The Role of Central Aortic Pressure in the Management of High Blood Pressure
Objective of Presentation

The presentation will describe data demonstrating the following:

- Clinical evidence supports incorporating non-invasive central aortic blood pressure measurements into blood pressure management.
- The SphygmoCor® System can help guide treatment decisions designed to prevent or reduce long-term target organ damage and cardiovascular events resulting from increased aortic pressure and therefore reduce the socioeconomic burden of hypertension.
Agenda

• Background
• Central Aortic Pressure as a Predictor of Cardiovascular (CV) Events
• Central Aortic Pressure Threshold Values for Management Decisions
• White Coat Hypertension: The Role of Central Pressure Measurements
• Implications for Pharmacotherapy
• Summary and Conclusions
Background
Hypertension: Socioeconomic Impact

Epidemiology (USA)
- Prevalence $\approx$ 45% of adults\(^1\)
- Responsible for $\approx$ 500,000 deaths\(^2\)
- CDC reports that hypertension is under control in only 24% of patients\(^2\)

Economics
- Average annual medical expenditure attributable to hypertension = $9,089 per diagnosed patient\(^3\)
- Relative to non-hypertensives: $1,920 higher annual adjusted incremental expenditure, 2.5x inpatient cost, 2x outpatient cost, and 3x prescription medication costs\(^3\)
- Adjusted annual incremental cost = $131 billion/year higher for adults with hypertension relative to adults without hypertension\(^3\)

Hypertension Management

Diagnosis and management based on cuff measurement of peripheral (brachial artery) pressures

- Widespread use of brachial BP has led to substantial but incomplete improvement in hypertension control and reduction in end-organ damage

Why are there ongoing problems with hypertension management?

- Various reasons: case finding (early diagnosis), continuity and continued follow-up of care, affordability of care, medication adverse effects and medication compliance, challenges in modifying lifestyle behavior

Additional issue: current monitoring based on brachial blood pressure

- Variable precision and reliability of measuring brachial BP (patient and health care provider factors)
- Brachial BP is a surrogate for central (i.e., aortic) blood pressures, which represent the actual pressures that are transmitted to organs effected by hypertension (e.g., heart, brain, kidney)
- Cuff brachial blood pressure measurement “is not so much a surrogate, but a compromised measure that is recorded because of technical limitations.” (Cheng et al)¹

Non-Invasive Measurement of Central Aortic Pressure

- Non-invasive pulse wave analysis (PWA) is a technique that transforms the data from peripheral arterial pressure waveforms obtained into an evaluation of central aortic pressures.
- Calculations are performed through a generalized transfer function that corrects for pressure wave amplification in the upper limb.
- Variables produced:
  - Central aortic systolic and diastolic pressures
  - Central aortic pulse pressure (systolic minus diastolic pressure)
  - Augmentation pressure (difference between (a) reflected wave added to incident wave, and (b) incident pressure during systole)
  - Augmentation index (augmentation pressure divided by the pulse pressure)
- Peripheral (brachial) blood pressures are highly correlated to central pressures
  - Brachial systolic pressure is higher than central aortic systolic pressure
  - Diastolic pressures are similar
The SphygmoCor® XCEL System

Dual Arterial Pressure Monitoring System

• Obtains brachial pressures immediately followed by measurement of central aortic pressures
• Performed in the same session
• The only FDA cleared medical device for non-invasive central arterial pressure waveform analysis in adults
Arterial Waveform Capture

- A cuff is applied on the upper arm in the standard position
- The cuff is partially inflated to record the brachial waveforms
- These waveforms are detected by sensing changes in the pressure inside the cuff related to arterial pulsation
- The ascending aortic waveform is subsequently derived using a validated mathematical transfer function*

*Generalized transfer function cleared by FDA
Brachial PressureDiffers from Central Pressure

Brachial Cuff Pressure vs. Central Aortic Pressure

Two patients with IDENTICAL BRACHIAL CUFF pressures (Figure 1), but with significantly DIFFERENT CENTRAL/AORTIC arterial pressure waveforms (Figure 2).

• The difference in waveform shapes, due to differences in arterial stiffness and the effects of wave reflections, effects the aortic but not the brachial systolic and pulse pressures.

Both Brachial and Central Aortic Pressure Measurements Provide Clinically Relevant and Complimentary Information
Central Aortic Pressure Predicts End-Organ Damage and Cardiovascular Events
Brachial BP Monitoring: A Key Success Factor Responsible for Lowering Cardiovascular Risk

Brachial BP

- Prominent risk factor for vascular-related end-organ damage, morbidity, and mortality
- Reductions proven to reduce vascular end-organ damage, morbidity, and mortality
  - Based on threshold (baseline) blood pressure $\geq 140/90$ mm Hg\(^1\)
  - SPRINT study suggests that the thresholds for initiation of pharmacotherapy could be lower\(^2\)
- ACA/AHA Guidelines (2017) Recommendation\(^1\)
  - Follow-up monitoring and lifestyle modifications at 120-139/80 mm Hg
  - Pharmacotherapy with risk factors for CV disease and 130-139/80 mm Hg
  - Pharmacotherapy with BP $>140/90$ mm Hg

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Central BP Predicts End-Organ Damage and Cardiovascular Risk

End-organ damage associated with hypertension is directly related to central pressures as these, rather than peripheral pressures, are the pressures that are transmitted to vital organs.

Central systolic pressures
- Correlated to peripheral systolic pressures (correlation coefficients 0.6 to 0.97)
- Multiple studies indicate that central BP is at least as predictive for CV risk and end-organ damage as peripheral blood pressure with some studies indicating superiority.

Objective of hypertension management
- Should include lowering central systolic pressures to values (or thresholds) that correspond to the targets set for peripheral systolic pressures for the purpose of reducing vascular risk.
Elevated Central BP is Associated with End-Organ Damage

**Study Objective**: determine relationship of blood pressures to organ damage

**Subjects**: N= 1,169, ≥ 16 years old, randomly recruited from Johannesburg, South Africa

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### Brachial BP (mm Hg)

<table>
<thead>
<tr>
<th>Optimal</th>
<th>Normal/High Normal</th>
<th>Hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;120/80</td>
<td>≥120/80 + &lt;140/90</td>
<td>≥140/90 or Treatment</td>
</tr>
</tbody>
</table>

### Aortic Systolic BP (mm Hg)

- Unadjusted Values
  - eGFR (ml/min/1.73m²) (n): 128±32 (244), 126±32 (108), 111±26 (149), 103±28 (443)
  - LVMI (g/m²) (n): 35.5±10.2 (181), 38.2±11 (82), 44.0±12.1 (109), 47.5±15.8 (318)

- Adjusted Values
  - eGFR (ml/min/1.73m²) (n): 118±29 (244), 115±27 (108), 108±26 (104), 112±30 (443)
  - LVMI (g/m²) (n): 40.0±14.3 (181), 40.7±13.2 (82), 44.5±12.6 (109), 44.0±14.6 (318)

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**Central pressure added relevant data determining risk of end-organ damage**

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eGFR: estimated glomerular filtration rate; LVMI left ventricle mass index
Multivariate adjustment for age, sex, BMI, diabetes mellitus and/or an HbA1c>6.1%, regular tobacco use, regular alcohol intake and pulse rate.

Booysen et al. Aortic, but not brachial blood pressure category enhances the ability to identify target organ changes in normotensives. J Hypertension 2013;31:1124-30.
Central BP Relates to Target Organ Damage

1,272 normotensive and untreated hypertensive (SBP ≥140 or DBP ≥90 mmHg) participants
Baseline values correlated to laboratory and clinical outcomes over a period of up to 10 years

<table>
<thead>
<tr>
<th></th>
<th>LVM</th>
<th>IMT</th>
<th>GRF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>r</td>
<td>Partial r</td>
<td>r</td>
</tr>
<tr>
<td>SBP-B</td>
<td>0.370</td>
<td>0.231</td>
<td>0.225</td>
</tr>
<tr>
<td>SBP-C</td>
<td>0.410</td>
<td>0.270</td>
<td>0.252</td>
</tr>
<tr>
<td>PP-B</td>
<td>0.219</td>
<td>0.112</td>
<td>0.204</td>
</tr>
<tr>
<td>PP-C</td>
<td>0.286</td>
<td>0.194</td>
<td>0.265</td>
</tr>
</tbody>
</table>

LVM: left ventricular mass
IMT: intima-medial thickness
GFR: glomerular filtration rate

*p<0.05
**not significant
p<0.001 for all other fields

SPB systolic blood pressure, PP pulse pressure, B brachial, C central
Partial r: adjusted for age, sex, heart rate, body mass index, current smoking, fasting plasma glucose, total cholesterol/high-density lipoprotein cholesterol, and carotid-femoral pulse wave velocity.

Central BP Relates to CV Mortality

Hazard ratios and 95% CI for all-cause and CV mortality by univariate analysis.

<table>
<thead>
<tr>
<th></th>
<th>All-Cause Mortality</th>
<th>CV Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Women</td>
<td>Men</td>
</tr>
<tr>
<td>SBP-B (10 mm Hg)</td>
<td>1.15 (1.04-1.27)</td>
<td>1.11 (1.00-1.22)</td>
</tr>
<tr>
<td>SBP-C (10 mm Hg)</td>
<td>1.23 (1.12-1.36)</td>
<td>1.11 (1.01-1.23)</td>
</tr>
<tr>
<td>PP-B (10 mm Hg)</td>
<td>1.25 (1.10-1.43)</td>
<td>1.36 (1.20-1.53)</td>
</tr>
<tr>
<td>PP-C (10 mm Hg)</td>
<td>1.50 (1.32-1.71)</td>
<td>1.36 (1.21-1.53)</td>
</tr>
</tbody>
</table>

SPB systolic blood pressure, PP pulse pressure, B brachial, C central

Central BP Relates to CV Mortality

<table>
<thead>
<tr>
<th>Model</th>
<th>BP Component</th>
<th>HR/10 mm Hg (CI)</th>
<th>HR/SD increment (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1</td>
<td>SBP-B</td>
<td>1.049 (0.800–1.374)</td>
<td>1.119 (0.590–2.122)</td>
</tr>
<tr>
<td></td>
<td>PP-B</td>
<td>1.138 (0.802–1.616)</td>
<td>1.238 (0.694–2.209)</td>
</tr>
<tr>
<td>Model 2</td>
<td>SBP-B</td>
<td>0.957 (0.787–1.164)</td>
<td>0.902 (0.567–1.434)</td>
</tr>
<tr>
<td></td>
<td>SBP-C</td>
<td>1.336 (1.107–1.612)</td>
<td>2.002 (1.276–3.140)</td>
</tr>
<tr>
<td>Model 3</td>
<td>SBP-B</td>
<td>1.076 (0.906–1.278)</td>
<td>1.189 (0.791–1.789)</td>
</tr>
<tr>
<td></td>
<td>PP-C</td>
<td>1.199 (0.941–1.530)</td>
<td>1.330 (0.908–1.947)</td>
</tr>
<tr>
<td>Model 4</td>
<td>PP-B</td>
<td>1.042 (0.835–1.299)</td>
<td>1.070 (0.743–1.540)</td>
</tr>
<tr>
<td></td>
<td>SBP-C</td>
<td>1.286 (1.089–1.520)</td>
<td>1.828 (1.226–2.726)</td>
</tr>
<tr>
<td>Model 5</td>
<td>PP-B</td>
<td>1.116 (0.895–1.393)</td>
<td>1.199 (0.832–1.728)</td>
</tr>
<tr>
<td></td>
<td>PP-C</td>
<td>1.190 (0.933–1.518)</td>
<td>1.314 (0.898–1.923)</td>
</tr>
<tr>
<td>Model 6</td>
<td>SBP-C</td>
<td>1.491 (1.154–1.928)</td>
<td>2.606 (1.408–4.821)</td>
</tr>
<tr>
<td></td>
<td>PP-C</td>
<td>0.786 (0.541–1.141)</td>
<td>0.685 (0.381–1.230)</td>
</tr>
</tbody>
</table>


Numbers in bold letters indicate statistical significance.

All adjusted for age, sex, heart rate, BMI, current smoking, fasting plasma glucose levels, cholesterol/HDL ratio, carotid-femoral pulse wave velocity, LVM, IMT, and eGFR. PP-B = brachial pulse pressure; PP-C = central pulse pressure; SBP-B = brachial systolic blood pressure; SBP-C = central systolic blood pressure.

BP Predicts CV Events: Meta-Analysis

Five studies included both central and brachial pressures

Relative Risk (RR) and 95%CI of clinical events for a 1 SD increase in (A) PP and (B) SP

Boxes = RR, Lines = 95% CI.

Diamonds = pooled RR, Diamond width = 95% CI.

Conclusion

Elevated central and peripheral systolic pressures and pulse pressures increased risk of CV events and all-cause mortality

Central BP Predicts CV Events

Study

- Design: systematic review and individual participant data meta-analysis from 15 studies
- Objective: evaluation of central aortic pressures for the prediction of cardiovascular events.
  - 22,433 participants, 908 had a myocardial infarction, 641 a stroke and 1,844 a CV event.

Results

- HR [95% CI] for combined CV events per SD increase in SBP, after adjustment for physiological confounders and cardiovascular risk factors
  - Brachial sBP 1.16 [1.06, 1.26]
  - Central sBP 1.20 [1.09, 1.33]

- **HR (combined CV events) after adjustment for peripheral SBP**
  - Central sBP 1.17 [1.00, 1.37]

Conclusion

- Central SBP was predictive of CV events even after adjustment for physiological confounders including adjustment for brachial SBP and is therefore an independent predictor of CVD events.
Central Pressure Threshold Values for Management Decisions
Hypertension Management Decisions are Based on Brachial BP

<table>
<thead>
<tr>
<th></th>
<th>Systolic BP (mm Hg)</th>
<th>Diastolic BP (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NICE (2019)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normotension</td>
<td>&lt;120</td>
<td>&lt;80</td>
</tr>
<tr>
<td>Stage 1 Hypertension</td>
<td>≥140</td>
<td>≥90</td>
</tr>
<tr>
<td>Stage 2 Hypertension</td>
<td>≥160</td>
<td>≥100</td>
</tr>
<tr>
<td>Severe hypertension</td>
<td>≥180</td>
<td>or ≥120</td>
</tr>
<tr>
<td><strong>ESH/ESC (2018)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normotension</td>
<td>&lt;120</td>
<td>&lt;80</td>
</tr>
<tr>
<td>Grade 1 Hypertension</td>
<td>140–159</td>
<td>and/or 90–99</td>
</tr>
<tr>
<td>Grade 2 Hypertension</td>
<td>160–179</td>
<td>and/or 100–109</td>
</tr>
<tr>
<td>Grade 3 hypertension</td>
<td>≥180</td>
<td>and/or ≥110</td>
</tr>
<tr>
<td><strong>ACC/AHA (2017)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normotension</td>
<td>&lt;120</td>
<td>and &lt;80</td>
</tr>
<tr>
<td>Elevated BP</td>
<td>120–129</td>
<td>and &lt;80</td>
</tr>
<tr>
<td>Stage 1 Hypertension</td>
<td>130–139</td>
<td>or 80–89</td>
</tr>
<tr>
<td>Stage 2 Hypertension</td>
<td>≥140</td>
<td>or ≥ 90</td>
</tr>
</tbody>
</table>

Management decisions for the treatment of hypertension are based on specific threshold values for systolic and diastolic brachial pressures regardless of age and gender.

ACC, American College of Cardiology; AHA, American Heart Association; BP, blood pressure; ESC, European Society of Cardiology; ESH, European Society of Hypertension; NICE, National Institute for Health and Care Excellence.
BP Thresholds and Recommendations for Treatment and Follow-Up


A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Colors correspond to Class of Recommendation in Table 1. *Using the ACC/ANA Pooled Cohort Equations (58.1.2-56, 56.1.2-57). Note that patients with DM or CKD are automatically placed in the high-risk category. For initiation of RAS inhibitor or diuretic therapy, assess blood tests for electrolytes and renal function 2 to 4 weeks after initiating therapy. †Consider initiation of pharmacological therapy for stage 2 hypertension with 2 antihypertensive agents of different classes. Patients with stage 2 hypertension and BP ≥160/100 mm Hg should be promptly treated, carefully monitored, and subject to upward medication dose adjustment as necessary to control BP. Reassessment includes BP measurement, detection of orthostatic hypotension in selected patients (e.g., older or with postural symptoms), identification of white coat hypertension or a white coat effect, documentation of adherence, monitoring of the response to therapy, reinforcement of the importance of adherence, reinforcement of the importance of treatment, and assistance with treatment to achieve BP target ACC indicates American College of Cardiology; AHA, American Heart Association; ASCVD, atherosclerotic cardiovascular disease; BP, blood pressure; CKD, chronic kidney disease; DM, diabetes mellitus; and RAS, renin-angiotensin system.

Threshold Values for Central Systolic BP and Organ Damage

Study Objective

- Prevalence of central hypertension and its association with end-organ damage in 1,983 elderly people

Hypertension Definition

- Brachial BP ≥140/90 mmHg or using antihypertensive medications
- Central BP ≥130/90 mmHg or using antihypertensive medications

Population Groups

<table>
<thead>
<tr>
<th>Brachial Hypertension</th>
<th>Central Hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>BCCN, 563 (28.4%)</td>
</tr>
<tr>
<td></td>
<td>ICH, 27 (1.4%)</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IBH, 46 (2.3%)</td>
</tr>
<tr>
<td></td>
<td>BCCH, 1347 (67.9%)</td>
</tr>
</tbody>
</table>

BCCN: brachial & central consistent normotension
BCCH: brachial & central consistent hypertension
IBH: isolated brachial hypertension (e.g., white coat hypertension)
ICH: isolated central hypertension (e.g., masked hypertension)
Threshold Values for Central Systolic BP and Organ Damage

Organ Damage

ANCOVA performed to compare the mean levels between subtypes of brachial and central hypertensions. The mean values of LVMI and UACR in different subtypes and the results of comparisons are displayed.

*p<0.05, compared with BCCN
LVMI, left ventricular mass index
UACR, urinary albumin-creatinine ratio.

Threshold Values for Central Systolic BP and Organ Damage

Results

• Measures of end-organ damage were significantly associated with concordant hypertension group

• Compared to isolated brachial or isolated central hypertension (adjusted odds ratio [95% CI])
  • LVH = 2.03 [1.55, 2.68]
  • LV diastolic dysfunction = 2.29 [1.53, 3.43]
  • Urinary albumin-creatinine ratio >30 mg/g: 1.97 [1.58, 2.44]

Conclusions

• Groups can be distinguished based on concordance and discordance of hypertension based on threshold values of 140/90 mm Hg (brachial pressure) and 130/90 (central aortic pressure) for risk evaluation and treatment decisions.

• Both measurements of central and peripheral pressures should be reviewed given that treatment decisions often constitute a life-commitment to pharmacotherapy.

Elevated Central BP is Associated with Target Organ Damage

Study Objective: determine relationship of blood pressures to target organ damage

Subjects: N= 1,169, ≥ 16 years old, randomly recruited from Johannesburg, South Africa

Booysen et al. Aortic, but not brachial blood pressure category enhances the ability to identify target organ changes in normotensives. J Hypertension 2013;31:1124-30.

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<tr>
<th>Brachial BP (mm Hg)</th>
<th>Optimal &lt;120/80</th>
<th>Normal/High Normal ≥120/80 + &lt;140/90</th>
<th>Hypertension ≥140/90 or Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Systolic BP (mm Hg)</td>
<td>-</td>
<td>&lt;112</td>
<td>≥112</td>
</tr>
<tr>
<td>Unadjusted Values</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>eGFR (ml/min/1.73m²) (n)</td>
<td>128±32 (244)</td>
<td>126±32 (108)</td>
<td>111±26 (149)</td>
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<td>LVMI (g/m²) (n)</td>
<td>35.5±10.2 (181)</td>
<td>38.2±11 (82)</td>
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<tr>
<td>Adjusted Values</td>
<td></td>
<td></td>
<td></td>
</tr>
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Central pressure added relevant data determining risk of end-organ damage

eGFR: estimated glomerular filtration rate; LVMI left ventricle mass index
Multivariate adjustment for age, sex, BMI, diabetes mellitus and/or an HbA1c>6.1%, regular tobacco use, regular alcohol intake and pulse rate.
Threshold Values for Central Aortic Systolic BP and CV Outcomes

Study

- **Objective**: determine thresholds for predication of CV outcomes
- **Design**
  - Derivation cohort (1,272 individuals, median follow-up of 15 years)
    - Determined diagnostic thresholds using guideline-endorsed cut-offs for brachial blood pressure with a bootstrapping method (resampling by drawing randomly with replacement) and an approximation method.
    - Validated with an independent cohort (validation cohort, 2,501 individuals, median follow-up of 10 years)

Results

- Derivation and validation cohort yielded similar threshold values for central aortic pressures.
- Relative to optimal (central BP < 110/80 mmHg), the risk of CV mortality in subjects with hypertension (central BP ≥ 130/90 mm Hg) was clinically and statistically elevated (hazard ratio: 3.08, 95% CI 1.05 to 9.05).

Conclusion

- Central BP ≥ 130/90 mm Hg was associated with the largest contribution to the prediction of cardiovascular events.

Threshold Values for Central Aortic Systolic BP and CV Outcomes

Proposed Threshold Values for Central Aortic Pressure

**Optimal:** BP<110/80 mmHg

**Prehypertension:** 110-129 / 80-89 mm Hg
- corresponding to “elevated” and Stage 1 hypertension in the 2017 Guidelines

**Hypertension:** ≥130/90 mm Hg
- corresponding to Stage 2 hypertension in the 2017 Guidelines

With increasing systolic BP cutoff values, specificity (SPE) improved at the expense of decreasing sensitivity (SEN). Reasonable cutoff limits for central SBP can be determined by approximating based on the sensitivity or specificity of the guideline-endorsed cuff SBP cutoff points.

Threshold Values for Central BP (CBP) and CV Outcomes

CBP Levels and CV Mortalities With Different Cuff SBP and DBP Cutoffs Based on Conventional Criteria in the Derivation Cohort

<table>
<thead>
<tr>
<th>Hypertension Staging</th>
<th>Category</th>
<th>Diagnostic Thresholds for Cuff BP, mm Hg</th>
<th>Cardiovascular Mortalities, %</th>
<th>Corresponding CBP Levels, mm Hg (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimal–pre-hypertension</td>
<td>SBP</td>
<td>120</td>
<td>2.7</td>
<td>112.80 (111.15–113.61)</td>
</tr>
<tr>
<td></td>
<td>DBP</td>
<td>80</td>
<td>4</td>
<td>80.92 (79.60–82.22)</td>
</tr>
<tr>
<td>Prehypertension–hypertension</td>
<td>SBP</td>
<td>140</td>
<td>4.3</td>
<td>132.43 (130.89–133.88)</td>
</tr>
<tr>
<td></td>
<td>DBP</td>
<td>90</td>
<td>5</td>
<td>90.98 (89.93–91.96)</td>
</tr>
</tbody>
</table>

The cutoff criteria are based on international standards. Point estimates and 95% CIs were obtained from the bootstrap distribution of 1,000 random samples with replacement of CBP levels for participants in the derivation cohort.

Hazard Ratios for Total, Cardiovascular, and Stroke Mortality in Relation to CBP at Entry in the Validation Cohort (n=2,501)

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>Total Death</th>
<th>Cardiovascular Death</th>
<th>Stroke Death</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>185 (7.4%)</td>
<td>34 (1.36%)</td>
<td>18 (0.72%)</td>
</tr>
<tr>
<td>Pre-hypertension vs. optimal BP</td>
<td>1.31 (0.87–3.35)</td>
<td>1.59 (0.57–4.43)</td>
<td>1.93 (0.45–8.31)</td>
</tr>
<tr>
<td>Hypertension vs. optimal BP</td>
<td>2.14 (1.36–3.35)</td>
<td>3.08 (1.05–9.05)</td>
<td>6.12 (1.43–26.21)</td>
</tr>
</tbody>
</table>

Values are n (%) or hazard ratio (95% CI). Hazard ratios were adjusted for sex, age, body mass index, smoking, and serum total cholesterol level.

Threshold Values for Central Aortic Systolic BP

Discussion

“…in current international guidelines, the classification of cuff BP values disregards age, sex, and other cardiovascular risk factors. In our multivariate model, the results were consistent after accounting for these factors. In line with current clinical practice and considering the higher clinical events in the aged population, we now propose diagnostic thresholds of central BP without age and sex specification.”

Regarding “spurious systolic hypertension” and “white coat hypertension”, the authors recognized the clinical utility of measuring central aortic BP in that the diagnosis can be inferred based on a high cuff (brachial) BP and low/normal central BP.
Threshold Values: Associations of Systolic Pressures with MACE*

Prospective study

- 13,461 patients using available central blood pressure measurements and follow-up data from administrative databases
- 1,327 MACE, median follow-up ≈9 years)

Hazard ratio for risk of MACE* (for 1 SD increase)

- Central SBP 1.16 (95% CI 1.09-1.22)
- Brachial SBP 1.15 (95%CI 1.09-1.22)
- Modeling data (AUC) for risk indicated a slightly higher risk using cSBP vs. brachial SBP that was statistically significant

Conclusion

- Central and brachial SBPs of 112 mm Hg (95% CI, 111.2–114.1) and 121 mm Hg (95% CI, 120.2–121.9) were identified as optimal BP thresholds.

*MACE: Major Adverse Cardiovascular Events

White Coat Hypertension: The Role of Central Pressure Measurements
White Coat Hypertension

Definition

• An elevated BP in an office setting with normal values for home-assessed blood pressure values (ambulatory blood pressure monitoring (ABPM) or home blood pressure monitoring (HBPM))

Prevalence

• Somewhat variable among published research
• Meta-analysis (7 studies, 11,502 participants): 13%\(^1\)
• National registry study: 35%\(^2\)
• National and international registries: 10% and 50%\(^3\)

Diagnosis

• Requires confirmation with repeated office and out-of-office BP measurements, including ABPM

Payer Response

• CMS has provided reimbursement for ABPM for suspected white coat hypertension since 2001
• In 2019, CMS expanded ABPM coverage to include masked hypertension

Reality

• Use of ambulatory blood pressure monitoring is low given the documented prevalence of white coat hypertension

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White Coat Hypertension: Summary

Definition
• ESH: clinic BP ≥ 140/90 mm Hg + mean 24-hour BP < 130/80 mm Hg
• ACC/AHA: clinic BP ≥ 130/80 + daytime ambulatory or home BP < 103/80 mm Hg
• NICE: clinic BP ≥ 140/90 mm Hg + daytime ambulatory or home BP < 103/80 mm Hg

Etiology
• Psychological factors (stress, anxiety)

Physiology
• Poorly understood, sympathetic and endocrine factors implicated, possible poor BP technique

Relevance*
• Increased risk of sustained hypertension
• Worse target organ damage
• Some studies – higher rates of CVD

*Cardiovascular (CV) clinical relevance compared to people with normal blood pressure


Threshold Values for Central Systolic BP and Organ Damage

Study Objective

- Prevalence of central hypertension and its association with end-organ damage in 1,983 elderly people

Hypertension Definition

- Brachial BP ≥140/90 mmHg or using antihypertensive medications
- Central BP ≥130/90 mmHg or using antihypertensive medications

Population Groups

<table>
<thead>
<tr>
<th>Brachial Hypertension</th>
<th>Central Hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>BCCN, 563 (28.4%)</td>
</tr>
<tr>
<td>Yes</td>
<td>IBH, 46 (2.3%)</td>
</tr>
</tbody>
</table>

BCCN: brachial & central consistent normotension
BCCH: brachial & central consistent hypertension
IBH: isolated brachial hypertension (e.g., white coat hypertension)
ICH: isolated central hypertension (e.g., masked hypertension)

Threshold Values for Central Systolic BP and Organ Damage

Organ Damage

ANCOVA performed to compare the mean levels between subtypes of brachial and central hypertensions. The mean values of LVMI and UACR in different subtypes and the results of comparisons are displayed.

*p<0.05, compared with BCCN
LVMI, left ventricular mass index
UACR, urinary albumin-creatinine ratio.

Central pressure added relevant data determining risk of end-organ damage

Role of Central BP in White Coat Hypertension

Study Objective

• Investigate whether prognosis of ISH in young-to-middle-age individuals differs according to central BP

Study Population

• Isolated systolic hypertension: 354 participants (18 to 45 years), Stage 1 hypertension, untreated
• Control group of 34 participants with normal blood pressure
• Divided into groups based on the group median central systolic pressure (120.5 mm Hg)
  • Low (ISH-low) <120.5 mm Hg
  • High (ISH-high) ≥120.5 mm Hg
• Duration of follow-up = 9.5 years

Role of Central BP in White Coat Hypertension

Incidence of Sustained Hypertension Needing Antihypertensive Treatment

(A) Median Central Pressure = 120.5 mm Hg

(B) Median Central Pressure = 125 mm Hg

NT: BP<140/90 mmHg; ISH-low: isolated systolic hypertension + central SBP<120.5 mmHg (figure a) [125 mm Hg for figure b]; ISH-high: isolated systolic hypertension + central SBP>120.5 mmHg; SDH: BP>140/90 mmHg (systolic/diastolic hypertension)
P-values adjusted for age, sex, baseline BMI and change during the follow-up, lifestyle factors, parental hypertension, follow-up duration, 24-h SBP and DBP, and 24-h heart rate.

Role of Central BP in White Coat Hypertension

Results
Odds ratio for developing sustained hypertension:
• ISH-high vs. control = 6.0 (95% CI 1.5 – 24.0, p=0.01)
• ISH-low vs. control group = 1.1 (95% CI 0.2 – 5.3, p=0.90)
• Associations remained statistically significant when a threshold central systolic pressure of 125 mm Hg was used and when the model included ambulatory blood pressure

Conclusion
Including central pressure measurement in the assessment and management of hypertension is clinically relevant.

Implications for Pharmacotherapy
Optimizing Hypertension Pharmacotherapy

Pharmacotherapy Concerns
- Undertreatment, overtreatment, compliance, drug cost, adverse events, drug interactions
- Generally, lifetime treatment
- All above impact a patient’s adherence behavior to prescribed treatment and the burden of hypertension

Prescription Optimization
- Optimizing prescription medication including self-administration of therapy is critical to controlling hypertension
Optimizing Hypertension Pharmacotherapy

Incorporation of PWA into the treatment paradigm for hypertension (i.e., in addition to brachial pressure monitoring) can provide clinically relevant value to patient care:

1. Confirmation of hypertension so that initiation of medication is more likely to be the correct decision for an individual patient
   **Scenario**: Concurrent elevation in brachial and central pressures

2. Avoiding initiation of medication when white coat hypertension is suspected
   **Scenario**: Elevated brachial pressure and normal central pressures

3. Confirmation that increased treatment may not be needed
   **Scenario**: Borderline high peripheral pressures and normal central pressures

4. Targeting when to consider reduction of medication
   **Scenario**: Normal peripheral and low central pressures, or extended period of normal peripheral and normal central pressures (particularly in the setting of medication tolerance issues)
Using Central Arterial Pressure to Guide Hypertension Management

BP Guide Study

- 286 hypertensive patients randomized to best-practice brachial BP management* +/- PWA

- Hypertension management guided by PWA resulted in significantly less medication needed to maintain brachial BP control

- 16% of PWA guided patients had complete cessation of medication vs. only 2% of usual care

- No adverse effects on LV mass, aortic stiffness, or quality of life in the PWA guided treatment cohort

Between-group change in daily defined dose (DDD) of antihypertensive medications.

*Best-practice usual care included office, home, and 24-hour ambulatory blood pressure

Using Central Arterial Pressure to Guide Hypertension Management

BP Guide Study: BP Results

No differences in between-group changes in 7-day home systolic BP. (Figure)

- Diastolic BP was higher in the intervention group at 6 and 12 months but was still below the threshold of raised home diastolic BP

No relevant changes office brachial BP, central BP or 24-hour ambulatory BP.

Morbidity from Hypertension Medications

• Overtreatment may occur if office-based cuff measurements are misleadingly high
• Potential consequences of over-treatment
  • Adverse effects specific to the medication class (e.g., cough with ACE inhibitors)
  • Adverse effects common to all anti-hypertensive medications (i.e., hypotension)
• Elderly patients are likely more susceptible to hypotension and associated adverse consequences
• Association of BP with CV events appears to be bimodal with higher rates at both low and high blood pressures.\(^1\)
• Several studies have noted an increased mortality in elderly patients related to lower treated blood pressure.\(^2,3\)
• Reduced kidney function was associated with lower BP in a study in older subjects.\(^4\)
• Older hypertensive patient have an increased risk of postural hypotension, balance and gait impairment, confusion, and dizziness.\(^5\)
• Increased risk for injuries related to falls may result from overly aggressive treatment of hypertension.\(^5\)

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Low BP and Increased Mortality in Patients with CAD

Study Group
10,001 patients with CAD followed ≈5 years

Results
Patients with pre-existing CAD + low BP (110–120/60–70 mmHg) had an increased risk of CV events other than stroke and mortality

Solid line: HR
Dotted lines: 95% CI

Mortality in Chronic Kidney Disease (CKD) and Low BP

**Study Design:** Historical cohort during 2005–2012 (Veterans Affairs Health Care Facilities)

**Patients:** 651,749 US veterans with CKD

**Results:**
- Lowest mortality: BP 130–159/70–89 mmHg
- Highest mortality: SBP and DBP concomitantly very high or very low
- Results were consistent in subgroups of patients with normal and elevated levels of urine microalbumin-creatinine ratio.

Increased Mortality in Chronic Kidney Disease (CKD) and Low BP

**Study Design:** Historical cohort during 2005–2012 (Veterans Affairs Health Care Facilities)

**Patients:** 651,749 US veterans with CKD

**HR (95%) CI for Mortality Across Hypertension Categories**

<table>
<thead>
<tr>
<th>SBP &lt;120 mm Hg and DBP &lt;80 mm Hg</th>
<th>SBP 120–139 mm Hg or DBP 80–89 mm Hg</th>
<th>SBP 140–159 mm Hg or DBP 90–99 mm Hg</th>
<th>SBP ≥160 mm Hg or DBP ≥100 mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.00 (reference)</td>
<td>0.94 (0.93–0.95)</td>
<td>1.08 (1.06–1.10)</td>
</tr>
<tr>
<td>2</td>
<td>1.00 (reference)</td>
<td>0.93 (0.92–0.95)</td>
<td>1.04 (1.02–1.06)</td>
</tr>
<tr>
<td>3</td>
<td>1.00 (reference)</td>
<td>0.94 (0.93–0.95)</td>
<td>1.06 (1.04–1.07)</td>
</tr>
<tr>
<td>4</td>
<td>1.00 (reference)</td>
<td>0.95 (0.94–0.96)</td>
<td>1.05 (1.03–1.07)</td>
</tr>
<tr>
<td>5</td>
<td>1.00 (reference)</td>
<td>0.95 (0.94–0.96)</td>
<td>1.05 (1.03–1.07)</td>
</tr>
</tbody>
</table>

†Models represent unadjusted association (model 1) and associations after adjustment for age, sex, and race (model 2); model 2 variables plus diabetes mellitus, CV and cerebrovascular disease, chronic heart failure, Charlson Comorbidity Index scores (model 3); model 3 variables plus medication use (angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers; α-blockers, β-blockers, and calcium channel blockers; loop and thiazide diuretics; and cholesterol-lowering agents) (model 4); and model 4 variables plus eGFR rates and blood cholesterol levels (model 5).

Effects of Intensive BP Control in Type 2 Diabetes Mellitus

Study Population
- 4,733 participants with type 2 diabetes, follow-up 4.7 years (mean)

Study Arms
- Intensive therapy (IT) (systolic<120 mm Hg) vs. standard therapy (ST) (systolic<140 mm Hg)

Primary Outcome
- Composite of nonfatal myocardial infarction, nonfatal stroke, or death from cardiovascular causes.

Results

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Intensive</th>
<th>Standard</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>1.9%</td>
<td>2.1%</td>
<td>0.2</td>
</tr>
<tr>
<td>Death¹</td>
<td>1.3%</td>
<td>1.2%</td>
<td>0.55</td>
</tr>
<tr>
<td>Serious Adverse Event²</td>
<td>3.3%</td>
<td>1.3%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Elevated creatinine</td>
<td>23.8%</td>
<td>15.5%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>eGFR³</td>
<td>4.2%</td>
<td>2.2%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Renal Failure⁴</td>
<td>0.2%</td>
<td>0.04%</td>
<td>0.12</td>
</tr>
</tbody>
</table>

1. Annual rates
2. Attributed to antihypertensive medications
3. eGFR: estimated glomerular filtration rate (<30 ml/min/1.73m²)
4. Represents 5 vs. 1 patient

Effects of Intensive BP Control in Type 2 Diabetes Mellitus

Increased Serious Adverse Events Attributed to Blood-Pressure Medications In the Intensive Therapy Group

<table>
<thead>
<tr>
<th>Serious Adverse Events n(%)</th>
<th>Intensive Therapy</th>
<th>Standard Therapy</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event attributed to blood-pressure medications</td>
<td>77 (3.3)</td>
<td>30 (1.27)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypotension</td>
<td>17 (0.7)</td>
<td>1 (0.04)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Syncope</td>
<td>12 (0.5)</td>
<td>5 (0.21)</td>
<td>0.10</td>
</tr>
<tr>
<td>Bradycardia or arrhythmia</td>
<td>12 (0.5)</td>
<td>3 (0.13)</td>
<td>0.02</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>9 (0.4)</td>
<td>1 (0.04)</td>
<td>0.01</td>
</tr>
<tr>
<td>Angioedema</td>
<td>6 (0.3)</td>
<td>4 (0.17)</td>
<td>0.55</td>
</tr>
<tr>
<td>Renal failure</td>
<td>5 (0.2)</td>
<td>1 (0.04)</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Summary
New Paradigm of Incorporating Central Pressures: Not a New Concept

Analogies to Advancement in Medical Evaluation
- Fasting blood glucose followed by introduction of HbA1C
- Electrocardiograms followed by introduction of echocardiogram
- COPD Guidelines: FEV$_1$ only, followed by incorporation of COPD exacerbations

Every-Day Analogies
- 2-factor identification
- Dead-bolt lock in addition to regular latch and lock

Common Sense Practice of Medicine
- BP measurement needs to be correct and confirmed
- Brachial pressures and central aortic pressures should be considered as part of management of all patients requiring blood pressure management, but particularly those with renal and/or cardiac disease
Economic Implications

- Reduced additional costs for confirmation of white coat hypertension (reduced ABPM, repeated office visits)
- Avoidance of medication costs for treatment when elevation in brachial blood pressure (untreated and treated hypertension) is not reflective of the usual physiologic state
- Reduced costs due to avoidance of medication adverse effects (medication specific, hypotension)
- Earlier treatment when there is confirmation of hypertension with associated reduction in socioeconomic costs due to subsequent reduced morbidity
- Guidance to attempting trials of medication reduction in treated patients who may have low or low-normal central pressures and normal brachial pressures
Summary and Conclusions (1)

Hypertension

• Responsible for continued morbidity and high socioeconomic costs despite the widespread availability and use of cuff brachial artery measurements for diagnosis and monitoring.

Brachial blood pressure monitoring

• Elevated pressure predicts CV events, mortality, and organ damage (e.g., LVH, intima-medial thickness and reduced GFR).
• Lowering elevated brachial BP reduces the risk of CV events and improves survival.

Central aortic systolic pressure monitoring

• Elevated pressure predicts CV events, mortality, and organ damage (e.g., LVH, intima-medial thickness and reduced GFR).
• Correlated to brachial systolic pressures.
• Risk of adverse outcomes with elevated central pressure is at least as high and possibly higher than with brachial pressure.
• Central systolic pressure is independently predictive of CV events and therefore provides additional risk information.

Conclusion

• Lowering elevated central systolic pressures will reduce the risk of CV events.
Summary and Conclusions (2)

Central Pressures

• Threshold values for the diagnosis and treatment of elevated central pressures have been defined.

Incorporation of central pressures into hypertension management has the following advantages:

• Confirmation of hypertension so that initiation of medication is more likely to be the correct decision for an individual patient (concurrent elevation in brachial and central pressures).

• Avoiding initiation of medication when white coat hypertension is suspected (elevated brachial pressure and normal central pressures).

• Confirmation that increased treatment may not be needed (borderline high peripheral pressures and normal central pressures).

• Targeting when to consider reduction of medication (normal peripheral and low central pressures, or extended period of normal peripheral and normal central pressures particularly in the setting of medication tolerance issues).

Conclusions

• Incorporation of central aortic pressure monitoring, which is complementary to continued reliance on brachial pressure monitoring, should be a part of the care of all patients with hypertension.

• The Dual Arterial Pressure SphygmoCor XCEL system provides both peripheral and central pressures in the same office-based setting and therefore represents a cost-effective addition to BP management.
How to Use Central Blood Aortic Blood Pressure
BP Thresholds and Recommendations for Treatment and Follow-Up


A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Colors correspond to Class of Recommendation in Table 1. 'Using the ACC/ANA Pooled Cohort Equations (58.1.2-56,56.1.2-57). Note that patients with DM or CKD are automatically placed in the high-risk category. For initiation of RAS inhibitor or diuretic therapy, assess blood tests for electrolytes and renal function 2 to 4 weeks after initiating therapy. †Consider initiation of pharmacological therapy for stage 2 hypertension with 2 antihypertensive agents of different classes. Patients with stage 2 hypertension and BP ≥160/100 mm Hg should be promptly treated, carefully monitored, and subject to upward medication dose adjustment as necessary to control BP. Reassessment includes BP measurement, detection of orthostatic hypotension in selected patients (e.g., older or with postural symptoms), identification of white coat hypertension or a white coat effect, documentation of adherence, monitoring of the response to therapy, reinforcement of the importance of adherence, reinforcement of the importance of treatment, and assistance with treatment to achieve BP target. ACC indicates American College of Cardiology; AHA, American Heart Association; ASCVD, atherosclerotic cardiovascular disease; BP, blood pressure; CKD, chronic kidney disease; DM, diabetes mellitus; and RAS, renin-angiotensin system.
Guidelines for Hypertension (2017)

Normal BP (BP < 120/80 mmHg)
- Promote optimal lifestyle habits
- Reassess in 1 year (Class IIa)

Elevated BP (BP 120-129/>80 mmHg)
- Nonpharmacological therapy (Class I)
- Reassess in 3-6 months (Class I)

Stage 1 HTN (BP 130-139/80-89 mmHg)
- Clinical ASCVD or est. 10-yr CVD risk ≥ 10%
- N
  - Nonpharmacological therapy (Class I)
  - Reassess in 3-6 months (Class I)
- Y
  - Nonpharmacological therapy and BP-lowering medication (Class I)
  - Reassess in 1 months (Class I)

Stage 2 HTN (BP > 140/90 mmHg)
- Nonpharmacological therapy and BP-lowering medication (Class I)

BP goal met?
- N
  - Assess and optimize adherence to therapy
  - Consider intensification of therapy
  - Reassess in 3-6 months (Class I)
- Y

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines
Selection of Central Pressure Variable for Incorporation into Guidelines

Overall

- All variables add value to the understanding of the physiology and impact of high blood pressure; however, for practical purposes, focus is one variable as the key to management decisions.

Variables considered

- Pulse Pressure – Ease of calculation, may be relevant, but not currently in any hypertension guidelines.
- Central diastolic pressure – expected to be similar to peripheral diastolic pressure with minimal if any additional value.
- Augmentation Index (or Pressure) – Although relevant, significant education would be required. Not in any current guidelines and threshold values not well-defined.
- Central systolic pressure – Peripheral systolic pressure is in guidelines (i.e., analogous variable), thresholds have been proposed, minimal increase in education.

Proposed Guideline

- Central systolic pressure (cSBP) is most practical variable for initial focus. Possible inclusion of augmentation index (or pressure) for specialized practices.
- Threshold cSBP values: normal < 113 mm Hg, elevated/stage 1 hypertension: 113 – 129 mm Hg, stage 2 hypertension: ≥130 mm Hg
**Normal BP**
(BP < 120/80 mmHg)

- Promote optimal lifestyle habits

**Normal cSBP**
(cSBP < 113 mmHg)

**Elevated cSBP**
(cSBP ≥ 113 mm Hg*)

Reassess in 1 year
(Class IIa)

---

**PROPOSED GUIDELINE**

**Scenario: Normal Brachial BP**

- No change in guideline

---

*cSBP cannot exceed brachial systolic BP (i.e., will always be < 120 mm Hg)*
Elevated BP (BP 120-129/>80 mmHg)

Normal cSBP (cSBP < 113 mm Hg)

Elevated cSBP Hypertension (cSBP 113 - 129 mmHg)

White Coat Hypertension

Nonpharmacological therapy (Class I)

Reassess in 3-6 months (Class I)

PROPOSED GUIDELINE

Scenario: Elevated Brachial BP

- Diagnosis of White Coat Hypertension when cSBP is normal
- Schedule routine follow-up
Scenario: Stage 1 Hypertension

- Largest impact in management decisions
- Diagnosis of White Coat Hypertension when cSBP is normal
- cSBP hypertension – confirmation of hypertension and initiation of treatment
- Incorporate cSBP in follow-up for management decisions related to increasing or decreasing medications
Scenario: Stage 2 Hypertension

- Diagnosis of White Coat Hypertension when cSBP is normal
- Schedule follow-up in 3 to 6 months
- Incorporate cSBP in follow-up for management decisions related to increasing or decreasing medications

**PROPOSED GUIDELINE**

Stage 2 HTN (BP > 140/90 mmHg)

Normal cSBP cSBP < 113 mmHg

Nonpharmacological therapy and BP-lowering medication (Class I)

Reassess in 3-6 months

CSPB Hypertension (cSBP ≥ 113 mmHg)

White Coat Hypertension

Reassess in 3-6 months

**BP goal met?**

- Y: Reassess in 3-6 months (Class I)
- N: Assess and optimize adherence to therapy
  - Consider intensification of therapy
CPT® Category I Code 93050: Arterial Pressure Waveform Analysis

- Coding request sponsored by Renal Physicians Association (RPA)
- CPT Category I code 93050 assigned, effective January 1, 2016

Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive

(Do not report 93050 in conjunction with diagnostic or interventional intra-arterial procedures)