METHOD AND DEVICE FOR BEAT-TO-BEAT BLOOD PRESSURE MEASUREMENTS

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Abstract: This paper is a part of research which is focused on the development of the convenient device for continuous non-invasive monitoring of arterial blood pressure by non-invasive and non-oscillometric way. Potentially useful parameter for continuous monitoring of blood pressure could be the pulse wave velocity between different regions of human body. It has been demonstrated that systolic blood pressure estimation from this parameter is possible with acceptable accuracy by personal calibration of the method for particular patient. However, most of previous studies are focused on utilizing such measurement on patients in critical conditions; the data of experiments with healthy subjects are quite limited. The blood pressure estimation method is based on a presumption that there is a singular relationship between the pulse wave velocity in arterial system and blood pressure. The measurement of pulse wave velocity involves the registration of two time markers, one of which is based on ECG R peak detection and another on the detection of pulse wave in peripheral arteries. As a result of current study it is shown that with the correct personal calibration it is possible to estimate beat-to-beat systolic arterial blood pressure with comparable accuracy to conventional noninvasive methods.

Introduction

Considering arterial hypertension purely as a major problem in modern medicine and health-care is significant underestimation of the severity of the problem, as most people will develop hypertension during their lifetime. Published data from the Framingham Heart Study suggest that even for those individuals who are normotensive at age 55, there is a 90% chance that they will eventually become hypertensive.[1]. It is a well-known demographic fact that as the population ages, the prevalence of hypertension will increase even further unless broad and effective preventive measures implemented. As traditionally defined – systolic blood pressure (BP) > 140 mm Hg, diastolic BP > 90 mm HG – hypertension affects approximately 50 million individuals in the United States and about one billion persons worldwide. Hypertension remains a common and serious problem, contributing in a major way to the most common causes of morbidity and mortality in developed societies. The risks of elevated BP have been determined from large-scale epidemiologic studies. It is estimated that the diastolic BP that is persistently higher by 5.0 mmHg is associated with at least a 34% increase in stroke risk and at least a 21% increase in coronary heart disease [2]. Improvements in the recognition and treatment of hypertension have played a major role in the significant reduction in cardiovascular diseases over the past two decades. Nevertheless, a great gap between the 3 categories of people – who are aware of their hypertension, who are being treated, and who are controlled – remains. In fact, more than 30% of the hypertensive populations are still unaware they have hypertension, mainly because of the asymptomatic nature of the disease for the first 15-25 years, even as it progressively damages the cardiovascular system.

Although the importance of reduction of BP is well-known from the data of numerous experimental, epidemiologic and clinical studies, only one quarter of hypertensive patients are adequately controlled to a BP of 140/90 mm Hg or less. This threshold suggests that approximately 45 million people only within the United States either are currently untreated or have inadequately treated BP. The situation turns out to be even worse if taking into account that in May 2003 the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC) announced new JNC 7 hypertension guidelines [3], which suggest that BP levels at which action should be taken, are 120-139 mm Hg for systolic and 80-89 mmHg for diastolic BP, a range that was designated as high normal or normal in JNC 6 guidelines [4]. Therefore, despite of sophisticated diagnostic methods and the number of hypotensive drugs available, adequate control of elevated BP and hence, adequate protection against the risk of cardiovascular diseases has yet to be achieved in the vast majority of hypertensive patients.

The early detection of elevated BP is complicated by several factors, among them the

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variability of the pressure on repeated measurements, both at a single visit and on repeated occasions, which is much greater than most physicians realize. The variability of BP can be detected in short-term, daytime and diurnal evaluation. The short-time variability at rest is affected by respiration and changes in heart rate, which is controlled by autonomic nervous system. Daytime variability determined by the degree of mental and physical activity mainly, diurnal variability is substantial, with an average fall in BP for about 15% during sleep. That is why, whenever possible, office measurements should be supplemented by out of the office measurements, particularly when apparent gap between the level of BP and the degree of target organ damage is present. Noninvasive 24-hour ambulatory BP monitoring has became an important and useful tool for stratifying cardiovascular risk and guiding therapy during the last 25 years. It provides multiple BP measurements, avoids potential for observer error, the measurements occur during usual activities of daily living and during sleep, can evaluate circadian variations of BP, exhibit closer correlation to surrogate end points such as left ventricular hypertrophy than office blood pressure, are more reproducible than clinic BP, can assess white-coat hypertension [5]. In addition, ambulatory BP monitoring is essential for the detection of persistently elevated pressure during 2-3 hours after awakening, when the largest proportion of sudden cardiac deaths, myocardial infarctions, and strokes occur. The ambulatory BP recordings are of great use in the assessment of therapeutic interventions efficacy and treatment resistance.

Some technical problems of 24-hour BP recording still exist. Commercially available monitors measure BP by means of auscultators or oscillometric methods. The advantage of the first method is that movement does not interfere with the recording, however, these monitors are sensitive to background noise. The results of the second method are not affected by the background noise, but arm movement can cause errors. In addition, the obstacle, that both measurement systems are based on cuff, which is attached to patient's arm and central unit containing the pump and memory chip, causes certain personal discomfort. The monitors are preprogrammed to record usually every 15-20 minutes during daytime and every 20-30 minutes during nighttime hours, which can cause inconveniences at everyday activities and a loss of important information between the measurements.

Materials and Methods

A potentially useful and convenient parameter for continuous monitoring of the blood pressure could be pulse wave velocity or pulse wave transit time (PWTT) between different regions of the human body [6,7]. It is suggested that although it may be difficult to estimate systolic blood pressure from PWTT with acceptable accuracy, possibilities remain to utilize changes of pulse arrival time as an indicator of changes in systolic blood pressure. During the exercise, arterial blood pressure increases, which is mainly achieved by increasing the contractility of the heart and vasculature resistance. Both of these values result in the increase of pressure wave speed in vascular system, which means that the time delay between the start of electromechanical contraction and pulse wave transit time (PWTT) to any particular point in the body decreases. Current paper is an extension of our previous studies and is focused on development of continuous blood pressure monitoring device with a simplified noninvasive calibration [8-13].

All devices and sensors used in our patient study to get comparable blood pressure data from different sensors are shown on Figure 1. The blood pressure

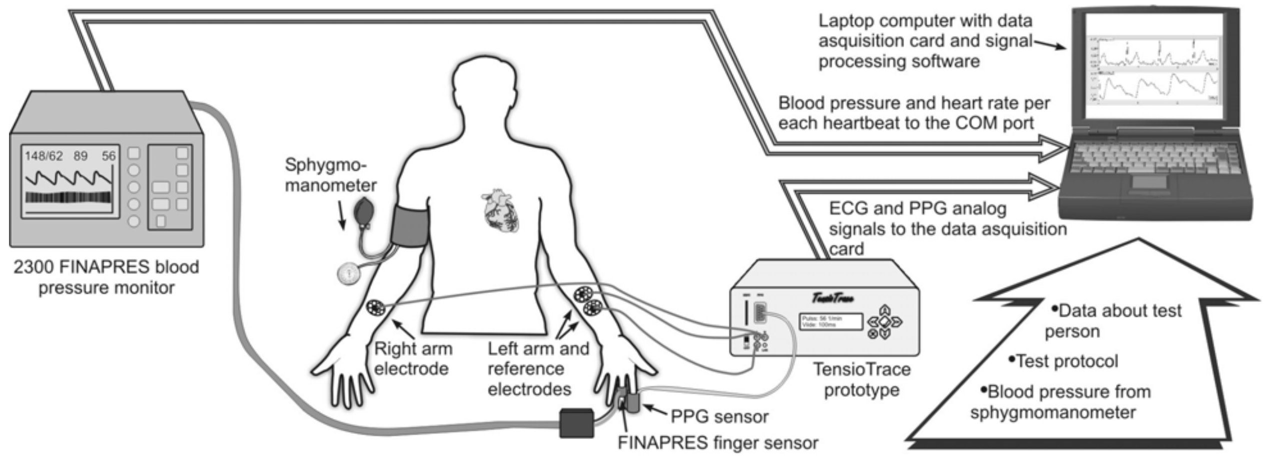

Figure 1: Devices and sensors used in experimental measurements

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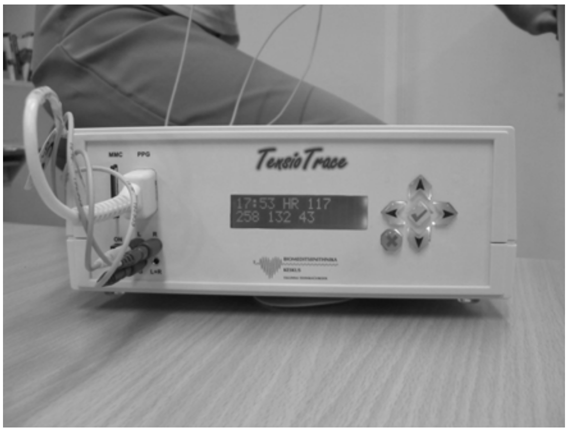

Figure 2: Experimental device TensioTrace for beat-to-beat blood pressure measurements.

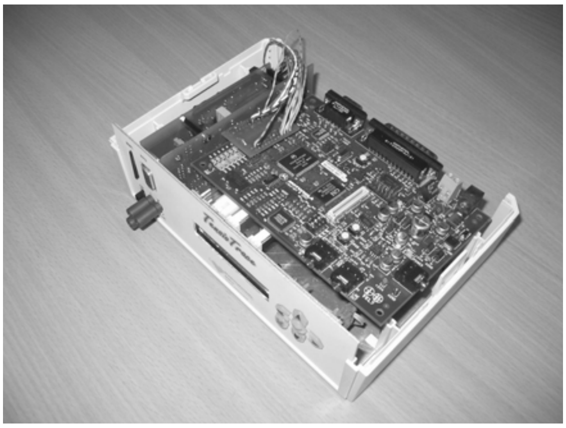

Figure 3: Inside view of an experimental device.

estimation method is based on a presumption that there is a singular relationship between the pulse wave velocity in arterial system and blood pressure. The measurement of pulse wave velocity involves the registration of two time markers, one of which is based on ECG R peak detection and another on the detection of pulse wave in peripheral arteries. With the correct personal calibration it is possible to estimate the beat-to-beat systolic arterial blood pressure during the exercise with comparable accuracy to conventional noninvasive methods.

A portable experimental blood pressure monitoring device TensioTrace consists of two analogue signal acquisition modules, one for ECG and another for PPG signal. The outside and inside view of this device are shown on Figures 2 and 3. The digital part of the device based on a Motorola signal processor (DSP56F803). The frequency of discretisation for the signals 500Hz. Pulse wave velocity calculated online, both analogue signals and the measured values are stored on a flash memory card and can later be reviewed by PC. The device can be calibrated in order to make online conversion of time values to systolic arterial pressure. A regular blood pressure measurement device can be used as a calibrator. Calibration means the measurement of arterial blood pressure during relaxed condition simultaneously with the time measurements and manual entering measured blood pressure values into device. The device thereafter calculates coefficients for linear conversion formula – slope and intercept. For correct calibration two measurements of blood pressure is needed in different levels. The ECG electrodes are placed on wrists and a regular pulse oximetry finger sensor is used for PPG registration.

Special software was adapted to the processor. The software detects R peaks from ECG and starting front of PPG pulse, thereafter it calculates time between ECG R-peak and 50% rising front of PPG pulse. The 50% location of PPG pulse was chosen because this is the point in PPG where the signals' change is the sharpest and it can more easily be detected compared to the beginning of the PPG pulse. Our earlier study showed that there is no remarkable difference in correlation of the time measured from the foot of the PPG pulse compared to 50% rising edge measurement [3].

Sixty-one subjects were included in this study with the mean age of 42±15 years. The group contained 38 healthy persons (mean age 36±13) and 23 persons with hypertension (mean age 50±12) and 10 subjects of the hypertension subgroup incorporated also CAD (mean age 48±11). To increase the arterial blood pressure a bicycle test was used. The test consisted of cycling sessions of increasing workloads during which the HR changed from 60 to submaximal heart rate. The workload was increased in steps of 25W after every third minute until the submaximal heart rate was achieved, thereafter 5-10 minute recovery period followed until the heart rate returned back to normal. The recording was made throughout the exercise and recovery.

In parallel to time delay measurement the reference blood pressure values were registered by PC (auscultatory and Finapres) and synchronized by time markers with time delay measurements. The computer

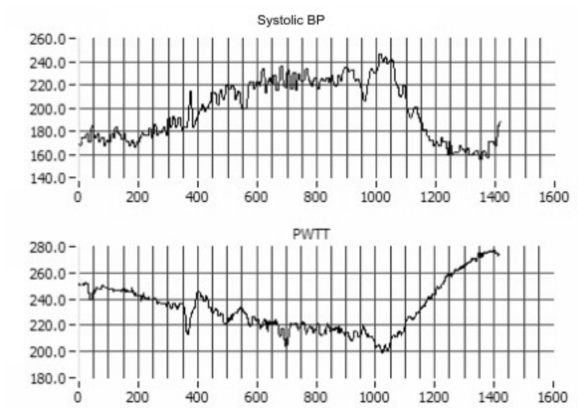

Figure 4: Systolic blood pressure (mm/Hg, upper curve) and PWTT (ms, lower curve). X-axis represents the number of heart beats.

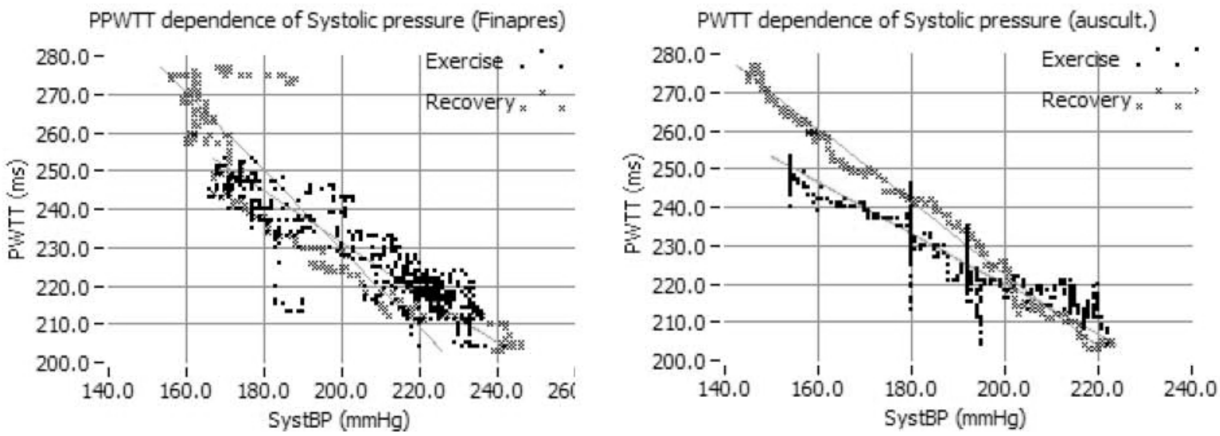

Figure 5: An example of relation of PWTT from systolic arterial pressure measured with two different methods.

later interpolated the auscultatory blood pressure signal in order to get individual value for every heart cycle.

Results

In Figure 4 we can compare the dependence of pulse wave velocity or pulse wave transit time (PWTT) and systolic blood pressure measured with blood pressure monitor Finapres 2300.

This is recording of one patient as example. With the help of bicycle test the systolic blood pressure was increased from 170 mm/Hg to 230 mm/Hg. The time delay, measured simultaneously in the same conditions, decreased from 250 ms to 210 ms correspondingly.

Dynamics of both changes are comparable. Sudden rise of systolic blood pressure between 300 and 400 heart beats and decreasing of time delay in the same time are both clearly visible.

In Figure 5 we can see an example of the dependence of PWTT from systolic blood pressure for a subject. The right side of the figure represents the relation to Finapres method and the left side of the figure represents the relation to interpolated auscultatory measurements. The exercise and recovery phases are printed in different styles. As we can see from the figure the dependence of PWTT from systolic pressure is quite linear, although the slopes during the exercise and recovery are slightly different with auscultatory method.

The difference in slope values of linear approximation function show how sensitive the PWTT change to blood pressure is for different individuals. The parameter is negative because when blood pressure increases the PWTT shortens. In our case it turned out that the healthy subgroup slope mean value was -1.41±0.39 mmHg/ms, whereas patients with hypertension had slightly poorer slope values – 1.61±0.47mmHg/ms and among them the CAD subgroup had -1.72±0.53mmHg/ms.

From Figure 6 we can see that dynamics of changes of PWTT and RR interval are different, especially in the recovering phase. RR interval reaches the stability level more quickly than PWTT. Additionally the time constants of these two signals are different, quick changes of PWTT are not visible in RR interval signal.

Figure 7 represents data from experiment where the patient was in silent situation and only moved his hand.

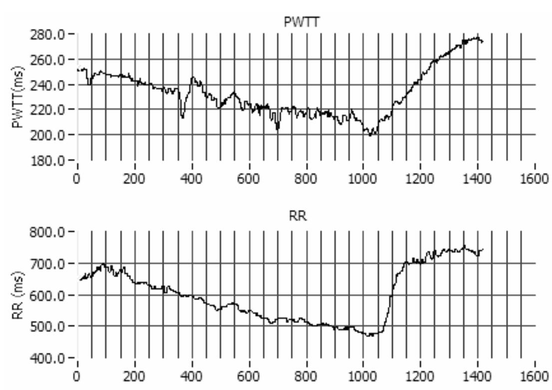

Figure 6: Dynamics of changes of PWTT and RR interval.

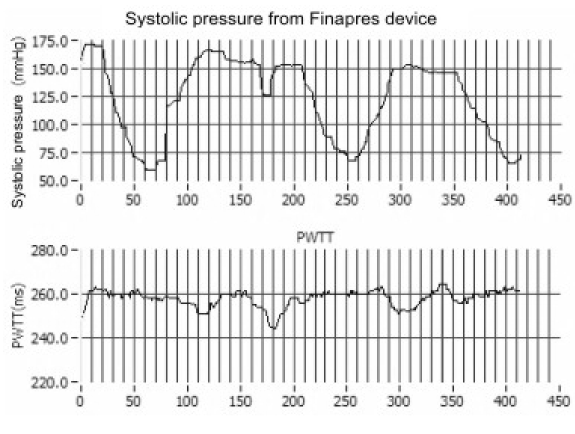

Figure 7: Systolic blood pressure (Finapres, mm/Hg, upper curve) and PWTT (ms, lower curve). X-axis represents the number of heart beats.

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Both sensors (PWTT and Finapres) were fixed on his moving hand. There are considerable changes of blood pressure measured by Finapres and smaller changes of PWTT. This experiment represents a serious disadvantage of most non-invasive measurement devices; they are very sensitive to sensor position and movements in reference to heart. PWTT signal mainly depends from blood concentrated near the heart and not so much depends from peripheral arteries. This is an advantage of TensioTrace where measured time difference not so critically depends from the place of sensors on the arm and the arm position in reference to heart.

Discussion

The method has several advantages compared to conventional methods with cuff. It enables to obtain new blood pressure value non-invasively after every heart cycle and at the same time the method itself does not affect the measured parameter, i.e. it can successfully be used for beat-to-beat blood pressure measurement.

Despite above-mentioned promising results the method may need an improvement in some aspects. As it was mentioned before, time delay between the signal of heart electrical activity and pulse wave is involved mainly with the pulse wave propagation velocity, but there is also another important parameter. That is the isovolumic contraction time (interval required for the heart to convent the electrical stimulus into a productive mechanical contraction capable of ejecting blood from the ventricles), which contributes to the delay between ECG R-peak and pulse wave. This period has been shown to be uncorrelated with arterial pressure and may make up a substantial part of the ECG-peripheral pulse delay. For further research it is important to find the relationship between PWTT and the isovolumic contraction period to eliminate this inaccuracy. Another problem related to the method arises from the fact that it requires calibration. For good results of non-invasive blood pressure estimation a precise calibration for every subject is needed.

It is a well known fact that the pulse wave velocity increases with age. This mostly happens due to the increase of arterial stiffness. PWTT should be inversely proportional to pulse wave velocity. An interesting finding that contradicts this fact is that our study showed the PWTT increase with subjects' age. One possible explanation to that could be that PWTT also includes electromechanical delay that is needed to convert the electrical signal into mechanical pumping force and isovolumic contraction time during which the pressure inside the left ventricle increases to the level of diastolic pressure inside the aorta and aortic valve can open. The reason for PWTT increase with age could be the lengthening of that period as inotropic properties of the heart muscle have been decreased in older subjects. For example, many drugs for treatment of hypertonic patients decrease the inotropic properties of the heart muscle.

Assuming linear relationship between the PWTT and systolic pressure at least two calibration points have to be taken into account and at least 15mmHg difference of systolic pressure between the calibration points in order to get reliable accuracy (one measurement for intercept determination and one for slope determination). In practical purposes this kind of calibration is quite complicated because a stable pressure difference should be created between the two measurements. In order to simplify the calibration procedure mean slope parameters could be used for calibration (age and/or health dependent). That way only one BP measurement made at rest for determination of the intercept could be used for calibration. At the same time it is clear that the simplification of calibration procedure reduces the precision of the algorithm, which based on our reference data was between 5-10%.

In most cases the PWTT and systolic pressure relationship during the exercise and during the recovery period differed slightly. This difference is probably initiated by the autonomous nervous system that affects the elasticity of the arteries and contractility of the heart.

Conclusions

1. The measurement of beat-to-beat systolic arterial blood pressure during the exercise is possible with comparable accuracy to conventional noninvasive methods. Individual calibration is still necessary.

2. The satisfactory correlation of systolic blood pressure with pulse wave velocity was also calculated for patients with higher blood pressure and also for such patients under treatment.

3. The method of pulse wave velocity is not very sensitive to sensor position or sensor movements in reference to heart and this gives some advantage when compare with most non-invasive blood pressure measurement devices.

4. The correlation of diastolic blood pressure with pulse wave velocity is much lower and in many cases the calculation gives result with insufficient accuracy.

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