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.

METHODS

A multicenter, observational, prospective study with the following objectives:

- The evaluation of non-invasive arterial stiffness estimation on target organ damage and patient’s cardiovascular prognosis;
- The definition of the normality thresholds for PWV, AI and other current and future indices derived from PWA according to outcome data;
- The assessment of the impact of non-invasive arterial stiffness estimation on future indices derived from PWA according to outcome data;
- 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 for hypertension management.

OBJECTIVE

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

- The evaluation of non-invasive arterial stiffness estimation on target organ damage and patient’s cardiovascular prognosis;
- The definition of the normality thresholds for PWV, AI and other current and future indices derived from PWA according to outcome data;
- The assessment of the impact of non-invasive arterial stiffness estimation on future indices derived from PWA according to outcome data;
- 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 for 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

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<tr>
<td>Male and female subjects, ≥18 years</td>
<td>Age &lt;18 years</td>
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<tr>
<td>Subjects referred to routine diagnostic evaluation for hypertension or established HT subjects</td>
<td>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</td>
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<td>ABPM performed for clinical reasons with a BPLab device</td>
<td>Upper arm circumference &gt;22 cm</td>
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<td>The minimum validity requirements are:</td>
<td>Pregnancy</td>
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<td>Interval between measurements not exceeding 30 minutes</td>
<td>Heart failure, significant left ventricular hypertrophy (LVH)</td>
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<td>At least 70% of expected number of readings</td>
<td>Diabetes</td>
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<td>At least 20 valid readings during the daytime and 7 during the nighttime</td>
<td>Severe obstructive sleep apnea, severe chronic renal failure</td>
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<td>Availability of individual measurements for ABPM on a .txt file (BPLab format) or data directly downloaded on the telemedicine platform of the study</td>
<td>No need of installing software, locally</td>
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<td>Availability of basic clinical information</td>
<td>Technology always updated</td>
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<td>Availability of a signed informed consent form</td>
<td>Standardized and centralized data collection</td>
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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
- Supine blood pressure, smoking status, alcohol drinking, coffee or tea drinking
- Diabetes
- Laboratory tests:
  - Office BP and HR obtained in the same treatment condition as ABPM;
  - Left ventricular mass index (LVMI) at echocardiogram;
  - When available, ankle-brachial index (ABI);
  - When available, pulse wave velocity (PWV), augmentation index (AI) and central blood pressure variability during the nocturnal period; (Figure 2). The advantages of the use of the telemedicine system are:

A web-based telemedicine platform (THOLOMEUS, www.tholomeus.net) will be used for data collection (Figure 2).

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 normality 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 for hypertension management.