidence of systemic bias. With respect to wave reflection indices, the AIx_{75} measured with the SphygmoCor device was slightly lower, but not significantly different from the estimation of AIx_{75} provided by the Mobil-O-Graph device (24.6% ± 10.6% vs. 27.1% ± 12.4%, $p = 0.428$, Table II). As shown in Figure 2(A), correlation analysis revealed a strong positive association between the SphygmoCor-derived and Mobil-O-Graph–derived AIx_{75} ($r = 0.816$, $p < 0.001$). Similarly, Bland–Altman analysis showed a between-methods mean difference of –2.5%, with 95% limits of agreement of –16.7% and 11.6% [Figure 2(B)].

As with the other parameters, we observed no statistically significant differences between the SphygmoCor and Mobil-O-Graph devices in their estimation of PWV (10.1 ± 3.1 m/s vs. 9.5 ± 2.1 m/s, $p = 0.397$). In correlation analysis, a strong positive association between tonometric and oscillometric PWV was evident [$r = 0.794$, $p < 0.001$, Figure 3(A)]. When the Mobil-O-Graph–derived PWV was plotted against the SphygmoCor-derived PWV, no evidence of systemic bias in the Bland–Altman graph was evident; the 95% limits of agreement between the two devices were –3.1 m/s and 4.4 m/s [Figure 3(B)].

Discussion

The aim of the present study was to assess, for first time, the accuracy of the newly-introduced oscillometric Mobil-O-Graph device in estimating central aortic BP and arterial stiffness indices in PD patients. The main findings of the study are that the estimates of aSBP, AIx_{75}, and PWV derived by the Mobil-O-Graph device under rest conditions are comparable with measurements taken with the established technique of applanation tonometry; that Mobil-O-Graph–derived parameters are strongly and positively associated with the corresponding tonometric measurements; and that Bland–Altman analysis showed no evidence of systemic bias and wide limits of agreement between paired measurements of aSBP, AIx_{75}, and PWV taken with the test and reference devices.

The results of the present study are in line with earlier validation studies conducted in non-ESRD populations. In a comparison study that enrolled 83 healthy volunteers, Luzardo *et al.* (7) showed that the Mobil-O-Graph–derived aSBP, AIx, and PWV were similar to measurements obtained with the SphygmoCor device in static

TABLE II Hemodynamic parameters and arterial stiffness indices obtained with the Mobil-O-Graph and SphygmoCor devices

Parameter	*Mean measurement*		*Absolute difference*	*95% CI*	p *Value*
	SphygmoCor	*Mobil-O-Graph*			
bSBP (mmHg)	134.5±19.7	131.0±20.7	3.5	–7.5 to 14.5	0.525
bDBP (mmHg)	85.1±12.4	84.6±14.3	0.6	–6.8 to 7.9	0.880
bPP (mmHg)	49.5±15.2	46.9±12.9	2.6	–5.1 to 10.3	0.502
aSBP (mmHg)	124.4±19.0	120.5±18.2	3.9	–6.2 to 14.1	0.438
aDBP (mmHg)	85.1±12.6	84.6±14.2	0.5	–6.8 to 7.9	0.888
aPP (mmHg)	39.1±12.8	35.9±10.0	3.3	–3.0 to 9.5	0.302
AIx_{75} (%)	24.6±10.6	27.0±12.4	–2.5	–8.8 to 3.8	0.428
AP (mmHg)	10.2±6.4	9.7±6.4	0.5	–3.0 to 3.9	0.783
PWV (m/s)	10.1±3.1	9.5±2.2	0.6	–0.80 to 2.1	0.397

CI = confidence interval; bSBP = brachial systolic blood pressure; bDBP = brachial diastolic blood pressure; bPP = brachial pulse pressure; aSBP = aortic systolic blood pressure; aDBP = aortic diastolic blood pressure; aPP = aortic pulse pressure; AIx_{75} = heart-rate-adjusted augmentation index; AP = augmentation pressure; PWV = pulse wave velocity.

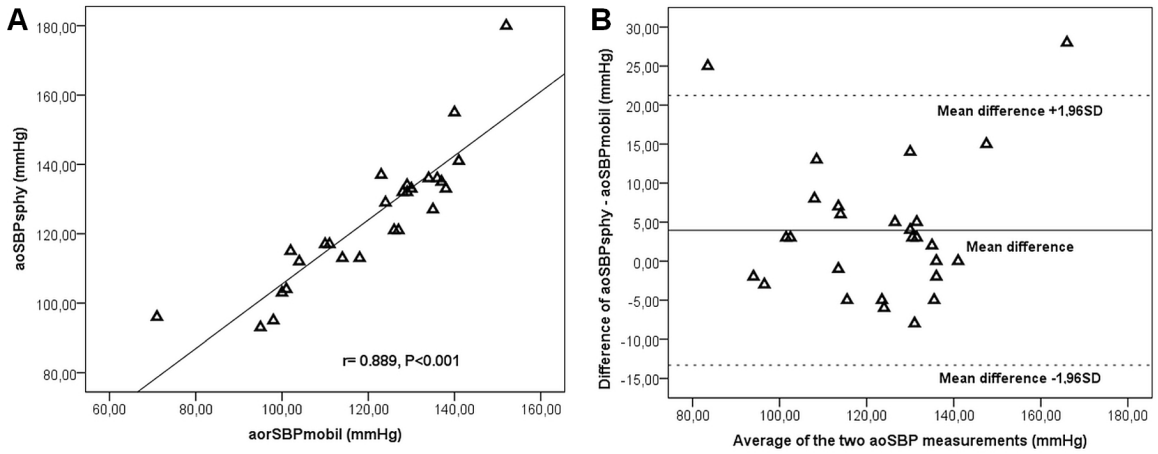

FIGURE 1 (A) Correlation analysis and (B) Bland–Altman analysis of the agreement between the Mobil-O-Graph (mobil) and SphygmoCor (sphy) devices in the estimation of aortic systolic blood pressure (aorSBP) in patients receiving peritoneal dialysis.

conditions (aSBP: 106.9 mmHg vs. 105.6 mmHg; AIx: 20.6% vs. 21.1%; PWV: 7.0 m/s vs. 7.3 m/s; $p > 0.10$ for all comparisons). In a subsequent study that enrolled 302 individuals (patients with hypertension and healthy volunteers), Wassertheurer *et al.* (8) showed that the mean difference in the estimation of aSBP between the Mobil-O-Graph and SphygmoCor devices was as low as –0.1 mmHg, with a standard deviation of 3.1 mmHg. Similarly, the mean difference between the two devices for the estimation of AIx was 1.2%, with a standard deviation of 7.9% (8). A validation study involving 120 patients undergoing aortic catheterization for suspected coronary artery disease tested the agreement of the Mobil-O-Graph–derived PWV with the invasive PWV measurements (16). The mean difference between the oscillometric PWV and the invasive PWV was 0.43 ± 1.24 m/s, and the Mobil-O-Graph–derived PWV showed a strong

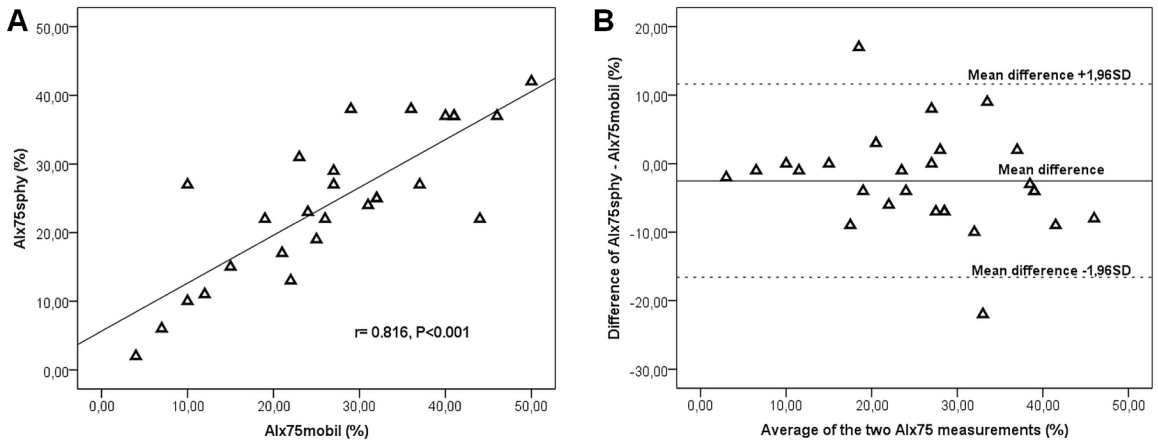

FIGURE 2 (A) Correlation analysis and (B) Bland–Altman analysis of the agreement between the Mobil-O-Graph (mobil) and SphygmoCor (sphy) devices in the estimation of heart-rate adjusted augmentation index (AIx_{75}) in patients receiving peritoneal dialysis.

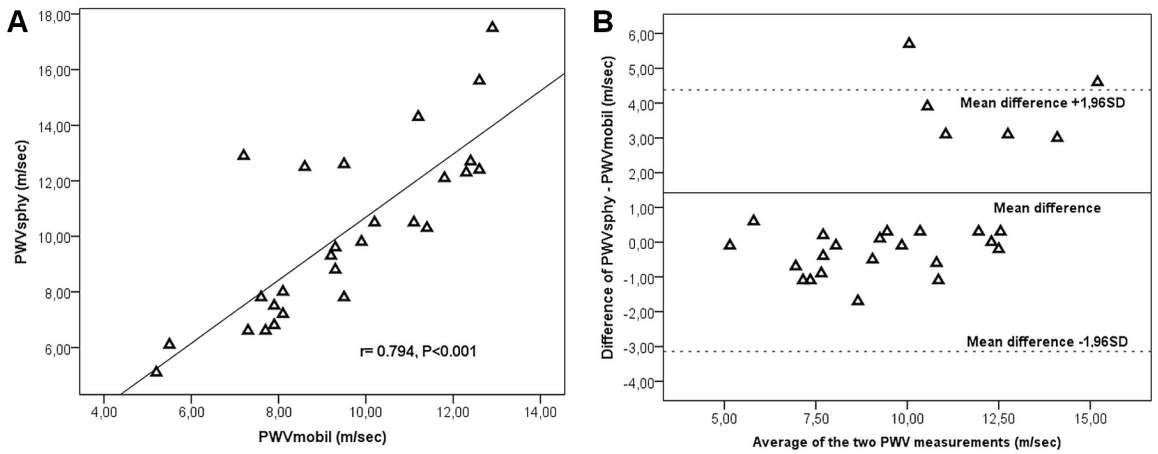

FIGURE 3 (A) Correlation analysis and (B) Bland–Altman analysis of the agreement between the Mobil-O-Graph (mobil) and SphygmoCor (sphy) devices in the estimation of pulse wave velocity (PWV) in patients receiving peritoneal dialysis.

linear correlation with the intra-aortic PWV ($r = 0.81$, $p < 0.001$) (16).

In an earlier comparison study of 73 patients with ESRD receiving HD, oscillometric measurements of aSBP and AIx_{75} obtained by Mobil-O-Graph shortly before the mid-week dialysis session were shown to correlate strongly and to show acceptable agreement with pre-dialysis tonometric measurements taken with the SphygmoCor device (10). The Mobil-O-Graph device underestimated, by 0.8 m/s, the SphygmoCor-derived PWV (10)—a finding that is close to the numerically lower PWV derived with the use of the Mobil-O-Graph in the present study.

The results of the present study expand earlier observations, suggesting that the Mobil-O-Graph device is at least as accurate as a widely-applied and established tonometric method for the estimation of central aortic BP and PWV in the whole spectrum of ESRD. The absence of acute shifts and fluctuations in metabolic- and volume-related parameters owing to the continuous nature of renal replacement therapy is suggestive of greater short-term reproducibility of

oscillometric measurements in patients receiving PD. Comparative studies using ambulatory recordings are necessary to ascertain similarities and differences in the short-term variability of central aortic BP and PWV for the PD and HD modalities.

The determination of aortic BP and PWV under ambulatory conditions is suggested to offer several advantages over conventional brachial ambulatory BP monitoring (ABPM). A growing body of evidence derived from studies conducted in non-ESRD populations has shown that 24-hour ambulatory aortic BP is superior to the 24-hour brachial ambulatory BP in detecting evidence of target-organ damage (such as echocardiographic LV hypertrophy and LV diastolic dysfunction) (17,18). Similarly, compared with 24-hour brachial BP variability, short-term 24-hour variability in the aortic BP showed stronger associations with adverse LV remodeling and carotid damage in patients with essential hypertension (19). Prospective observational studies have shown that, in patients with ESRD receiving HD, 48-hour intra- and interdialytic ambulatory PWV is a powerful predictor of future cardiovascular events and all-cause mortality (20). Notably, the predictive value of ambulatory PWV remained significant even after adjustment for pre-dialysis and interdialytic ambulatory BP (20). Those promising results call for properly designed studies aiming to elucidate whether aortic ABPM has an additive role to that of brachial ABPM in the overall management of hypertension.

The present study has several strengths and limitations that have to be acknowledged. The analysis provides novel findings supporting the accuracy of oscillometric measurements obtained by the newly introduced Mobil-O-Graph device in a patient population characterized by accelerated arterial stiffening, such as those on long-term PD. It has to be acknowledged, however, that our study provides only a comparison with another indirect method for estimating central aortic BP and PWV. Whether oscillometric measurements are superior to tonometric indices has to be clarified in future validation studies using "gold-standard" intra-aortic measurements as the reference. In addition, although Bland–Altman analyses excluded any visual evidence of asymmetry or bias, the 95% limits of agreement between the two devices mark a wide range, possibly because of the small sample size in our study. Thus, larger comparative studies are warranted to confirm or refute our observations.

Conclusions

The present study suggests that oscillometric measurements of aSBP, AIx_{75}, and PWV taken under static conditions with the use of the Mobil-O-Graph device are strongly associated with and show a wide range of agreement with the established and widely-applied tonometric measurements derived from the SphygmoCor device in patients with ESRD receiving PD. The availability of a validated monitor to perform brachial and aortic ABPM might facilitate an accurate determination of the severity of arterial damage in a population at high risk for cardiovascular morbidity and mortality. Future studies are warranted to elucidate the determinants and prognostic value of ambulatory arterial stiffness indices in patients receiving PD.

Disclosures

We understand that *Advances in Peritoneal Dialysis* requires disclosure of any conflicts of interest, and we declare that we have no conflicts relevant to this work to disclose.

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