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Vascular health assessment of the hypertensive patients (VASOTENS) Registry: rationale, design and methods of an international registry for ambulatory blood pressure and arterial stiffness telemonitoring

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BACKGROUND

Ambulatory (A) blood pressure (BP), central BP and pulse wave velocity (PWV) are parameters recommended by hypertension guidelines for estimating BP control and vascular impairment. Recent advances in technology made available devices allowing combined non-invasive estimation of these parameters over the 24-h during ABP monitoring (ABPM). However, at present, there is limited evidence on the usefulness of such an approach for routine hypertension management.

TABLE 1. Current recommendations on pulse wave analysis (PWA) according to ESH/ESC guidelines

Index	Recommendation
Carotid-femoral PWV	It is the "gold standard" for measuring aortic stiffness (a PWV >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.
Central BP and augmentation index (AI)	More investigation is needed before recommending their routine clinical use. Only exception is isolated systolic hypertension in the young
Ambulatory PWV, central BP and AI	No recommendation

OBJECTIVE

We recently launched an investigator-initiated, international, multicenter, observational, prospective study with the following objectives:

- The evaluation of non-invasive ambulatory blood pressure and arterial stiffness estimates (through PWA) in hypertensive subjects undergoing an ABPM for clinical reasons in the selected centers;
- The evaluation of the changes in blood pressure 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 cardiovascular prognosis;
- The definition of the normalcy thresholds for PWV, AI and other current and future indices derived from PWA according to outcome data;
- The definition of the relationship between arterial stiffness, blood pressure absolute level and blood pressure 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 on the clinical relevance of non-invasive arterial stiffness assessment, in order to favor the inclusion of such evaluation in recommendations on hypertension management.

METHODS

Approximately 2000 subjects, referred to 20 hypertension clinics for routine diagnostic evaluation and follow-up of hypertension, will be recruited.

TABLE 2. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria

• Male and female subjects, ≥18 years;
• Subjects referred to routine diagnostic evaluation for hypertension or established HT subjects;
• ABPM performed for clinical reasons with a BPLab device;
• The minimum validity requirements are:
  • Interval between measurements not exceeding 30 minutes;
  • At least 70% of expected number of readings;
  • At least 20 valid readings during the day-time and 7 during the nigh-time;
• Availability of individual measurements for ABPM on a .bpw file (BPLab format) or data directly downloaded on the telemedicine platform of the study;
• Availability of basic clinical information;
• Availability of a signed informed consent form.
	• Age <18 years;
	• Atrial fibrillation, frequent ectopic beats, second or third degree atrioventricular blocks, or other conditions which might make difficult or unreliable the automatic blood pressure measurement with the oscillometric technique;
	• Upper arm circumference <22 cm;
	• Pregnancy.

Data collection will include ABPM, performed with a device allowing simultaneous non-invasive assessment of BP and arterial stiffness (BPLab), and clinical data (including cardiovascular outcomes). As recommended by current guidelines, each patient will be followed-up with visits occurring at regular intervals (ideally every 6 months, and not less than once a year) (**Figure 1**).

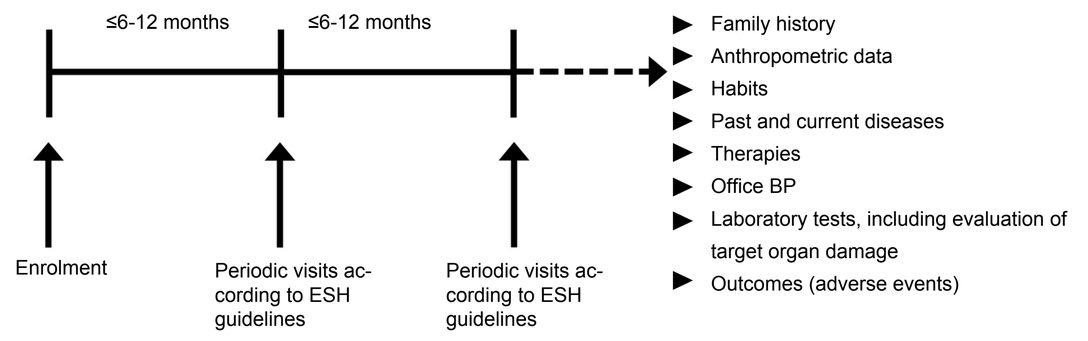

FIGURE 1. Study flow-chart

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 HR 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).

A web-based telemedicine platform (THOLOMEUS, www.tholomeus.net) will be used for data collection (**Figure 2**). The advantages of the use of the telemedicine system are:

- 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.

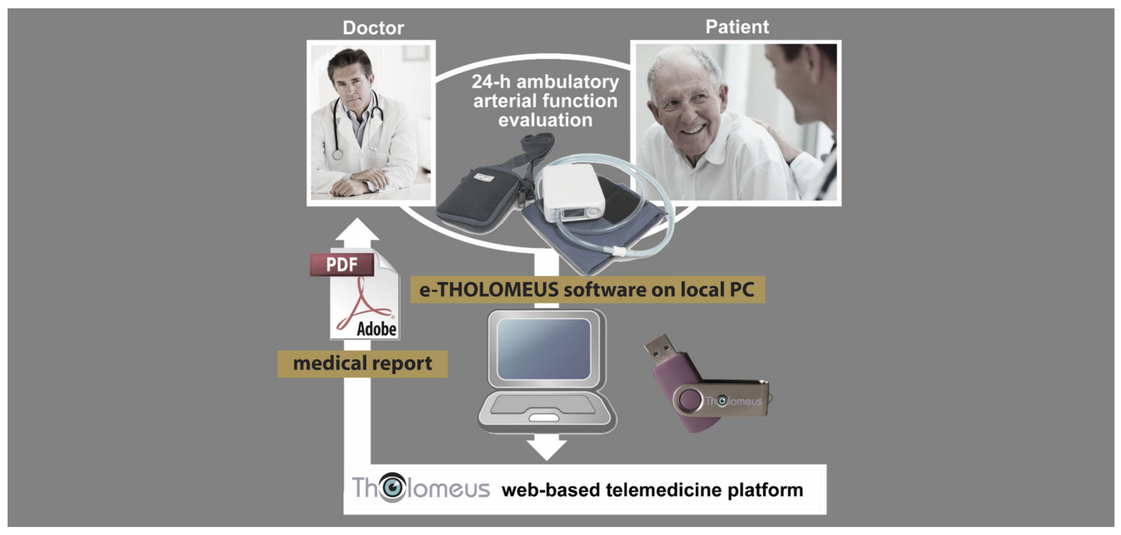

FIGURE 2. The THOLOMEUS telemedicine system

CONCLUSIONS

First follow-up results of the study are expected to be available in the next 2-years. They will help defining the normalcy thresholds for current and future indices derived from 24-h PWA, according to outcome data. They will also provide supporting evidence for the inclusion of such evaluation in recommendations on hypertension management.