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Limitations of the of the oscillometric method for blood pressure measurements in dialyzed patients

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B Data Collection
C Statistical Analysis
D Data Interpretation
E Manuscript Preparation
F Literature Search
G Funds Collection

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Summary

Background: Despite more frequent use of the oscillometric method (OSC) for arterial blood pressure (BP) measurement, little is known about OSC's accuracy when used with hemodialysed patients. This study was undertaken to determine if hemodialysis (HD) and individual features in examined patients can affect the accuracy of OSC for BP measurement.

Material/Methods: In 54 hemodialysed patients (57±15 years), during 2 sessions (before and after HD), 3 pairs of BP measurements each were performed on arms, alternately employing OSC and auscultatory method, with mercury manometers by 2 observers (REF).

Results: No difference was found in systolic BP measured before and after HD (SBP before HD: REF –147.3±27.3, OSC –147.5±25.0 mmHg, p>0.05, SBP after HD: REF-141.1±33.9, OSC-141.2±31.5 mmHg, p>0.05, respectively), but diastolic BP (DBP) was significantly higher both before and after HD during REF measurement in comparison with OSC (DBP before HD: REF –79.0±17.0, OSC –76.7±15.0 mmHg, DBP after HD: REF –78.6±18.8, OSC –76.7±16.7 mmHg, p<0.001, respectively). No significant correlation between loss of body weight caused by HD and differences in BP measured by REF and OSC after HD was indicated (Pearson's correlation coefficients: for SBP –0.041, for DBP 0.030). However, a significant correlation between differences in BP measured by REF and OSC before HD and differences in BP measured by REF and OSC after HD was observed (Spearman's rank correlation coefficients: for SBP 0.502 and for DBP 0.557, p<0.000001).

Conclusions: Our study found that individual features, not HD, determine the accuracy of OSC for BP measurement in hemodialysed patients.

key words: **blood pressure • dialysis • end-stage renal disease**

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Background

Arterial blood pressure (BP) measurement is a basic method used to diagnose and monitor arterial hypertension accompanying end-stage renal disease (ESRD). In hemodialysed patients one can observe considerable BP fluctuations, and BP level is dependent on:

- severity of illness,
- time of BP measurement (before, during, after or between hemodialysis [HD]),
- manner of BP measurement (by doctor or medical staff, home BP measurement, ambulatory BP monitoring [ABPM])
- device and method for BP measurement (oscillometric method [OSC], auscultatory method).

We currently possess extensive knowledge regarding clinical usefulness of BP measurements depending on the time of measurement [1–3]. Strengths and limitations of individual methods of BP measurement are well known [2–5]. The significance of 24- and 44-hour ABPM in diagnosis of hypotension episodes in ESRD patients, connected with impetuous fluid movement or water-electrolyte metabolism disorders accompanying chronic dialysotherapy, has been emphasized [6,7]. ESRD patients' differences from the general population have also been described by a reverse epidemiology phenomenon, connected with a higher cardiovascular risk and increased mortality in patients with low BP, even in younger age groups [8].

However, we know much less about the accuracy of OSC for BP measurement in hemodialysed patients. This method is used in devices designed for automatic BP monitoring, home BP measurements, and professional BP measurements in doctors' offices [9]. The accuracy of OSC for BP measurement can be influenced by cyclical changes in body fluid levels that take place during HD. It has been shown that rapid blood redistribution in healthy young people affects the accuracy of OSC for BP measurement regardless of the device's model and manufacturer [10–12]. The accuracy of OSC for BP measurement may also be affected by stable changes in arterial stiffness caused by ESRD.

This study was undertaken to determine which parameters influence the accuracy of OSC for BP measurement in hemodialysed patients. We analyzed the influence of HD and individual features of the examined patients.

Table 1. Demographic and clinical characteristics of participants of the study.

Patients HD	Mean ±SD and range
Female/Male (n)	20/34
Age (years)	57±15 (21–83)
Arm circumference (cm)	26.4±3.5 (17–34)
Height (m)	1.68±0.08 (1.45–1.83)
Weight before HD (kg)	67.8±14.6 (37.0–98.6)
Weight after HD (kg)	65.9±14.3 (35.0–96.2)
Weight loss after HD (kg)	1.97±1.44 (–0.5–8.5)
BMI (kg/m^2)	23.9±4.4 (13.7–33.3)
HD sessions' length (hours)	4.25±0.46 (3.5–6.0)
HD vintage (months)	45±52 (3–203)
Creatinine (mg/dl) before HD	8.69±2.54
Creatinine (mg/dl) after HD	146.4±35.7
Urea (mg/dl) before HD; after HD	146.4±35.7
Urea (mg/dl) after HD	74.16±116
Hemoglobine (g/dl)	11.4±1.17
Sodium (mmol/l) before HD	138±2.3
Sodium (mmol/ after HD	138±2.41
Potassium (mmol/l) before HD	5.42±0.77
Potassium (mmol/l) after HD	3.75±0.34
Phosphorus (mmol/l) before HD	1.7±0.36
Calcium (mmol/l) before HD	2.32±0.25

SBP – systolic blood pressure; DBP – diastolic blood pressure; HD – hemodialysis; BMI – Body Mass Index (calculated from weight before HD).

Material and Methods

The study included

54 patients with ESRD treated with HD. In the examined group, ESRD was caused by: chronic glomerulonephritis (25 patients), diabetic nephropathy (12 patients), hypertensive nephropathy (6 patients), chronic pyelonephritis (3 patients), polycystic kidney (2 patients), systemic lupus erythematosus (2 patients), and amyloidosis, kidney stones, Fabry disease or Goodpasture's syndrome (1 patient each). Patients were treated with standard bicarbonate 30 mmol/l, with glucose in 1.0 g/liter dialysate dialysis 3 times a week. Blood flow rate was between 200–300 ml and the dialysate flow rate 500 ml respectively. Fresenius 4008S (Fresenius, Germany) and Gambro AK90, AK 95, AK 200 Ultra (Gambro, Sweden) machines were used. All patients were dialyzed with single-use polysulfone dialyzers HPS F6, F7, F10 (Fresenius, Germany).

Patients with frequent ectopic beats, atrial fibrillation or arteriovenous fistulas on both arms were excluded from the study. The demographic and clinical characteristics of study participants are presented in Table 1. The Bioethics Committee of the Medical University of Warsaw approved the protocol for this study.

The accuracy of OSC for BP measurement was analyzed by using the Omron HEM-907 (Omron Healthcare Co., Ltd., Kyoto, Japan) for professional use, with 3 exchangeable cuffs: small (17–22 cm), medium (22–32 cm) and large (32–42 cm). The device measures BP by employing OSC

Table 2. SBP and DBP before and after HD measured by observers (REF) and oscillometric method for BP measurement: Omron HEM-907 (OSC).

	No of readings	REF		OSC		p (REF *vs.* OSC)
SBP before HD (mmHg)	162	147.3±27.3	(90.3–197.7)	147.5±25.0	(96.3–198.0)	0.5721
DBP before HD (mmHg)	162	79.0±17.0	(51.2–118.7)	76.7±15.0	(52.0–118.3)	0.000002
SBP after HD (mmHg)	162	141.1±33.9	(77.0–242.2)	141.2±31.5	(81.3–231.0)	0.8639
DBP after HD (mmHg)	162	78.6±18.8	(48.3–138.0)	76.7±16.7	(53.3–123.0)	0.00007

BP – blood pressure; SBP – systolic blood pressure; DBP – diastolic blood pressure; HD – hemodialysis; REF – blood pressure measurement on arm, auscultatory method, mercury manometers; OSC – osillometric method for BP measurement (Omron HEM-907).

(IntelliSense technology) in the range of 0–299 mmHg, and heart rate in the range of 30–199 beats/min. OSC readings were compared with classical BP measurement on the arm, using the auscultatory method and mercury manometers: the 2 Riester (Rudolf Riester GmbH&Co. KG, Jungingen, Germany) mercury sphygmomanometers (REF). As a systolic BP (SBP) value, phase I of Korotkoff sounds was adopted; and as a diastolic BP (DBP), phase V of Korotkoff sounds was used. Patients in whom it was not possible to determine a DBP level based on phase V Korotkoff sounds were not included in the study.

A team of 2 qualified observers measured BP using a Riester duplex stethoscope with 2 earpieces (Rudolf Riester GmbH&Co. KG, Jungingen, Germany). Their individual results were documented in such a way as to prevent any contact between the observers. The research team also included a third person, who operated the Omron HEM-907 and watched over the measurement results of both observers. The precision of BP measurements performed by both observers had been confirmed earlier by an expert, in accordance with International Protocol guidelines [13]. Each patient was weighed immediately before and after HD on the day when BP measurements were taken. BP readings were obtained before and after HD in a quiet, warm room, in a sitting position, after at least 10 minutes of rest, during the same HD session. The measurements were performed on an arm that did not have an arteriovenous fistula, with 46 people having measurements taken on their right arm, and 8 on their left arm. Measurements were performed using a cuff properly sized for arm circumference. Measurements were performed using a cuff properly sized for arm circumference (3 patients – small cuff, 48 patients – medium cuff, 3 patients – large cuff). In each case, 8 measurements were made, with no more than 60 s between measurements. However, the first 2 measurements (the first measurement by the observers and the first using OSC) were not included into analysis of this study. Measurements 3 to 8, alternately performed by the observers or OSC, were analyzed. If the BP measurements performed by the observers differed by more than 4 mmHg, they were repeated. The mean of BP measurements obtained simultaneously by 2 observers was adopted as a BP value in REF. Correlation coefficients were calculated by analyzing 3 pairs of BP measurements (REF and OSC) before and after HD (total number of 162 OSC measurements and 162 REF measurements before and after HD, respectively).

To evaluate the changes of BP measured by OSC and REF before and after HD, the t test for independent samples was used. To evaluate the relationship between the change in body weight due to ultrafiltration during HD and the accuracy of OSC readings in relation to REF readings, Spearman rank correlation (nonparametric test) or Pearson's correlation were used. Spearman coefficient R can be interpreted as the regular Pearson correlation coefficient, except that Spearman R is computed from ranks and not just from values. In order to compute Spearman R, it is assumed that the variables were measured on at least an ordinal (rank order) scale; that is, the individual observations were ranked into 2 ordered series. To evaluate the extent of the relationship between the accuracy of BP measurements (REF versus OSC), the correlation coefficient (Pearson) was also used. The standard level of significance was $p<0.05$.

Results

In hemodialysed patients, no differences were found in SBP measured by REF and OSC, both before and after HD (Table 2). DBP was significantly higher both before and after HD during REF measurement in relation to OSC (Table 2). The differences between BP measured by REF and BP measured by OSC were, respectively: 0.19±5.73mmHg for SBP before HD, –0.03±6.68 mmHg for SBP after HD, 2.35±6.15mmHg for DBP before HD and 1.88±6.00 mmHg for DBP after HD. SBP was higher before HD than after HD, regardless of the measurement method employed, respectively: for REF $p=0.005$ and for OSC $p=0.002$ (Table 2). No significant differences were found in DBP measured before HD in relation to DBP measured after HD, regardless of measurement method employed, respectively: for REF $p=0.68$ and for OSC $p=0.96$ (Table 2).

In further analysis, we estimated whether there was a correlation between loss of body weight caused by HD ultrafiltration (δW) and the accuracy of OSC readings in relation to REF. Pearson's correlation coefficients between δW and a value of differences in BP measured by REF and OSC after HD (δBP after HD) were calculated. Pearson's correlation coefficients were, respectively: for SBP –0.041 and for DBP 0.030, and in both cases the correlations were not significant ($p>0.05$). We also computed the correlation coefficients between δW and a value of differences calculated by subtracting δBP after HD from the difference between BP measured by REF and OSC before HD (δBP before HD), determined individually for each pair of BP measurements (REF-OSC) ($\delta\delta BP$). Pearson's correlation coefficients between δW a $\delta\delta BP$ were, respectively: for SBP –0.024 and for DBP 0.003, and were also not significant ($p>0.05$).

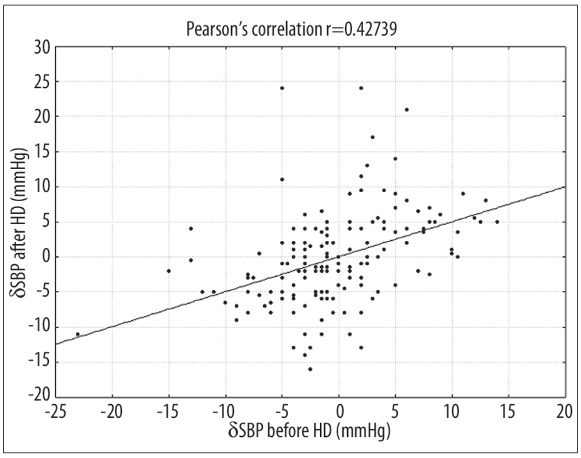

Figure 1. Correlation between the differences in the systolic blood pressure (SBP) measured by REF and OSC before HD (δSBP before HD) and the differences in the systolic blood pressure (SBP) measured by REF and OSC after HD (δSBP after HD).

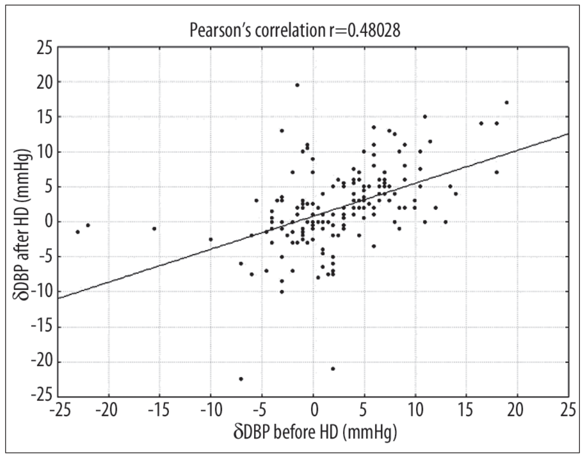

Figure 2. Correlation between the differences in the diastolic blood pressure (DBP) measured by REF and OSC before HD (δDBP before HD) and the differences in the diastolic blood pressure (DBP) measured by REF and OSC after HD (δDBP after HD).

A significant correlation between δBP before HD and δBP after HD was found: respectively, for SBP (Pearson's correlation coefficient 0.427, $p<0.05$ – Figure 1) and for DBP (Pearson's correlation coefficient 0.480, $p<0.05$ – Figure 2). Taking into consideration an insignificant deviation from assumption as far as employing parametric tests is concerned, the analysis was repeated employing nonparametric test (Spearman's rank correlation coefficient). The results were similar, respectively: for SBP 0.502 ($p<0.000001$) and for DBP 0.557, ($p<0.000001$).

A relative value for δBP before HD and δBP after HD was also evaluated by calculating, for all 162 measurements, a quotient between δBP and a mean BP value calculated for measurements performed by REF and OSC in a given measuring point. Significant correlations between a relative value for δBP before HD and a relative value for δBP after HD, both for SBP and DBP, were indicated; Spearman's rank correlation coefficients were, respectively: 0.514, $p<0.000001$ and 0.518, $p<0.000001$.

Only for DBP a significant correlation was found between the age of patients and δBP before HD (linear correlation coefficient: –0.18, $p<0.05$), as well as a significant correlation between the age of patients and δBP after HD was indicated (linear correlation coefficient: –0.31, $p<0.05$). For SBP, these correlations were insignificant (respectively: –0.11 and –0.12, $p>0.05$).

Discussion

OSC for BP measurement tends to overestimate SBP and underestimate DBP in comparison with REF [14,15]. The results of this study do not confirm that SBP was overestimated during OSC measurement in comparison with REF, both before and after HD (Table 2). A tendency to underestimate DBP during OSC measurement (observed previously and in the present study) is not a binding principle, since other authors indicated overestimation of DBP measured by OSC in comparison with REF [16]. The differences in the accuracy of BP measurement might be caused by the variety of algorithms employed to evaluate DBP by producers of devices for BP measurement [17].

Many devices employing OSC fulfill the accuracy criteria of BP measurement in comparison with REF. The HEM-907 device used in this study met the required accuracy criteria of the basic conditions of measurement [18–20]. The HEM-907 device was evaluated twice in hemodialysed patients. In both studies, the accuracy of the SBP readings in relation to REF was confirmed; however, in the case of DBP the opinions of the authors were divergent [21,22]. The above observations indicate that, in dialyzed patients, traditional methods of evaluating the accuracy of machines for BP measurement may be insufficient.

We are not familiar with any other oscillometric device for BP measurement that could fulfill the accuracy criteria of SBP and DBP readings both before and after HD.

OSC for BP measurement is based on BP oscillations recorded with the help of a cuff placed on the arm. The moment of the largest oscillations is adequate for the highest BP inside a pressed vessel [17]. SBP and DBP values in OSC are calculated on the basis of algorithms determined experimentally [16,17]; however, the amplitude of oscillations does not depend solely on BP level – its value can be affected by other factors, of which the most important is arterial stiffness [16,23]. Vascular stiffening develops from a complex interaction between stable and dynamic changes involving the vessel wall [24]. In hemodialysed patients, arterial stiffness is influenced by fluctuations of body fluid volumes during HD (dynamic changes), as well as by the process of arteriosclerosis accompanying ESRD (stable changes) [25,26]. The first factor is reversible and is a result of cyclical fluctuations of body fluids volume, whereas the second leads to progressive remodeling of vessel walls, including the brachial artery on which BP is measured. We assumed that fluctuations in arterial stiffness can influence the accuracy of BP measurements by OSC in relation to REF. The aim of this study was to evaluate which of the 2 factors defining the level of arterial stiffness, described above, can have a greater influence on the accuracy of OSC for BP measurement. If HD showed such an influence, one could expect fluctuations in the accuracy of the OSC readings in relation to REF depending on whether BP measurement was performed before or after HD. The results of the present study contradict this hypothesis. For both SBP and DBP, HD did not influence the accuracy of OSC readings in relation to REF, and the absence of this influence was independent of maintaining or not maintaining the accuracy of the readings of BP measurement by OSC in relation to REF (Table 2). SBP measurements performed by OSC and REF were not significantly different both before and after HD, whereas DBP measured by OSC was significantly lower in relation to REF both before and after HD (Table 2). The second method employed to determine if HD affects the accuracy of the readings of OSC for BP measurement consisted in evaluating the dependence of loss of body weight caused by HD and the accuracy of OSC readings in relation to REF. As mentioned above, HD causes fluctuations in arterial stiffness [23]. We did not have to our disposal a method allowing us to measure brachial artery stiffness before and after HD. However, we used a widely available parameter – body weight before and after HD. These 2 parameters are related, since in hemodialysed patients, fluctuations of body fluid volumes affect vessel stiffness [23]. Significant correlations between δW and δBP after HD, both for SBP and DBP, were not found, nor were significant correlations found between δW and δδBP, both for SBP and DBP. The above results indicate that HD does not affect the accuracy of the readings of BP measurement by OSC.

The second factor that can affect the accuracy of the OSC for BP measurement is arteriosclerosis resulting from the natural vessel aging process accelerated by mineral abnormalities in ESRD patients [25]. Increase in arterial stiffness affects the accuracy of BP measurement by OSC in relation to REF [26]. Our study demonstrated significant correlations between δBP before HD and δBP after HD, both for SBP and DBP (Figures 1 and 2). We found that the degree of accuracy in OSC for BP measurement in relation to REF is characteristic for individual patients, and the value of the difference in BP between OSC and REF after HD depends on the value of the difference of BP between OSC and REF before HD. In the present work we did not correlate the accuracy of indications of the 2 methods for BP measurement (REF and OSC) with vessel stiffness resulting from arterial media calcification, which is estimated by pulse wave velocity [27,28]. Pulse wave velocity is higher in ESRD patients than in hypertensive patients without kidney disease [29]. Positive correlations between SBP value and pulse wave velocity have been found in some studies [30]. It would be interesting to investigate the correlation between arterial vessel stiffness and the accuracy of OSC indications for BP measurement in younger HD patients, in whom a differentiated degree of damage to arterial vessels could be expected [31]. Cyclical fluctuations of body fluids volume could influence the accuracy of OSC to a greater degree in comparison to REF in this population of patients. Our results suggest that stable changes related to arteriosclerosis, and not dynamic changes related to cyclical fluctuations of body fluids volume related with HD, were particularly influential on the accuracy of BP measurement in HD patients.

O'Brien et al. [37] suggested that in case of high SBP and DBP values, the accuracy of OSC readings in relation to REF could be lower. Since, in this study, SBP was higher before than after HD, there was a probability that this difference could affect the degree of correlation between δBP before HD and δBP after HD. That is why the calculations were repeated using a relative value δBP – δδBP. This parameter took into consideration the BP level in relation to the value of the difference observed in BP measured by OSC and REF. However, the results of the correlation between δδBP before HD and δδBP after HD were not different from the correlation between δBP before HD and δBP after HD.

The process of arteriosclerosis consists of irreversible changes in the structure of the arterial wall, and increases with the aging process [25]. Therefore, one could expect differences in the accuracy of the readings of OSC for BP measurement depending on the age of the patients examined. In the case of SBP, such a correlation was not found. However, it was found that in young patients OSC for BP measurement underestimates DBP, and in elderly patients it overestimates DBP in comparison with REF both before and after HD. Our observations concerning both SBP and DBP are in accordance with the results of Thompson et al. [31], although they evaluated a device employing OSC for BP measurement made by a different manufacturer, and probably determining BP level with the use of different algorithms. In the case of DBP, the correlation coefficients between age and δBP before HD and between age and δBP after HD were lower than the correlation between δBP before HD and δBP after HD, which indicates that age is not the most important factor determining the accuracy of BP measurement by OSC in hemodialysed patients.

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Conclusions

Individual features, not HD, determine the accuracy of OSC for BP measurement in hemodialysed patients with ESRD.

OSC does not appear to be adequate for BP measurement in HD patients with ESRD.

Disclosure

All the authors declare no competing interests.

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