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ORIGINAL ARTICLE

Invasive Validation of Arteriograph Estimates of Central Blood Pressure in Patients With Type 2 Diabetes

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BACKGROUND
Central blood pressure (BP) has attracted increasing interest because of a potential superiority over brachial BP in predicting cardiovascular morbidity and mortality. Several devices estimating central BP noninvasively are now available. The aim of our study was to determine the validity of the Arteriograph, a brachial cuff-based, oscillometric device, in patients with type 2 diabetes.

METHODS
We measured central BP invasively and compared it with the Arteriograph-estimated values in 22 type 2 diabetic patients referred to elective coronary angiography.

RESULTS
The difference (invasively measured BP minus Arteriograph-estimated BP) in central systolic BP (SBP) was 4.4 ± 8.7 mm Hg ($P = 0.03$). The limits of agreement were ±17.1 mm Hg.

CONCLUSIONS
Compared with invasively measured central SBP, we found a systematic underestimation by the Arteriograph. However, the limits of agreement were similar to the previous Arteriograph validation study and to the invasive validation studies of other brachial cuff-based, oscillometric devices. A limitation in our study was the large number of patients (n = 14 of 36) in which the Arteriograph was unable to analyze the pressure curves. In a research setting, the Arteriograph seems applicable in patients with type 2 diabetes.

CLINICAL TRAIL REGISTRATION
ClinicalTrials.gov ID NCT01538290

Keywords: blood pressure; brachial cuff-based, oscillometric devices for measurement of central BP; cardiovascular disease; cardiovascular risk; central blood pressure (BP); diabetes; hypertension; invasive validation of brachial cuff-based, oscillometric devices noninvasive measurement of central BP.

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For decades, brachial blood pressure (BP) has been established as a robust predictor of cardiovascular (CV) morbidity and mortality. Diastolic BP (DBP) and mean arterial pressure (MAP) are relatively constant throughout the arterial tree, but systolic BP (SBP) increases peripherally as a result of central wave reflections and pulse pressure amplification.[1] Thus, brachial SBP differs from SBP at the level of the ascending aorta (i.e., central SBP), to which heart, brain and kidneys are exposed. From a physiological perspective, it seems reasonable to hypothesize that central BP may provide prognostic information over and beyond that obtained from brachial BP. Indeed, central BP has been reported to be superior in predicting CV morbidity and mortality compared with brachial BP in several,[2–8] but not all,[9] studies. Another interesting aspect of central hemodynamics is the differential effects of antihypertensive medications on central and brachial BPs.[10,11]

Consequently, measurement of central BP has attracted growing attention. Arteriograph (TensioMed, Budapest, Hungary) is one of the newer devices on the market offering brachial cuff-based, oscillometric noninvasive measurement of arterial stiffness and central BP indices. In 2011, the first—and to date only—study on invasive validation of the Arteriograph was published.[12] Horváth *et al.*,[12] found a strong correlation between invasively measured and noninvasively calculated central (aortic) SBP. Moreover, the Arteriograph was found to fulfill the B grade of the British Hypertension Society (BHS) criteria for the evaluation of BP

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measuring devices. In the study by Horváth *et al.*, information on the number of patients with diagnosis of diabetes was not reported.[12]

Diabetic patients have increased arterial stiffness compared with nondiabetic patients.[13,14] Furthermore, diabetes may affect elastic (i.e., aorta, carotid) and muscular (i.e., radial, brachial) arteries differently,[13] which may result in different pulse wave characteristics centrally and peripherally. It is unclear whether these potential differences in diabetic patients affect the accuracy of the Arteriograph.

Hence, the aim of our study was to evaluate the accuracy of the Arteriograph-estimated central BP as compared with invasively measured central BP in patients with type 2 diabetes.

METHODS

The study was approved by the Central Denmark Region Committees on Health Research Ethics and the Danish Data Protection Agency. All patients provided informed consent. The study was registered at ClinicalTrials.gov with ID NCT01538290.

Study population

Inclusion criteria were type 2 diabetes and aged >18 years in consecutive patients referred to elective coronary angiography (CAG) at the Department of Cardiology, Aarhus University Hospital, Skejby, Denmark. Exclusion criteria were atrial fibrillation or other cardiac arrhythmias and stenosis of subclavian or brachial arteries. Status of type 2 diabetes was based on the referral diagnosis. The medical record of each patient was individually evaluated, checking whether the diagnosis of type 2 diabetes was correct (patients receiving only oral antidiabetic or GLP-1 treatment or insulin treatment initiated >1 year after diagnosis).

From November 2011 to March 2012, 57 patients were invited to participate in the study. Two patients declined participation, and 4 patients were excluded according to criteria and other conditions. Seven were not examined because of time constraints (arrival of acute patients), and 4 were excluded because of cardiac arrhythmias developed during the CAG (atrial fibrillation or frequent ventricular extrasystoles). Invasive data were not valid in 2 patients (lack of flushing of catheter) and not available in another 2 patients (print error). Among the remaining 36 patients, the Arteriograph was unable to analyze the pressure curves in 12 patients, and a further 2 were deleted because of unacceptable quality (amplitude of pressure curves with unacceptable variation). Thus, data from 22 patients were available for analysis.

Arteriograph

The Arteriograph applies a brachial cuff-based, oscillometric method for the estimation of aortic pulse wave velocity, aortic augmentation index, and central (aortic) BPs. In a 2-minute sequential procedure, the Arteriograph initially measures brachial BP. Immediately after, the BP cuff is first inflated to diastolic and then suprasystolic BP (brachial SBP + 35 mm Hg), creating a stop-flow condition in the brachial artery. In this suprasystolic phase (duration of 8 seconds), the conduit arteries (subclavian, axillary, and brachial arteries) transfer changes in central pressure, and a high-fidelity sensor records the oscillations from the brachial artery. The Arteriograph software determines the parameters by analysis of the pressure curves obtained during the suprasystolic phase. Aortic augmentation index is calculated from the brachial augmentation index and a previously published regression equation, obtained from the validation study.[12] Central SBP is calculated from a proprietary algorithm. DBP is assumed to be equal centrally and peripherally, and brachial MAP is calculated as DBP + 1/3(SBP − DBP).

The Arteriograph used in our project was the Medexpert Arteriograph Bluetooth (TL2) with software version 3.0.0.0 (updated 11 September 2012). The Arteriograph software suggests cuff size based on arm circumference. Recommended bladder dimensions are 6 × 18 cm, 8 × 26 cm, and 8 × 34 cm for arm circumference range of 18–25 cm, 26–33 cm, and 34–43 cm, respectively.

Invasive BP data

The invasive BP data were obtained with a fluid-filled 6F Boston Scientific Expo Angiographic catheter (Boston Scientific, Natick, MA) attached to a NAMIC transducer (Navilyst Medical, Marlborough, MA). The catheters were 100 cm long with an internal diameter of 1.4 mm. Transducers were placed at the midaxillary line and calibrated to zero before each examination. Catheters were inserted through a femoral sheath into the ascending aorta and flushed every 2 minutes. When the CAG procedure was finished, the catheter was placed in the ascending aorta. After ensuring that the pressure curve was stable, the Arteriograph measurement was made. Immediately after, the invasive BP data were recorded, and a copy containing pressure curve and invasive BP data was printed.

Baseline data

Information on diabetes duration, smoking habits, height, weight and use of medication was obtained from the patients. Biochemical data from the time of hospitalization (fasting glucose, HbA1c, cholesterol, and creatinine) were obtained from the patients´ electronic medical records.

Statistical analysis

Baseline data are presented as mean ± SD or median (range) for skewed data. Assumptions of normal distributions were tested by histograms and QQ plots. Differences between invasively measured and Arteriograph-estimated central SBP were assessed by paired *t* test. Agreement between invasively measured and Arteriograph-estimated central SBP was assessed by the approach described by Bland and Altman.[15] A 2-tailed P value < 0.05 was considered statistically significant. Stata IC 11.2 for Windows (StataCorp, College Station, TX) was used for data analysis.

RESULTS

Patient characteristics are presented in Table 1. The study population was characterized by a predominance of men, and the range of age, diabetes duration, and BMI was wide. All patients were receiving antihypertensive and antidiabetic treatment, and their median HbA1c was 7.0%. A total of 91% of the patients were in lipid-lowering therapy, and the mean total cholesterol was 3.8 mmol/L.

Brachial (Arteriograph) and central (Arteriograph-estimated and invasively measured) BPs are shown in Table 2.

In the 22 patients, we analyzed paired measurements of invasively measured and Arteriograph-estimated central BP. The mean difference between invasively measured and Arteriograph-estimated central SBP was 4.4 ± 8.7 mm Hg ($P = 0.03$). The limits of agreement (mean difference ± 1.96 SD of the difference) were ±17.1 mm Hg. The mean difference between invasively measured and Arteriograph-estimated central DBP was −13.3 ± 7.4 mm Hg ($P < 0.001$). The limits of agreement were ±14.4 mm Hg. The Bland–Altman plot comparing invasively measured and Arteriograph-estimated central SBP is depicted in Figure 1. The difference between invasively measured and Arteriograph-estimated central SBP did not increase with increasing average of invasively measured and Arteriograph-estimated central SBP. The correlation between invasively measured and Arteriograph-estimated central SBP was high ($r = 0.891$; $P < 0.001$) (Figure 2).

Table 1. Baseline characteristics

Sex, male/female	16/6
Age, y	66 ± 10
Diabetes duration, y	8.6 (0.4–31.4)
HbA1c, %	7.0 (5.4–11.2)
Fasting blood glucose, mmol/L	8.8 ± 2.3
Total cholesterol, mmol/L	3.8 ± 0.9
BMI, kg/m^2	31.6 (23.5–47.4)
Smoking, present/previous/never	8/10/4
Antihypertensive treatment, no. (%)	22 (100)
ACE inhibitors	10 (46)
ARBs	10 (46)
BBs	15 (68)
CCBs	11 (50)
Diuretics	15 (68)
Antidiabetic treatment, no. (%)	22 (100)
Oral antidiabetics	19 (86)
Insulin	8 (36)
GLP-1 agonists	3 (14)
Lipid-lowering therapy, no. (%)	20 (91)
Antithrombotic treatment, no. (%)	19 (86)
Aspirin	18 (82)
Clopidogrel	4 (18)

Values are mean ± SD, median (range), or numbers (%).

Abbreviations: ACE, angiotensin-converting enzyme; ARBs, angiotensin receptor blockers; BBs, beta blockers; BMI, body mass index; CCBs, calcium channel blockers; GLP-1, glucagon-like peptide 1.

Table 2. Brachial (Arteriograph) and central (Arteriograph-estimated and invasively measured) blood pressures

	Brachial (Arteriograph)	Central: Arteriograph-estimated	Central: invasively measured
SBP	134.3 ± 13.8	133.4 ± 16.4	137.8 ± 19.2
DBP	81.0 ± 14.1	81.0 ± 14.1[a]	67.8 ± 17.0
PP	53.3 ± 11.8	52.3 ± 13.5	70.0 ± 15.1
MAP[b]	98.8 ± 12.9		95.0 ± 17.5

Values are mean ± SD and in mm Hg.

Abbreviations: DBP, diastolic blood pressure; MAP, mean arterial pressure; PP, pulse pressure; SBP, systolic blood pressure.

[a]Of central blood pressures, the Arteriograph only reports SBP and PP. Central DBP was calculated as follows: Central DBP = central SBP – central PP.

[b]Brachial MAP was calculated as DBP + 1/3(SBP − DBP). Invasive MAP was calculated on the basis of the area under the curve.

DISCUSSION

To our knowledge, this study is the first to determine the validity of the Arteriograph in patients with type 2 diabetes.

The previous validation study on the Arteriograph by Horváth *et al.*,[12] found a mean difference between Arteriograph-estimated and invasively measured central SBP of only 0.56 mm Hg, with limits of agreement about ±17 mm Hg (calculated SD about ±8.5 mm Hg). Furthermore, Horváth *et al.*, report that the Arteriograph fulfilled the B grade of the BHS criteria for the evaluation of BP measuring devices.[16] This criterion is not fulfilled in our study because of the systematic underestimation of 4.4 mm Hg. However, according to the guidelines by the Association for the Advancement of Medical Instrumentation (AAMI),[17] it is required that "blood pressures measured by an automated BP device achieve a mean difference of ±5 mm Hg and a standard deviation of ±8 mm Hg against a reference standard". Neither the study by Horváth *et al.*, nor our study fulfills these criteria, although the SDs come close. We acknowledge that these criteria were not developed to validate devices for the noninvasive assessment of central BP against invasive pressures. However, until internationally accepted criteria for validation of noninvasive devices have been developed, we find it reasonable to refer to the guidelines stated by the AAMI.

The limits of agreement in our study are very similar to what was found by Horváth *et al.*, The discrepancy of the difference between invasively measured and Arteriograph-estimated central SBP may have several explanations. First, the study populations are different. Our study

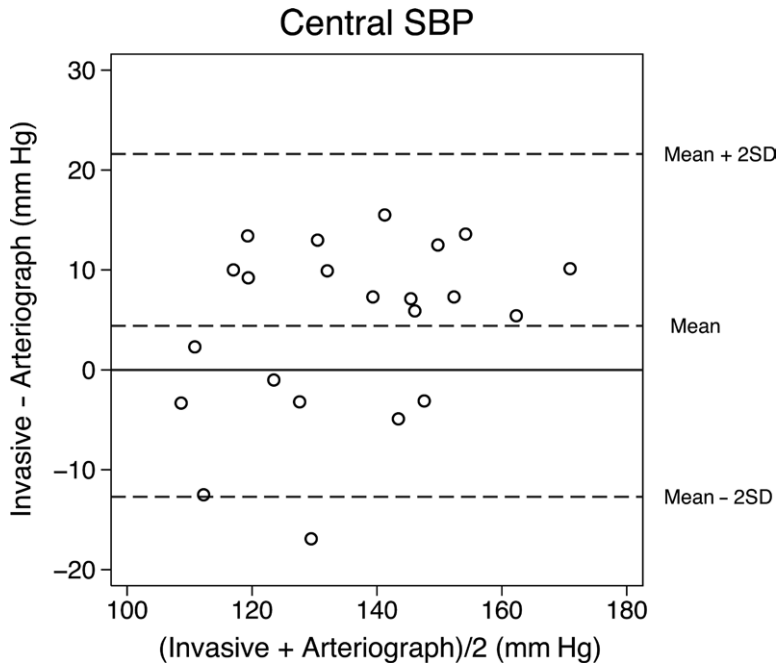

Figure 1. Bland–Altman plot of invasively measured and Arteriograph-estimated central systolic blood pressure (SBP).

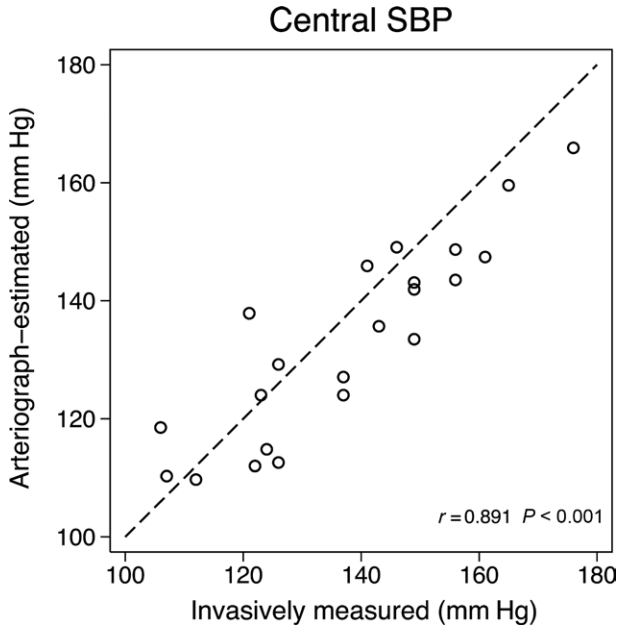

Figure 2. Correlation plot of invasively measured and Arteriograph-estimated central systolic blood pressure (SBP).

population consisted entirely of diabetic patients, who may have different characteristics of elastic arteries than non-diabetic patients. Furthermore, the proportion of patients receiving antihypertensive drugs and the level of BP differ in the 2 studies.

Second, the Arteriograph software versions are different. It is our experience that different versions of Arteriograph software in some cases yield different results on the same data. The explanation given by the distributor is that newer versions of software are less sensitive to noise and artifact. Thus, a larger number of pressure curves are object for analyses, which may give rise to different—and more precise—results. Importantly, according to the distributor, the underlying algorithm is unaltered.

Third, the Arteriograph cuff dimensions and recommendations have changed. The measurement of brachial BP by the Arteriograph is based on the TensioDay ABPM device (TensioMed, Budapest, Hungary), which was validated by Németh *et al.*,[18] The cuff dimensions recommended for the Arteriograph are much smaller than for the TensioDay device, which comply with the BHS recommendations.[19] Furthermore, cuff dimensions and the recommended applied cuff size have changed in different Arteriograph versions. In earlier versions, the recommendation was to use a tight fit of the smallest cuff possible. In present versions, cuff size recommendation is based on arm circumference, but the cuffs are less wide than they were previously. Cuff size is not reported by Horváth *et al.*, but considering the time of the study, it seems possible that an earlier version of Arteriograph was used. The significance of these differences is uncertain and remains speculative, and we expect that the Arteriograph algorithm for oscillometric measurement of the brachial BP has been adjusted for the changes in applied cuff size.

A major limitation in our study is the large number of missing Arteriograph results. In 14 of 36 (39%) patients the Arteriograph was unable to analyze the pressure curves adequately to yield a valid result. Horváth *et al.*, do not report the number of patients in whom Arteriograph results were not available. However, other validation studies of devices for noninvasive estimation of central BP have reported similar difficulties.[20,21] The measurement circumstances may be

the major problem. We have considered several potentially disturbing circumstances in the technical setup (e.g., vibrations from examination bed, disturbances from aortic catheter). All of these may have interfered with the high-fidelity sensor. We have examined >100 patients in normal clinical settings, and under these circumstances we rarely have difficulties achieving high-quality pressure curves.

A generally accepted limitation in devices estimating central BP is the use of oscillometric measured brachial BP for calibration. It is well known that oscillometrically determined DBP is significantly overestimated compared with invasive values and SBP is slightly underestimated.[22] Thus, the estimated central BP is only as accurate as the brachial BP is. Another interesting aspect of this issue is the puzzling fact that the Arteriograph uses MAP calculated as DBP + 1/3(SBP − DBP) instead of the oscillometric-derived MAP. The fundamental working principle in oscillometric BP measurement defines MAP as the lowest cuff pressure at which the oscillation amplitude is maximal. MAP determined in this way is the only oscillometric-derived BP parameter with a direct physiological link to invasive MAP and should therefore logically be the foundation for calibration. However, the assumption of the maximal amplitude algorithm for calculating MAP being superior to the traditional rule of thumb was recently challenged on a theoretical background.[23]

A final limitation in our study is the use of fluid-filled catheters, which are prone to dampening effect.

We found a large difference between invasively measured and Arteriograph-estimated central DBP (Table 2). Arteriograph brachial and central DBP are equal, so it seems clear that the Arteriograph employs the principle of DPB being relatively constant peripherally and centrally. We believe that the overestimation of central DBP is explained by the overestimation of invasive brachial DBP by oscillometric measurements. In the study by Horváth *et al.*,[12] central DBP was not reported, thus we do not know if our results are substantially different.

Surprisingly, we found an unexpectedly small difference between Arteriograph measured brachial SBP and Arteriograph-estimated central SBP (Table 2). We speculate that the small difference may be explained by the fact that oscillometric BP devices underestimate invasive brachial SBP. Moreover, diabetic patients have more pronounced arteriosclerosis, which may reduce the effect of amplification. In the study by Horváth *et al.*,[12] Arteriograph-estimated central SBP was 158.6 mm Hg, and brachial SBP was reported as 154 mm Hg in the "Participants Characteristics" section. This indicates an unexpected negative amplification. However, it is not clear whether the reported brachial SBP was obtained with the Arteriograph during the invasive validation or obtained before, potentially even recorded with a different device.

In studies estimating central BP by the brachial cuff-based, oscillometric method,[12,21,24,25] the differences between invasive values and estimates are not only substantial, but they also vary between devices. However, the limits of agreement are close (Table 3). It seems reasonable to argue that the difference between estimates and invasive values is less important compared with limits of agreement when comparing different devices. As a consequence of these substantial differences, it is currently unrealistic to establish general reference intervals for central BP. Moreover, the current methods for brachial cuff-based, oscillometric estimation of central BP have all been based on primary validation studies on limited numbers of patients. Invasive validation studies with larger numbers, but also in different populations, are needed. However, invasive validation may paradoxically become unnecessary if parameters claimed to be representative of central BP measured in the clinic or by 24-hour ambulatory monitoring[26] can be shown to improve correlation with end-organ damage (i.e., left ventricular hypertrophy) or cardiovascular endpoints prognosis.

In general, the principle of noninvasive central BP measurement faces several challenges.[27] The superiority of invasively measured central BP over brachial BP in the prediction of CV events remains to be fully established. The added value of noninvasively measured central BP compared with brachial BP is still debatable. Internationally accepted guidelines on validation of devices are lacking, especially clarifying the need for invasive validation as opposed to comparison with existing devices. Because of the many different technologies applied, the estimated values are not interchangeable across devices, and device specific ranges of "normality" will be required. Hence, the use of devices measuring noninvasive central BP in daily clinical practice needs thorough consideration.

Table 3. Overview of differences between invasively measured and noninvasively estimated central systolic blood pressure and associated limits of agreements in devices estimating central blood pressure by the brachial cuff-based, oscillometric method

Device (Author of validation study)	Invasively measured – noninvasively estimated	Limits of agreement
Colin (Cheng *et al.*,[24])	−0.1 ± 7.6	±14.9
Mobil-O-Graph; calibration with brachial MAP and DBP (Weber *et al.*,[25])	3.0 ± 9.5	±18.7
Mobil-O-Graph; calibration with brachial SBP and DBP (Weber *et al.*,[25])	14.4 ± 9.7	±19.0
Vicorder (Pucci *et al.*,[21])	6.4 ± 7.4	±14.5
Arteriograph (Horváth *et al.*,[12])	−0.56 ± 8.5	±17
Arteriograph (Rossen *et al.*,)	4.4 ± 8.7	±17.1

Values are in mm Hg.
Abbreviations: DBP, diastolic blood pressure; MAP, mean arterial pressure; SBP, systolic blood pressure.

In conclusion, we have compared invasively measured and Arteriograph-estimated central SBP in patients with type 2 diabetes. We found a systematic underestimation by the Arteriograph, but limits of agreement were similar to the results of the single previous validation study to date. Thus, in a research setting, the Arteriograph seems applicable in patients with type 2 diabetes.

DISCLOSURE

The authors declared no conflict of interest.

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