An intradialytic blood pressure assessment extended by two weeks predicts cardiovascular events with an accuracy comparable to that of home blood pressure measurements among hemodialysis patients

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Abstract

Introduction. Pressure measurements obtained before and after hemodialysis (HD) are marked by their high variability and poor reliability, which undermine their ability to estimate cardiovascular events (CVs).

Objective. This study sought to determine whether more measurements performed over a longer period of time enable a more accurate evaluation of the CVs associated with arterial hypertension.

Material and methods. This study included 40 patients (23 men and 17 women) aged between 27 and 82 years with a mean age of 58.8 ± 13.6 years who underwent chronic HD for 4 to 338 months. On days without HD, blood pressure home measurements (HMs) were recorded in the morning, afternoon and evening, and the results were obtained each day for 8 days. Furthermore, pressure measurements were recorded five times during 7 subsequent planned HD procedures: before HD, after HD and three times during HD. After 12 months, the number of CVs was determined with respect to the pressure measurement method.

Results. The correlation coefficients between the HMs and HD with regard to systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were 0.85, 0.80, and 0.84, respectively ($P < 0.001$). The receiver operating curve (ROC) values for SBP were 137.8 mmHg for HM and 140.4 mmHg for HD. The sensitivity and specificity of the HMs for SBP were 0.667 and 0.727, respectively. CVs occurred in 66.7% of the patients with SBPs ≥ 137.8 mmHg. The sensitivity and specificity of the HD measurements of SBP were 0.611 and 0.818, respectively. CVs occurred in 73.3% of patients with SBPs ≥ 140.4 mmHg.

Conclusions. Increasing the number of pressure measurements over a longer period of time in patients with HD likely improves the reliability of CV risk estimates.

Key words: cardiovascular events, hemodialysis, hemodialysis unit blood pressure measurements, home blood pressure measurements

Arterial Hypertens. 2017, vol. 21, no. 1, pages: 42–50
DOI: 10.5603/AH.2017.0006

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Background

In the general population, the diagnosis of arterial hypertension and the assessment of the related cardiovascular risks are based on precisely defined and commonly accepted principles pertaining to the conditions and methods of blood pressure measurement [1]. Unfortunately, similar uniform principles have not been established for blood pressure measurements in chronically hemodialyzed patients. Pressure values obtained from pre- and post-hemodialysis (HD) measurements are marked by their high variability and poor reliability, which undermines their usefulness in individual patient prognosis [2–4].

Nevertheless, the blood pressure values recorded from measurements performed during HD, evaluated in conjunction with readings from pre- and post--HD measurements, are highly consistent with the "gold standard" (i.e., 44-hour ambulatory blood pressure monitoring) [5]. Therefore, the blood pressure values obtained from peridialytic measurements (before, after and during dialysis) should be recognized as advantageous and of a higher prognostic value. Increasing the number of measurements performed at a dialysis unit throughout a single treatment and repeating them over subsequent treatments enables a more accurate estimation of hypertension-related cardiovascular risk. When evaluating the agreement between home measurements (HMs) and the "gold standard" (i.e., 44-hour ambulatory blood pressure monitoring performed between subsequent dialyses), the advantage of HMs over peridialytic measurements must be indicated [6, 7]. The high reliability of HMs validates their considerable usefulness with regard to estimating the risk for cardiovascular complications [3, 8]. Thus, the application of this method of measurement, which is comparable with ambulatory measurements, encourages the undertaking of additional trials in which pressure readings are taken over a longer period of time than previous reports [3, 5]. Studies performed to date have involved pressure HMs over a one-week period. Furthermore, extending this period will likely improve the validity and reliability of the obtained results [8].

The current study assumes that HMs taken over a longer period of time, as well as pressure readings taken before, after and during HD (i.e., peridialytic measurements), would meet the above requirements. An additional advantage of HMs is that the patient is personally committed to the treatment process, which increases the effectiveness of therapy [9]. On the other hand, HMs might be unavailable to certain chronically hemodialyzed patients. For this group, one alternative solution is blood pressure monitoring based on the peridialytic measurements taken by the dialysis unit staff.

The present study sought to determine:

1. the agreement between the blood pressure values obtained from peridialytic recordings and HMs and
2. the applicability of peridialytic recordings and HMs in estimating the risk of cardiovascular complications within 12 months based on the pressure measurements taken over two weeks among patients receiving chronic HD treatment.

Material and methods

Material

The Bioethics Committee at the Nicolaus Copernicus University Collegium Medicum in Bydgoszcz approved the study protocol (permission no. KB 622/2011). All of the patients included in this study signed their written agreement for participation.

The study included 40 patients (23 men and 17 women) aged between 27 and 82 years, with a mean age of 58.8 ± 13.6 years. These patients received chronic HD treatment for 4 to 338 months (median, 27 months). The patient inclusion criteria were written agreement for participation, age over 18 years, dialysis treatment received for at least 3 months, and unchanged type/dose of antihypertensive drugs for at least 2 weeks prior to inclusion (Table I).

Sixteen patients had diabetes mellitus, and 23 patients had a residual diuresis (57.5%) between 100 mL and 2,800 mL, with a mean volume of 1,015 ± ± 780 mL. Five patients did not receive any high blood pressure medication. The remaining patients received 1 to 6 medications across different drug groups. The most common option was the use of 2 or 3 drugs, and the most common group of drugs was β-blockers (27 patients).

Methods

Prior to commencing the study, the patients were instructed with regard to recording their own blood pressure. First, they were familiarized with the operation of the automatic blood pressure monitor used for this study. They were asked to take their readings after a five-minute rest. The measurement was taken in a sitting position, with the cuff placed around the arm without vascular access and at the level of the heart. If a patient was unable to take their blood pressure without assistance, then the family member providing care to the patient was included in this study.

The patients or their family member performed blood pressure measurements on days without

Table I. Sample characteristics

	Mean ± SD	Median	Minimum	Maximum
Body weight [kg]	72.7 ± 13.3		46.0	110.0
Dialysis therapy time [months]		33	3	96
BMI [kg/m^2]	25.8 ± 4.2		17.5	35.6
CRP [mg/L]		4.27	0.26	103.77
Albumin [μmol/L]	565.1 ± 52.2		405.7	666.5
Creatinine [μmol/L]	658.6 ± 2.47		315.6	1,131.5
PTH [ng/L]		303	6	1,900
Tsat%	37.9 ± 20.5		14.0	95.1
Hemoglobin [mmol/L]	6.9 ± 0.78		4.7	8.4
Kt/V	1.38 ± 0.18		0.83	1.67
Phosphate [mmol/L]		1.49	0.69	3.61
Iron [μmol/L]	14.9 ± 7.5		15.5	121.0
TIBC [μmol/L]	37.4 ± 7.2		22.7	51.7
Total cholesterol [mmol/L]	4.3 ± 1.2		2.0	7.4
HDL cholesterol [mmol/L]	1.0 ± 0.3		14.6	2.0
LDL cholesterol [mg/dL]	2.3 ± 0.8		0.5	4.6
Triglycerides [mg/dL]		2.1	0.5	5.8

Data are presented as means ± SDs unless otherwise stated. CRP — C-reactive protein; PTH — parathormone; Tsat% — transferrin saturation; Kt/V — HD treatment adequacy; TIBC — total iron binding capacity

dialysis, in the morning (7:00–8:00 am), afternoon (2:00–3:00 pm) and evening (9:00–10:00 pm), and the results were obtained for 8 days. Pressure readings were taken three times throughout the day. The morning measurements were taken as the mean of three morning measurements; the afternoon measurements were taken as the mean of three afternoon measurements; and the evening measurements were taken as the mean of three evening measurements.

The mean blood pressure HMs were calculated as the arithmetic mean of the morning, afternoon and evening readings. All blood pressure measurements were taken using the UA-631 A&D blood pressure monitor, A& D Medical, Kitamo, Japan.

At the dialysis unit, the readings were taken during 7 subsequent planned HD treatments. During one treatment, the nursing staff recorded the blood pressure readings five times: before HD, three times during HD (every hour) and immediately after HD. All blood pressure measurements were taken using an attested device integrated with the B Braun Dialog Plus dialysis machine.

The means of the subsequent measurements taken during HD were calculated as the arithmetic mean of the readings obtained from the 7 dialysis periods.

MAP (mean arterial pressure) =
= DBP (diastolic blood pressure) + 1/3 pulse pressure

Pulse pressure = SBP (systolic blood pressure) – DBP

The patients were then observed over 12 months to evaluate the occurrence of new cardiovascular events (CVs) or the aggravation of the previously diagnosed CVs.

Statistics

The normality of the variable distributions were analyzed using the Shapiro-Wilk test. In the case of variables with approximately normal distributions, the results were presented as means and standard deviations (SDs), and these means were compared using Student's t-test for independent and dependent variables as well as repeated-measures analyses of variance followed by Tukey's post hoc test. For variables whose distribution deviated from normal, the results were presented as medians and ranges, and significant differences between groups were determined using the Mann-Whitney U test for independent variables. Group proportions were analyzed using the chi-square (χ^2) test; correlations between variables were determined using Pearson's correlation coefficient; and the agreement between measurements was analyzed using a Bland-Altman plot.

To find the best parameters and optimal cut-off value, receiver operating curves (ROCs) were plotted, and the area under the curve (AUC) was calculated. To determine the prognostic value of the obtained cut-off values, the sensitivity, specificity, positive and negative predictive values, accuracy and likelihood ratio (LR) were calculated. The positive predictive value was calculated as the quotient of the number of patients correctly classified by the test over the group of patients with aggravated disease symptoms plus the total number of patients with positive results. The negative predictive value was calculated as the quotient of the number of patients correctly classified by the test over the group of patients without aggravated disease symptoms plus the total number of patients with negative results. Accuracy was calculated as the quotient of the sum of the number of patients correctly classified by the test over the group of patients with aggravated disease symptoms and the patients correctly classified by the test over the group of patients without aggravated disease symptoms plus the total number of patients. The LR was calculated as the quotient of sensitivity over 1-specificity.

The significance level was set at $P = 0.05$. All calculations were performed using Statistica v.10.0 PL (StatSoft, Inc.).

Results

Figure 1 presents the relationship between the ultrafiltration volume achieved during each HD treatment and the body weight gain after each dialysis. The data show that changes in body weight caused by the accumulation of water between treatments were regularly and adequately removed during HD.

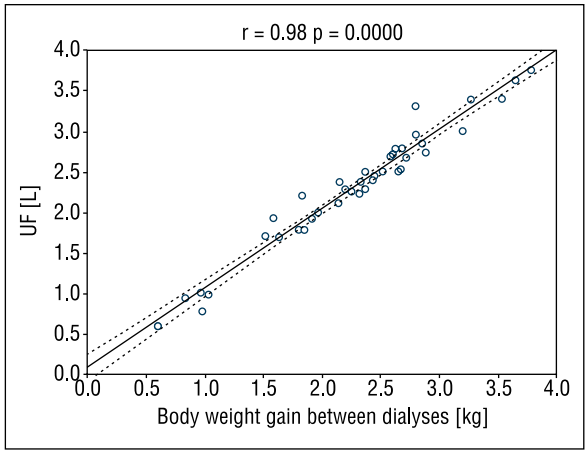

Figure 1. Correlation between the mean body weight gain and mean UF volume over two weeks

Table II. Mean HM blood pressure values and those taken at a dialysis unit

	HM	Dialysis unit measurement	P value
	Mean ± SD	Mean ± SD	
SBP [mmHg]	136.9 ± 21.4	133.4 ± 18.3	0.0537
DBP [mmHg]	73.6 ± 12.1	72.3 ± 8.5	0.2717
MAP [mmHg]	94.8 ± 12.8	92.7 ± 10.6	0.0681

Data are presented as means ± SDs. SBP — systolic blood pressure; DBP — diastolic blood pressure; MAP — mean arterial blood pressure

The mean HM and dialysis unit blood pressure readings and their relationships are presented in Table II and Figures 2A-C, respectively. Figure 3A-C presents the Bland-Altman plots of the mean differences in the SBP, DBP and MAP values obtained from the HM and dialysis unit readings. Table III presents the results of the analysis using the Bland-Altman method. The mean differences between the HM and dialysis unit pressure values were not significant; therefore, a lack of agreement exists between those two clinical measurements.

At the beginning of the observation, CVs were diagnosed in 34 patients from the study group, and the most frequent condition was chronic heart failure. In 32 patients, chronic heart failure co-occurred with other conditions related to cardiovascular diseases. After 12 months of observation, aggravation of the initially diagnosed conditions or the occurrence of new symptoms was found in 18 patients (see Fig. 4).

No significant differences were found between patients diagnosed with CVs at the beginning of the 12-month observation and those without such complications with regard to the SBP, DBP or MAP means. This lack of differences pertained to the pressure values obtained from both the HM and dialysis unit readings (data not presented).

Similarly, no differences were found between these groups in terms of the Kt/V, volume of ultrafiltration or body weight gain when the dialyses were expressed as percentages over the same period of observation (data not presented).

Higher SBP values were found among patients diagnosed with aggravations to their initially diagnosed conditions or new cardiovascular symptoms after 12 months, regardless of the measurement method (Table IV).

ROC curves were plotted to evaluate the applicability of MAP regarding the estimation of the likelihood of CVs. The ROC analysis enables the determination of the optimal analyzed blood pressure cut-off values that best divide a given group into a subgroup with a higher risk of complications and a subgroup

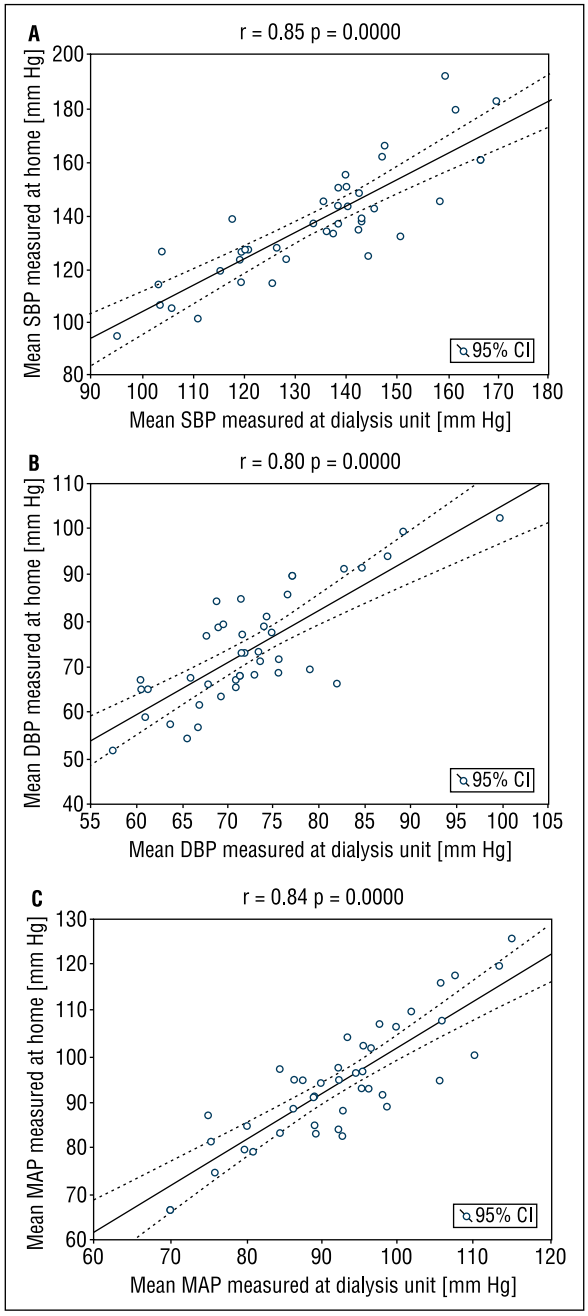

Figure 2. Correlation between the mean SBP and DBP values obtained from measurements taken at a dialysis unit and the same values obtained from HMs

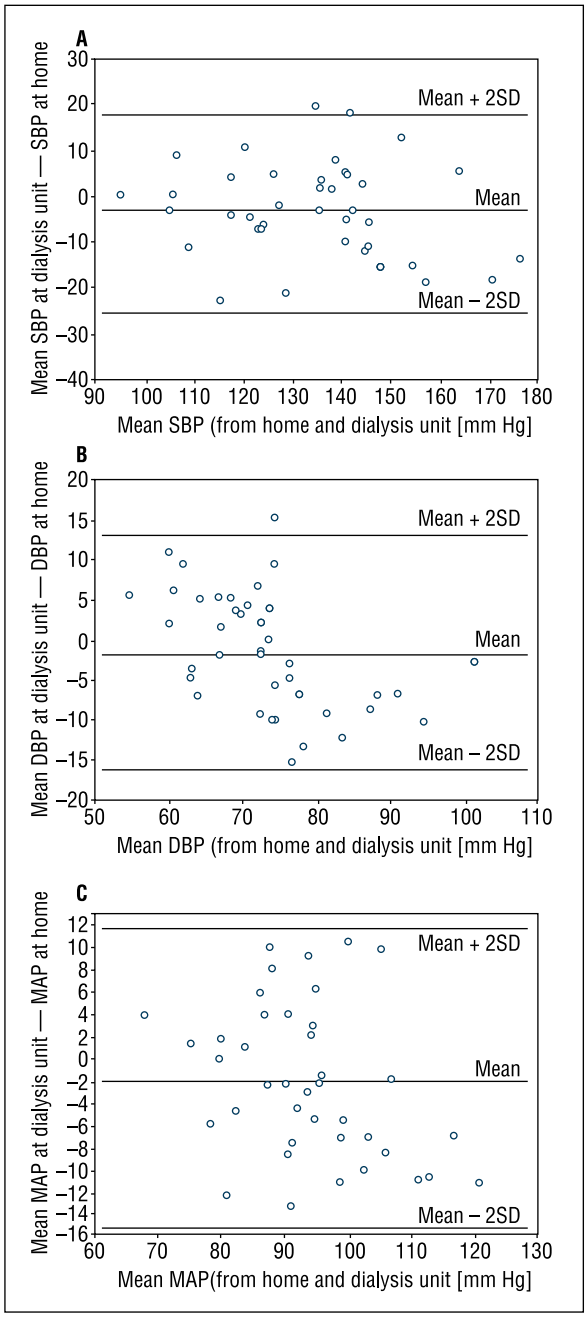

Figure 3. Difference between MAP values based on HM and dialysis unit measurements as a function of their means

Table III. The agreement between HMs values and those taken at a dialysis unit using the Bland-Altman plot

	Mean difference [mmHg] (95% confidence intervals)	p value	Reliability coefficient (2 x SD)	Limits of agreement	
				Lower	Upper
SBP	–3.5 (–7.1; 0.1)	0.0537	22.4	–-25.9	18.9
DBP	–1.3 (–3.7; 1.1)	0.2717	14.8	–16.1	13.5
MAP	–2.0 (–4.2; 0.2)	0.0681	13.8	–15.8	11.8

SBP — systolic blood pressure; DBP — diastolic blood pressure; MAP — mean blood pressure

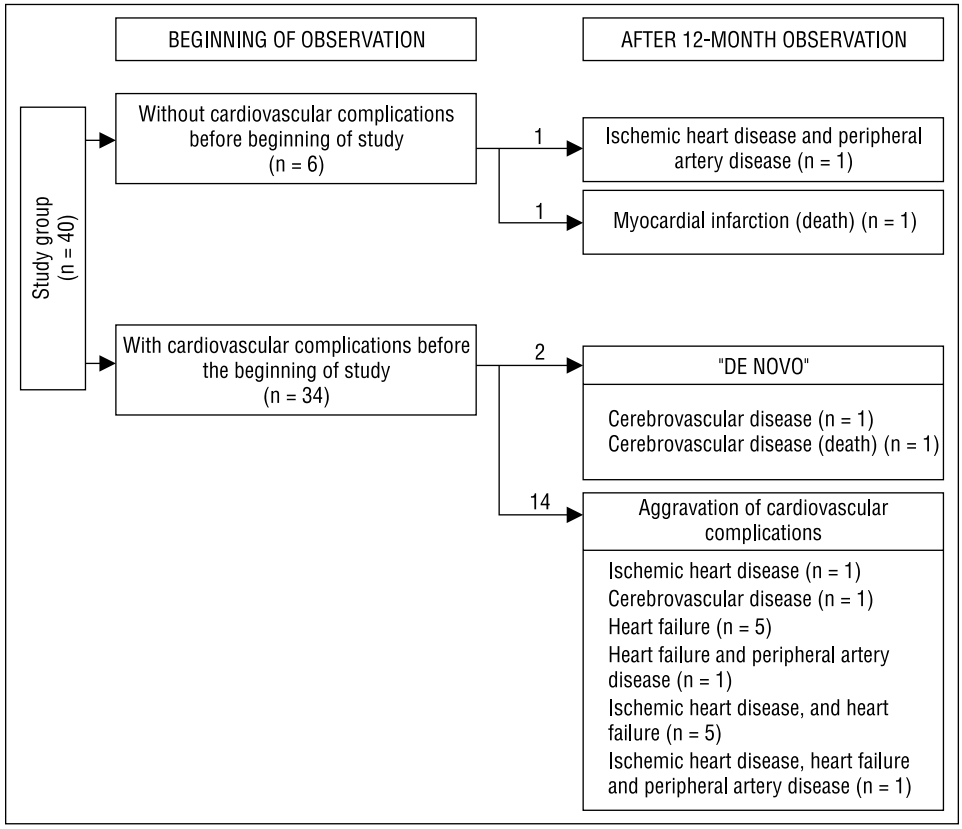

Figure 4. Course of cardiovascular complications over a 12-month observation period

Table IV. Mean HM blood pressure values and those taken at a dialysis unit among patients with and without aggravated disease symptoms

Mean ± SD		HM	Dialysis unit measurement	p value
		Mean ± SD		
Without aggravation of symptoms N = 22	SBP [mmHg]	128.5 ± 15.6	128.1 ± 16.6	0.8267
	DBP [mmHg]	71.4 ± 12.8	71.2 ± 8.7	0.8996
	MAP [mmHg]	90.4 ± 11.7	90.2 ± 9.4	0.8393
With aggravation of symptoms N = 18	SBP [mmHg]	147.2 ± 23.5	140.0 ± 20.1	**0.0178**
	DBP [mmHg]	76.4 ± 11.0	73.7 ± 8.2	0.1841
	MAP [mmHg]	100.1 ± 12.4	95.9 ± 11.4	**0.0234**

Data are presented as means ± SDs. SBP — systolic blood pressure, DBP — diastolic blood pressure, MAP — mean blood pressure

with a lower risk of complications. Moreover, the AUC was calculated for the analyzed pressure values and obtained cut-off points. Table V presents the cut-off points and AUCs. The AUCs for SBP and MAP were higher concerning HMs than in those taken at a dialysis unit. The highest AUC values exceeding 0.7 applied to the SBP values obtained from HMs at a cut-off value of 137.8 mmHg and to the MAP values obtained from HMs at a cut-off value of 94.9 mmHg (Table V). Complications occurred in patients more often for the SBP cut-off point based on HMs of > 137.8 mmHg (66.7%) than for the SBP of < 137.8 mmHg (27.3%; P < 0.01). In addition, HMs revealed more frequent complications regarding MAP values > 94.9 mmHg (68.4%) than MAP values < 94.9 mmHg (23.8%; P < 0.005). For SBP values obtained from readings taken at a dialysis unit, complications occurred in 73.3% of cases for

Table V. Predictive blood pressure values at a given cut-off

Parameter	Cut-off value [mmHg]	AUC	Sensitivity	Specificity	Accuracy	Positive predictive value	Negative predictive value	LR
SBP at home	137.8	0.740	0.667	0.727	0.700	0.667	0.727	2.4
SBP at a dialysis unit	140.4	0.692	0.611	0.818	0.720	0.733	0.720	3.4
DBP at home	78.6	0.619	0.389	0.773	0.600	0.583	0.607	1.7
DBP at a dialysis unit	75.4	0.592	0.389	0.818	0.625	0.636	0.621	2.1
MAP at home	94.9	0.737	0.722	0.727	0.725	0.684	0.762	2.6
MAP at a dialysis unit	101.7	0.649	0.389	0.955	0.700	0.875	0.656	8.6
PP at home	54.6	0.689	0.722	0.591	0.650	0.591	0.722	1.8
PP at a dialysis unit	55.1	0.684	0.778	0.591	0.675	0.609	0.765	1.9

SBP — systolic blood pressure, DBP — diastolic blood pressure, MAP — mean blood pressure, PP — pulse pressure; LR — likelihood ratio

the cut-off value > 140.4 mmHg, a frequency that was significantly higher ($P < 0.005$) than the cut-off of < 140.4 mmHg.

Discussion

A new conclusion of major clinical importance drawn from the present study is that it is possible to estimate the direction of changes in blood pressure values during the interdialytic period based on two-week-long peridialytic measurements. Hence, two-week peridialytic measurements can reflect the direction of changes in blood pressure when HMs are unavailable to a patient.

This study did not reveal significant differences between the readings taken using different measurement methods or high-positive linear correlation coefficients between these methods. Our results allowed us to formulate the aforementioned conclusions, indicating the applicability of an alternative method to HMs for taking the blood pressure of hemodialyzed patients. Importantly, however, this high comparability between blood pressure values was achieved not only by increasing the number of measurements itself but also by extending the period during which they were taken. The results of the present study are comparable with those obtained in studies in which the median of all peridialytic measurements was used instead of their mean [10]. Moreover, given that peridialytic measurements might constitute an alternative to HMs and considering the findings of other authors, the current method may be applicable for monitoring the treatment of arterial hypertension [11].

The present study determined the optimal pressure values by dividing the study group into a subgroup with a higher risk of cardiovascular complications and a subgroup with a lower risk of complications based on the ROC analysis. The analysis of the ROCs and AUCs (Table V) indicates that the best parameter for differentiating the study group in terms of CVs is the SBP from HMs (cut-off point, 137.8 mmHg) and the SBP from dialysis unit recordings (cut-off point, 140.4 mmHg). The sensitivity of the SBP values from HMs was 0.667, and the specificity was 0.727. CVs occurred in 66.7% of patients with SBP values ≥ 137.8 mmHg (positive predictive value). The sensitivity of the SBP values from dialysis unit measurements was 0.611, and the specificity was 0.818. CVs occurred in 73.3% of patients with SBP values ≥ 140.4 mmHg (positive predictive value). Thus, both blood pressure measurement methods are equally applicable for determining the critical blood pressure values regarding clinical CVs. Our findings reveal the predominant role that SBP plays in the development of organ-specific complications [12, 13].

The aforementioned observational studies were supplemented by data that enabled the identification of correlations between left ventricular hypertrophy and the SBP values obtained from HMs [14, 15]. Nevertheless, the data analysis presented in Table V indicates a limit to the applicability of the pressure readings with regard to predicting the occurrence of complications, regardless of the measurement method used. The sensitivity and specificity values demonstrate that approximately 1/3 of patients with SBP values above the cut-off will not experience complications, whereas approximately 1/3 of patients with SBP values below the cut-off will experience

complications. Similar values in terms of specificity were obtained in a study that analyzed sensitivity and specificity with respect to the left ventricular hypertrophy and HMs [15]. In that case, the data cast considerable doubt regarding the theory that blood pressure is a cause of CVs among chronically hemodialyzed patients. This finding might result from the role that arterial hypertension plays a role in the pathogenesis of malleable complications. Hypertension seems to have a significantly more negative effect on the development of complications among patients who have just begun treatment than in those who receive long-term dialysis [16].

Considering the additional conclusions drawn from this analysis, it must be indicated that the cut-off value above which the risk for complications increases remained undetermined for approximately 20–30% of the patients included in the present study, regardless of the measurement method used (HM vs. peridialytic). This unknown implies the need for further studies.

Despite the above results, the limitations of the present study must be discussed.

A small sample size hinders a more thorough statistical analysis and the generation of more reliable results. Importantly, the current study was performed among patients who received treatment at only one dialysis unit. Given that, this sample significantly changed over one year because of possible kidney transplantation and, in some cases, death, and it was difficult to include a sufficient number of patients in this study. The study group was also heterogeneous in terms of the overall duration of HD in individual patients as well as with regard to their age. These facts, coupled with the small sample size, increase the difficulty of providing a conclusive evaluation of the results.

A vast majority of the patients received antihypertensive drugs. As such, the current results should be interpreted cautiously because they do not reflect the true relationship between blood pressure and its related complications. Importantly, the results of previous studies were also limited in this regard.

The evaluation of CVs was based solely on clinical manifestations and is therefore somewhat subjective. Undoubtedly, clinical assessments that include, for example echocardiography, would provide much more information, thereby enabling more possibilities to interpret the results. Unfortunately, we have decided not to use the echo test because of its limited availability.

The blood pressure readings obtained via HMs should be assumed to contain an undetermined amount of error. The simultaneous use of 44-hour ambulatory blood pressure monitoring would allow us to verify the data obtained.

Furthermore, blood pressure measurement itself challenges the reliability of the current results because it was limited to one arm due to the presence of vascular access on the other, which made it impossible to compare the results across both arms.

In conclusion, increasing the number of measurements during HD and extending the period during which they are taken enables the evaluation of the pressure changes that occur between dialyses and the related cardiovascular complications at a level comparable with that of between-dialysis HMs. The proposed method for taking measurements during dialysis might constitute a valuable alternative to HMs in cases in which the latter is impossible.

Pressure values obtained from measurements before or after HD are marked by high variability and poor reliability, which undermine their ability to estimate cardiovascular risk. Therefore, the total peridialytic results obtained before, after and during HD are more suitable, and more measurements recorded over a longer period of time should enable a more accurate evaluation of the cardiovascular risk associated with arterial hypertension.

Contribution statement

Both authors contributed equally to this study. RN designed and performed the study, RN and JM analyzed the data, discussed the results and commented on the manuscript. JM approved the final version to be published. RN and JM are accountable for all aspects of the work.

Acknowledgment

The authors thank B Braun Avitum Poland sp. z o.o. for allowing them to perform studies at the dialysis units in Nakło and Notecią.

Compliance with Ethical Standards

Funding

Neither of the Authors has been granted by grant therefore both Authors declare no conflict of interests

Ethical approval

The Bioethics Committee at the Nicolaus Copernicus University Collegium Medicum in Bydgoszcz approved this study (permission no. KB 622/2011) in accordance with amendments of 1964 Helsinki declaration. All of the patients included agreed to their participation in writing and informed consent was signed by each of participants.

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