INTERNATIONAL REGISTRY FOR AMBULATORY BLOOD PRESSURE AND ARTERIAL STIFFNESS TELEMONITORING

VASOTENS Registry

Vascular health ASsessment Of The hypertENSive patients

Project Coordinator:
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Clinical Research Unit
Italian Institute of Telemedicine
Solbiate Arno (Varese)
Italy

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Russia
Agenda of the start-up meeting

18:00  Welcome

Stefano Omboni
Igor Posokhov

18:05  24-hour ambulatory arterial stiffness estimation: current status and perspectives

Stefano Omboni

18:20  The VASOTENS Registry: protocol, activities and schedule

Stefano Omboni
Igor Posokhov

18:45  Discussion
24-hour ambulatory arterial stiffness estimation: current status and perspectives
ABP, central BP and PWV are parameters indicated by current hypertension guidelines as useful for better estimating BP control and vascular impairment of the hypertensive patient.

Recent advances in technology made available devices allowing combined non-invasive estimation of BP and arterial stiffness in ambulatory conditions over the 24-hours.

At present, there is limited evidence on the usefulness of such an approach in the clinical practice and much has still to be done to prove its actual benefit for hypertension management.
Expert consensus document on arterial stiffness: methodological issues and clinical applications

Stephane Laurent\textsuperscript{1*}, John Cockcroft\textsuperscript{2}, Luc Van Bortel\textsuperscript{3}, Pierre Boutouyrie\textsuperscript{1}, Cristina Giannattasio\textsuperscript{4}, Daniel Hayoz\textsuperscript{5}, Bruno Pannier\textsuperscript{6}, Charalambos Vlachopoulos\textsuperscript{7}, Ian Wilkinson\textsuperscript{8}, and Harry Struijker-Boudier\textsuperscript{9} on behalf of the European Network for Non-invasive Investigation of Large Arteries

\textsuperscript{1}Department of Pharmacology and Hôpital Européen Georges Pompidou, Université Paris-Descartes, Faculté de Médecine, Assistance Publique–Hôpitaux de Paris, INSERM U652, 20 rue Leblanc, 75015 Paris, France; \textsuperscript{2}Cardiology Department, University of Wales, Cardiff, UK; \textsuperscript{3}University of Ghent, Heymans Institute of Pharmacology, Ghent, Belgium; \textsuperscript{4}Department of Internal Medicine, Milano-Bicocca University, Monza, Italy; \textsuperscript{5}Service of Angiology, CHUV, University of Lausanne, Switzerland; \textsuperscript{6}Department of Nephrology, Manhes Hospital, Fleury-Merogis, France; \textsuperscript{7}Cardiovascular and Sexual Health Unit, Hippokration Hospital, Athens; \textsuperscript{8}Clinical Pharmacology Unit, Addenbrooke’s Hospital, Cambridge, UK; and \textsuperscript{9}Department of Medicine, Cardiovascular Research Institute, University of Maastricht, Maastricht, The Netherlands

Received 6 May 2006; revised 22 August 2006; accepted 31 August 2006; online publish-ahead-of-print 25 September 2006

See page 2497 for the editorial comment on this article (doi:10.1093/eurheartj/ehi312)
Position statement: Methods for measuring arterial stiffness in clinical practice and research

- **Carotid-femoral PWV** is considered as the “gold standard” measurement of arterial stiffness, has the largest amount of epidemiological evidence for its predictive value for CV events, and requires little technical expertise.

- **Central pulse-wave analysis** provides additional information concerning wave reflections.

- Pulse wave should be analyzed through three major parameters (central pulse pressure, **central systolic pressure and augmentation index**) and should be optimally obtained at the central level (at the site of the carotid artery or the ascending aorta, and either directly recorded or computed from the radial artery waveform using a transfer function analysis).

- Pulse wave analysis has demonstrated predictive value in ESRD, hypertensive and CAD patients, and requires little technical expertise.

Laurent S. et al., Eur Heart J 2006;27:2588-2605
Aortic stiffness expressed as aortic PWV is a strong predictor of future CV events and all-cause mortality. The predictive ability of arterial stiffness is higher in subjects with a higher baseline CV risk.
PWV may enable better identification of high-risk populations that might benefit from more aggressive CVD risk factor management (e.g. younger subjects, diabetics)
Central hemodynamic indexes are independent predictors of future CV events and all-cause mortality. AI predicts clinical events independently of peripheral pressures.
A reduction in central to brachial amplification by some classes of antihypertensive drugs (e.g. beta-blockers and thiazide diuretics) will result in lesser reductions in cSBP despite achievement of target bSBP, and in different effects on AI.

Long-term antihypertensive treatment is associated with significant reductions in PWV vs. placebo, regardless of the magnitude of BP reduction and class of drug.

*\(p<0.05\) vs. placebo; changes are adjusted by age, gender, mean BP, HR and BMI.

Ong K.T. et al., J Hypertens 2011;29:1034-1042
ESH and ESC Guidelines

2013 ESH/ESC Guidelines for the management of arterial hypertension

The Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC)

List of authors/Task Force Members: Giuseppe Mancia (Chairperson) (Italy)*, Robert Fagard (Chairperson) (Belgium)*, Krzysztof Narkiewicz (Section co-ordinator) (Poland), Josep Redón (Section co-ordinator) (Spain), Alberto Zanchetti (Section co-ordinator) (Italy), Michael Böhm (Germany), Thierry Christiaens (Belgium), Renata Cifkova (Czech Republic), Guy De Backer (Belgium), Anna Dominiczak (UK), Maurizio Galderisi (Italy), Diederick E. Grobbee (Netherlands), Tiny Jaarsma (Sweden), Paulus Kirchhof (Germany/UK), Sverre E. Kjeldsen (Norway), Stéphane Laurent (France), Athanasios J. Manolis (Greece), Peter M. Nilsson (Sweden), Luis Miguel Ruilope (Spain), Roland E. Schmieder (Germany), Per Anton Sirnes (Norway), Peter Sleight (UK), Margus Viigimaa (Estonia), Bernard Waeber (Switzerland), and Faiez Zannad (France)
# Predictive value, availability, reproducibility and cost–effectiveness of some markers of organ damage

<table>
<thead>
<tr>
<th>Marker</th>
<th>Cardiovascular predictive value</th>
<th>Availability</th>
<th>Reproducibility</th>
<th>Cost-effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrocardiography</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Echocardiography, plus Doppler</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Estimated glomerular filtration rate</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Carotid intima–media thickness and plaque</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td><strong>Arterial stiffness (pulse wave velocity)</strong></td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Ankle–brachial index</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
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<tr>
<td>Fundoscopy</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
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<tr>
<td><strong>Additional measurements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary calcium score</td>
<td>++</td>
<td>+</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Endothelial dysfunction</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Cerebral lacunae/white matter lesions</td>
<td>++</td>
<td>+</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Cardiac magnetic resonance</td>
<td>++</td>
<td>+</td>
<td>+++</td>
<td>++</td>
</tr>
</tbody>
</table>

Mancia G. et al., Eur Heart J 2013;34:2159-219
<table>
<thead>
<tr>
<th>Marker of organ damage</th>
<th>Sensitivity for changes</th>
<th>Time to change</th>
<th>Prognostic value of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVH/ECG</td>
<td>Low</td>
<td>Moderate (&gt;6 months)</td>
<td>Yes</td>
</tr>
<tr>
<td>LVH/echo</td>
<td>Moderate</td>
<td>Moderate (&gt;6 months)</td>
<td>Yes</td>
</tr>
<tr>
<td>LVH/cardiac magnetic resonance</td>
<td>High</td>
<td>Moderate (&gt;6 months)</td>
<td>No data</td>
</tr>
<tr>
<td>eGFR</td>
<td>Moderate</td>
<td>Very slow (years)</td>
<td>No data</td>
</tr>
<tr>
<td>Urinary protein excretion</td>
<td>High</td>
<td>Fast (weeks–months)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Carotid wall thickness</td>
<td>Very low</td>
<td>Slow (&gt;12 months)</td>
<td>No</td>
</tr>
<tr>
<td>Pulse wave velocity</td>
<td>High</td>
<td>Fast (weeks–months)</td>
<td>Limited data</td>
</tr>
<tr>
<td>Ankle/brachial index</td>
<td>Low</td>
<td>No data</td>
<td>No data</td>
</tr>
</tbody>
</table>

Sensitivity to detect treatment-induced changes, time to change and prognostic value of change by markers of asymptomatic organ damage

Mancia G. et al., Eur Heart J 2013;34:2159-219
## Current recommendation on PWA according to ESH/ESC guidelines

<table>
<thead>
<tr>
<th>Index</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid-femoral PWV</td>
<td>It is the “gold standard” for measuring aortic stiffness (a PWV &gt;10 m/s may indicate asymptomatic organ damage). It is useful for stratification of total CV risk because it has additive value of above and beyond traditional risk factors.</td>
</tr>
<tr>
<td>Central BP and AI</td>
<td>More investigation is needed before recommending their routine clinical use. Only exception is ISH in the young</td>
</tr>
<tr>
<td>Ambulatory PWV, central BP and AI</td>
<td>No recommendation</td>
</tr>
</tbody>
</table>

Mancia G. et al., Eur Heart J 2013;34:2159-219
Non-invasive technologies for PWA

Applanation tonometry
Mechanotransducers
Finger photoplethysmography
Non-invasive technologies for PWA

<table>
<thead>
<tr>
<th>Pneumosystems (oscillometry)</th>
<th>Ultrasonography</th>
<th>MRI</th>
</tr>
</thead>
</table>

![Pneumosystems Image](image1)

![Ultrasonography Image](image2)

![MRI Image](image3)

Flow velocity vs. Time

www.vasotens.org
Techniques for 24-hour PWA

- All based on oscillometric measurements (Mobil-O-Graph, BPLab) or applanation tonometry (BPro) and transfer function analysis
- Different algorithms for the different devices
- All devices are validated against intra-arterial or SphygmoCor method
- Non-invasive estimation of central hemodynamics and arterial stiffness is device/technique dependent
Oscillometric technologies

Some studies of devices used for oscillometric pulse wave velocity measurements

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of observations</th>
<th>Device</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magometschnigg⁷</td>
<td>100</td>
<td>TensioClinic</td>
<td>Comparison with brachial PWV (ShygroCor)</td>
<td>m: 9.1; SD: 1.8 m/second vs m: 8.4; SD: 1.5 m/second</td>
</tr>
<tr>
<td>Rajzer et al¹⁷</td>
<td>64</td>
<td>Arteriograph</td>
<td>Comparison with ShygroCor and with Complior</td>
<td>r = 0.29 (P = 0.043) and r = 0.36 (P = 0.0048)</td>
</tr>
<tr>
<td>Baulmann et al⁸</td>
<td>51</td>
<td>Arteriograph</td>
<td>Comparison with ShygroCor and with Complior</td>
<td>r = 0.67 (P &lt; 0.001) and r = 0.69 (P &lt; 0.001)</td>
</tr>
<tr>
<td>Jatoi et al²⁷</td>
<td>254</td>
<td>Arteriograph</td>
<td>Comparison with Complior</td>
<td>r = 0.60 (P &lt; 0.001)</td>
</tr>
<tr>
<td>Horváth et al¹⁸</td>
<td>22</td>
<td>Arteriograph</td>
<td>Comparison with invasively measured PWV</td>
<td>Pearson’s r = 0.91 (P &lt; 0.001)</td>
</tr>
<tr>
<td>Ageenova and Purygina¹⁰</td>
<td>90</td>
<td>BPLab</td>
<td>Reproducibility and repeatability study</td>
<td>Reproducibility and repeatability: good</td>
</tr>
<tr>
<td>Luzardo et al²⁸</td>
<td>35</td>
<td>Mobil-O-graph</td>
<td>Comparison with ShygroCor at rest</td>
<td>m: 7.3 vs m: 7.0 m/second</td>
</tr>
<tr>
<td>Luzardo et al²⁸</td>
<td>83</td>
<td>Mobil-O-graph</td>
<td>Comparison with ShygroCor (ambulatory)</td>
<td>m: 7.9 vs m: 7.4 m/second</td>
</tr>
</tbody>
</table>

Abbreviations: m, mean; PWV, pulse wave velocity; r, correlation coefficient; SD, standard deviation.
### Published clinical studies based on 24-hour PWA

<table>
<thead>
<tr>
<th>Author Study (year)</th>
<th>Device</th>
<th>Subjects</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theilade et al. (2013)</td>
<td>BPro</td>
<td>629 type 1 diabetics and 86 controls</td>
<td>Aortic SBP was higher in patients and increased with diabetic complications and was stronger associated to complications than peripheral SBP</td>
</tr>
<tr>
<td>Williams et al. AmCAP Study (2013)</td>
<td>BPro</td>
<td>171 hypertensive patients treated with aliskiren (ASSERTIVE Study)</td>
<td>Brachial and central pressure show different diurnal patterns, which are not modulated by BP-lowering therapy, with relatively higher night-time central pressures</td>
</tr>
<tr>
<td>Protogerou et al. SAFAR Study (2014)</td>
<td>Mobil-O-Graph</td>
<td>229 individuals (75% hypertensives)</td>
<td>Aortic SBP, when compared to brachial SBP, improves the individualized assessment of the hypertension-associated heart damage (LVH)</td>
</tr>
<tr>
<td>Elsurer et al. (2014)</td>
<td>Mobil-O-Graph</td>
<td>339 hypertensive CKD patients</td>
<td>Serum uric acid is associated independently with AI, but not with PWV.</td>
</tr>
<tr>
<td>Kuznetsova (2014)</td>
<td>BPLab</td>
<td>467 healthy volunteers</td>
<td>Reference values for PWV, AI and central BP</td>
</tr>
<tr>
<td>Omboni et al. (2015)</td>
<td>BPLab</td>
<td>142 normotensives and 611 hypertensives</td>
<td>Non-invasive assessment of 24-hour arterial stiffness and central hemodynamics in daily life conditions may help in assessing the arterial function impairment in hypertensive patients</td>
</tr>
<tr>
<td>Maloberti (2015)</td>
<td>Mobil-O-Graph</td>
<td>119 pediatric patients and 23 controls in Williams-Beuren syndrome</td>
<td>Increased night-time AI in sick children is an early hallmarks of cardiovascular dysfunction</td>
</tr>
<tr>
<td>Karpetas (2015)</td>
<td>Mobil-O-Graph</td>
<td>153 ESRD patients during successive dialytic sessions</td>
<td>A gradual interdialytic increase in AI and to a less extent in PWV is observed</td>
</tr>
</tbody>
</table>
The Vasotens technology

A. Waveform of brachial artery

B. Amplitude and phase characteristics of the Vasotens transfer function

C. Waveform of aorta and main calculations

SBP, DBP = systolic and diastolic BP; SBPao, DBPao = BP in aorta; AP = augmentation pressure [Alxao = (SBPao-DBPao)/AP]; RWTT = reflected wave transit time, used in PWV formula; PWV = (k)2L/RWTT, where L = superficial morphological distance
The Vasotens technology
Screen of analysis window in BPLab / Vasotens software
A clinically validated CE and ISO technology

### BP measurement

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Subjects</th>
<th>BHS grade</th>
<th>SBP diff. Mean (SD)</th>
<th>DBP diff. Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Koudryavtcev (2011)</td>
<td>85 adults (18-87 years)</td>
<td>A / A</td>
<td>1.1 (6.4)</td>
<td>-1.2 (7.1)</td>
</tr>
<tr>
<td>Ledyaev (2015)</td>
<td>30 children (5-15 years)</td>
<td>A / A</td>
<td>1.6 (2.2)</td>
<td>0.7 (3.1)</td>
</tr>
<tr>
<td>Dorogova (2015)</td>
<td>30 pregnant women (20-35 years)</td>
<td>A / A</td>
<td>0.0 (2.1)</td>
<td>0.2 (2.2)</td>
</tr>
</tbody>
</table>

### PWA

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Subjects</th>
<th>Results (BPLab vs. SphygmoCor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rogoza (2012)</td>
<td>160 patients and healthy volunteers (18-81 years)</td>
<td>Aortic SBP: 122.5 vs. 121.2 (-1.3 mmHg)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aortic AI: 26.1 vs. 26.8 (-0.7%)</td>
</tr>
<tr>
<td>Kotovskaya (2014)</td>
<td>99 subjects (18-77 years) (ARTERY protocol)</td>
<td>Aortic SBP: 123 vs. 120 (2.9 mmHg)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aortic AI: 13 vs. 11 (2.6 %)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aortic PWV: 7.7 vs. 7.0 (0.7 m/s)</td>
</tr>
</tbody>
</table>
### Accuracy of 24-hour PWA across devices

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Mobil-O-Graph</th>
<th>BPro</th>
<th>BPLab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aortic SBP</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(intra-arterial comparison)</td>
<td>+3.0 (6.0)¹</td>
<td>-0.4 / -0.9 (6.2 / 13.0)²</td>
<td>-</td>
</tr>
<tr>
<td>(Sphygmocor comparison)</td>
<td>-1.4 / +1.2 (3.1 / 10.0)⁵</td>
<td>-0.3 / -3.6 (4.4 / 4.8)²</td>
<td>+1.3 / +2.9 (2.4 / 3.5)²</td>
</tr>
<tr>
<td><strong>Aortic AI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(intra-arterial comparison)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(Sphygmocor comparison)</td>
<td>-0.7 / +1.2 (7.9 / 9.5)³</td>
<td>-</td>
<td>-0.8 / +2.6 (10.4 / 13.0)²</td>
</tr>
<tr>
<td><strong>Aortic PWV</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(intra-arterial comparison)</td>
<td>+0.6 (1.0)¹</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(Sphygmocor comparison)</td>
<td>-0.3 / -0.6 (1.1 / 1.3)²</td>
<td>-</td>
<td>+0.7 (1.4)¹</td>
</tr>
</tbody>
</table>

Superscripts refer to the number of studies included in the comparison:
- Mobil-O-Graph: 2 studies vs. intra-arterial (n=150) and 5 studies vs. SphygmoCor (n=631)
- BPro: 2 studies vs. intra-arterial (n=72) and 2 studies vs. SphygmoCor (n=781)
- BPLab: 2 studies vs. SphygmoCor (n=259)
<table>
<thead>
<tr>
<th>Reference</th>
<th>What is described</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rogoza AN, Kuznetsov AA. <em>Research Reports in Clinical Cardiology.</em> 2012</td>
<td>Validation of aortic BP vs SphygmoCor</td>
</tr>
<tr>
<td>Ageenkova OA, Purygina MA. <em>Vasc Health Risk Manag.</em> 2011</td>
<td>Reproducibility and repeatability of CBP and RWTT</td>
</tr>
<tr>
<td>Dorogova IV, <em>Vasc Health Risk Manag.</em> 2015</td>
<td>BHS – 93 validation in pregnant women</td>
</tr>
<tr>
<td>Kuznetsova TY et al. <em>Vasc Health Risk Manag.</em> 2014</td>
<td>Contribution of 24-h pulse wave velocity (day/night), aortic augmentation index and central blood pressure in normotensive volunteers</td>
</tr>
<tr>
<td>Omboni S et al, <em>Int J Hypertens.</em> 2015</td>
<td>Feasibility of evaluation of 24-Hour Arterial Stiffness Indices and Central Hemodynamics in Healthy Normotensive Subjects versus Treated or Untreated Hypertensive Patients</td>
</tr>
</tbody>
</table>
Research Article

Evaluation of 24-Hour Arterial Stiffness Indices and Central Hemodynamics in Healthy Normotensive Subjects versus Treated or Untreated Hypertensive Patients: A Feasibility Study

Stefano Omboni, Igor N. Posokhov, and Anatoly N. Rogoza

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2Hemodynamic Laboratory, P.O. Box 69, Nizhny Novgorod 603009, Russia
3Department of New Methods of Diagnostics, Russian Cardiology Research and Production Complex, Moscow 121552, Russia

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Copyright © 2015 Stefano Omboni et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.
24-hour ambulatory aortic SBP, PWV and AI in a large database of normotensive and hypertensive subjects

Aortic SBP

- Healthy subjects (n=142)
- Hypertensive patients (n=661)

Aortic PWV

- Healthy subjects (n=142)
- Hypertensive patients (n=661)

Aortic AI

- Healthy subjects (n=142)
- Hypertensive patients (n=661)

*, p=0.0001, ** p=0.025, unadjusted

Omboni S., Posokhov I, Rogoza AN. Int J Hypertens 2015:601812
Day-time and night-time aortic SBP, PWV and AI in normotensive vs. hypertensive subjects

*** p<0.001; ** p<0.01

Healthy subjects (n=142)  Hypertensive patients (n=661)
SBP variability vs. Aortic SBP

Weighted SD

- Unadjusted
- Adjusted

ARV

- Unadjusted
- Adjusted

$p=0.0001$

SD <median vs. SD >=median

SD <median

SD >=median

SBP variability vs. Aortic PWV

Weighted SD

ARV

SD <median  SD >=median

p=0.0001  p=0.0001  p=0.0001  p=0.001

Prognostic value of ambulatory central BP and clinical value of 24-hour arterial stiffness estimation (PWV and AI)
The VASOTENS Registry Protocol, activities and schedule
Project objectives - 1

- The evaluation of non-invasive ambulatory BP and arterial stiffness estimates (through pulse wave analysis, PWA) in hypertensive subjects undergoing an ABPM for clinical reasons in the selected centers
- The evaluation of the changes in BP and arterial stiffness estimates following treatment initiation according to current guidelines
- The assessment of the impact of non-invasive arterial stiffness estimation on target organ damage and patient’s CV prognosis
- The definition of the normalcy thresholds for pulse wave velocity (PWV), augmentation index (AI), and other current and future indices derived from PWA in hypertensive subjects, according to outcome data
Project objectives - 2

- The definition of the relationship between arterial stiffness, BP absolute level and variability, and outcomes
- The setup of a worldwide network of centers performing ambulatory PWA, and the validation and promotion of the use of such technique for hypertension screening and follow-up
- The provision of evidence of the clinical relevance of non-invasive arterial stiffness assessment, in order to favor the inclusion of such evaluation in recommendations on hypertension management
Population

- Male and female subjects
- Age ≥18 years
- Subjects referred to routine diagnostic evaluation for hypertension or established hypertensive subjects
- ABPM performed for clinical reasons with a BPLab device
- Valid ABPM (interval between measurements ≤30 minutes, at least 70% of expected number of readings, at least 20 valid readings during the day-time and 7 during the night-time)
- Availability of individual measurements for ABPM on a .bpw file (BPLab format) or data directly uploaded on the telemedicine platform of the study
Study flow-chart

- Family history
- Anthropometric data
- Habits
- Past and current diseases
- Therapies
- Office BP
- Laboratory tests, including evaluation of target organ damage
- Outcomes (adverse events)

Enrolment
≤6-12 months
Periodic visits according to ESH guidelines
≤6-12 months
Periodic visits according to ESH guidelines

www.vasotens.org
Clinical data

- Age and gender
- Ethnicity
- Height, weight and waist circumference
- Superficial distance between jugulum and symphysis (surrogate of aortic length)
- Smoking status, alcohol drinking, coffee or tea drinking
- Dyslipidemia (± therapy)
- Diabetes (± therapy)
- Diagnosis of hypertension (± therapy)
- Family and personal medical history for CV disease
Laboratory tests

- Office BP and heart rate obtained in the same treatment condition as ABPM
- Left ventricular mass index (LVMI) at echocardiogram
- When available, diameter of the aorta (aortic annulus, root and sinotubular junction) and/or cardiac output, assessed by the echocardiogram
- Intima-media thickness (IMT) at carotid ultrasonography
- ECG (indication on left ventricular hypertrophy, Sokolow–Lyon and Cornell index)
- When available, ankle-brachial index (ABI)
- Microalbuminuria and serum creatinine (calculation of estimated glomerular filtration rate - eGFR)
- When available, pulse wave velocity (PWV), augmentation index (AI) and central blood pressure taken during the office visit with a validated device different for the one used in the study (e.g. Sphygmocor or Complior)
The telemedicine system

www.tholomeus.net

Doctor

24-h ambulatory arterial function evaluation

Patient

e-THOLOMEUS software on local PC

medical report

Tholomeus web-based telemedicine platform
Advantages of web-based telemonitoring in the study

- No need of installing software, locally
- Technology always updated
- Standardized and centralized data collection
- Data validation by experts and counselling to remote centers
- Setup and maintenance of the Registry
- Prompt data analysis
The study website

www.vasotens.org

VASOTENS Registry

The "INTERNATIONAL REGISTRY FOR AMBULATORY BLOOD PRESSURE AND ARTERIAL STIFFNESS TELEMONITORING", also called VASOTENS (Vascular health Assessment Of The hypertENSive patients) Registry, has been devised in order to collect evidence on the clinical value of ambulatory arterial stiffness estimation. The final goal of the project is to achieve a possibly standardized and widespread use of integrated ambulatory blood pressure and arterial stiffness evaluation in the clinical management of hypertension, also by providing specific instructions and recommendations to the clinicians on the use of this modern technology. The project is an investigator initiated observational, prospective trial.

Basically, the Vasotens Registry is an open project, collecting common archive of ambulatory blood pressure recordings from all collaborators for subsequent analysis, intending to reach a strong evidence base and to improve risk stratification in arterial hypertension management. The members of the Registry are authors of studies or scientific publications on 24-hour ambulatory monitoring of brachial and central aortic blood pressure and 24-hour pulse wave analysis. Given the open nature of the project, any investigator ready to contribute with ambulatory blood pressure data, which strictly correspond to the established criteria can join the Registry.
THANK YOU FOR ATTENTION!

For any request or communication please e-mail to:

coordinator@vasotens.org