EVALUATION OF A NON-INVASIVE DEVICE FOR MONITORING INSTANTANEOUS BLOOD PRESSURE IN RADIAL ARTERY USING THE VOLUME-COMPENSATION METHOD

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Abstract: For the non-invasive and precise measurement of instantaneous blood pressure (BP) in radial artery, accuracy of a device based on the principle of the volume-compensation method was assessed by the experiments of simultaneous measurement of direct (invasive) radial artery pressure using four healthy male and female subjects aged from 22 to 48 years. During the experiments, blood pressure level was changed by the light ergometer exercise (50 W, 5 min). Bias and precision of the Bland-Altman Plots calculated for the present system vs. the direct method averaged -0.018 ± 3.16 mmHg and 0.034 ± 4.68 mmHg, for a wide range of systolic BP (SBP) and diastolic BP (DBP), respectively. These results cleary indicate that, using this system, instantaneous radial artery pressure can be noninvasively measured with high accuracy.

Introduction

Non-invasive, convenient and reliable measurement of arterial blood pressure is highly required for medical as well as health care. Usually, cuff-sphygmo-manometry with auscultatory and/or cuff-oscillometric method has been widely adopted using the upper-arm as a measuring site. With this, encircling a band-type cuff around the arm often makes a subject troublesome and discomfortable due to the arm occlusion. Besides, these methods cannot allow a continuous measurement of pressure waveforms as well as BP values on a beat-by-beat basis. To address these practical and method-ological problems, we have developed a device based on the BP measurement by volume-compensation method with a local pressur-ization technique using a disk-type cuff applicable to radial artery [1]. In this study, accuracy of this device was assessed by the experiments of simultaneous measurement of direct BP using four healthy subjects.

Materials and Methods

Outline of the system

Figure 1 shows a block diagram of the Digital Signal Processor (DSP) based volume servo-control system for

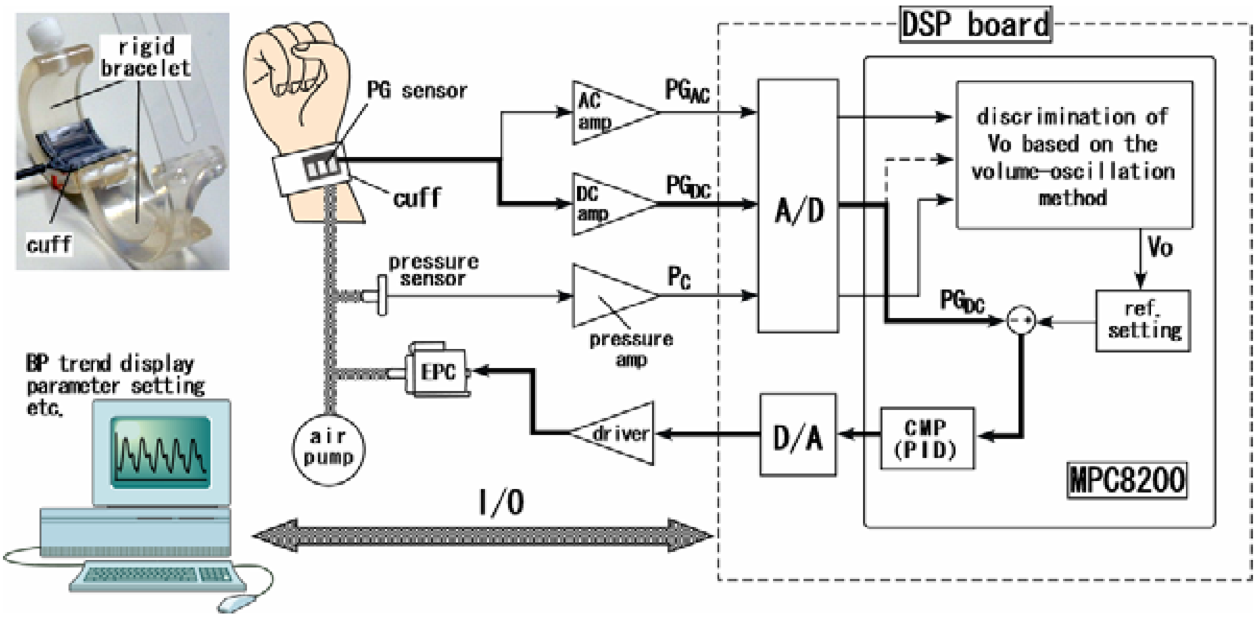

Figure 1: Schematic block diagram of the prototype system for instantaneous blood pressure monitoring in radial artery based on the volume-compensation method.

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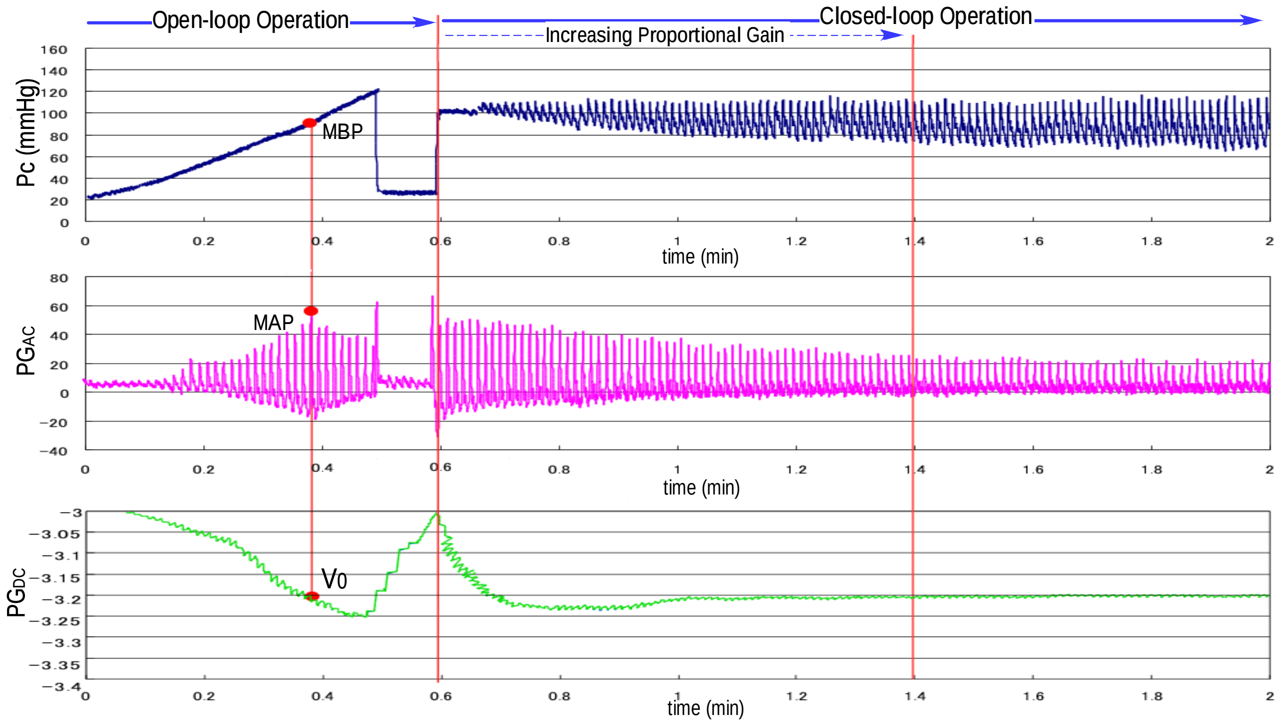

Figure 2: An example of simultaneous recordings of cuff pressure (Pc), pulsatile component of PG (PG_{AC}) and DC componet of PG (PG_{DC}) during the sequense of starting the measurement.

non-invasively measure instantaneous BP using the volume-compensation method. In this system, the radial artery is chosen as a measuring site so as to avoid venous congestion during long term monitoring. A specially designed disk-type cuff unit (25mm x 25mm), fixed inside a C-type rigid bracelet (about 5 mm thick and 35 mm wide), was provided as a partially occlusive cuff, inside which a reflectance-type photo-plethysmographic (PG) sensor was installed for detecting vascular volume changes. The MATLAB software tool Simulink was used to design algorithms of the servo control system including PID compensator (CMP). All the analogue signals, *i.e.*, the DC component of PG (PG_{DC}), the pulsatile component of PG (PG_{AC}), and the cuff pressure (Pc), were A/D converted with sampling frequency of 10kHz.

In Figure 2 are shown, typical recordings of PG_{DC}, PG_{AC} and Pc during the sequence of starting the measurement. The measuring procedure is briefly described as follows. During the period of "Open-loop Operation" shown at the left part of the figure, Pc is gradually increased by an air pump, and the unloaded vascular volume (Vo) was determined from the mean level of PG_{DC} at the point of maximum amplitude (MAP) of the pulsation signal of PG_{AC} based on the principle of the volume-oscillation method [2], [3]. After this procedure, the sequence moves to the "Closed-loop Operation", and a servo control error, produced by subtracting the instantaneously measured arterial volume from the reference value Vo, is then fed to the miniature electro-pneumatic converter (EPC) to clamp the vascular volume at the reference value. In this way, the intra-arterial pressure can be indirectly obtained by measuring Pc.

Subjects and method

Using the device mentioned above, experiments were carried out to evaluate the accuracy of the system in measuring instantaneous blood pressure in radial artery. The subjects enrolled were 4 healthy males and females aged from 22 to 48 years. For the instantaneous indirect BP measurement by the system, the subject's right wrist was used. At the same time, in the left wrist, direct BP monitoring was carried out as a reference. During the measurement (altogether 8 minutes), light ergometer exercise (50 W, 5 minutes) was conducted in supine position in order to change blood pressure level. All the experiments were carried out after obtaining Informed Consent.

Results

Figure 3 shows an example of a trend chart of BP waveform non-invasively obtained by the present system (blue line). BP waveform obtained by the direct method (red line) is also shown in the "time-expanded" recording (lower part of Figure 3). As shown in this figure, beat-by-beat BP waveform was clearly monitored by the system and a considerable increase in BP was clearly seen during the ergometer exercise. Also shown is that the non-invasively obtained BP waveform coincides well with those obtained by the direct method (lower part of Figure 3)

Figure 4 is a pair of scatter diagrams of the values of SBP (left) and DBP (right) showing the relationships between the simultaneous results obtained by the indirect and direct method. The values of the indirect method were found to have a very close correlation with

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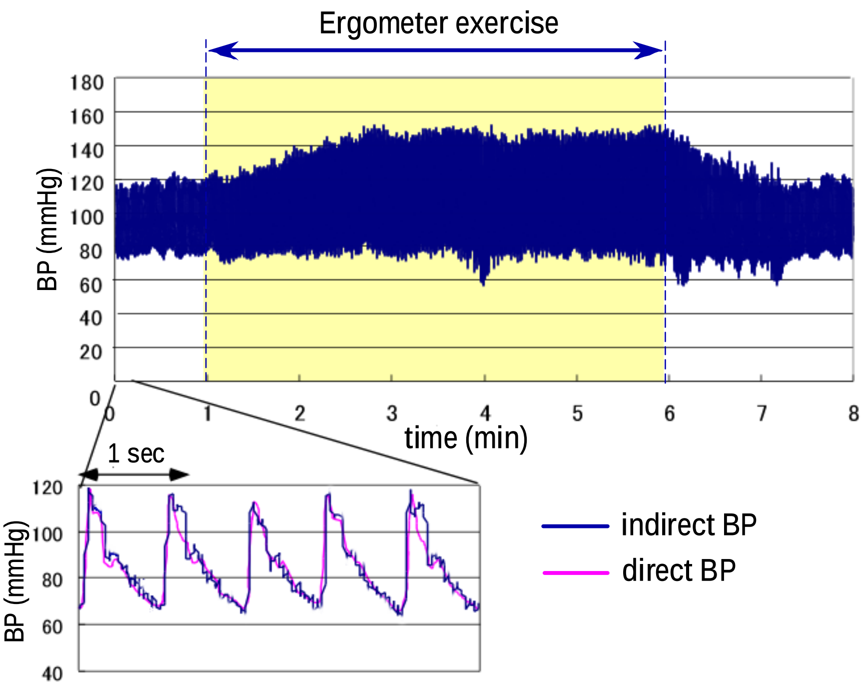

Figure 3: An example of trendchart showing indirect beat-by-beat blood pressure in the right radial artery during an ergometer exercise. BP waveform obtained by the direct method are also shown in the time-expanded recording (lower part).

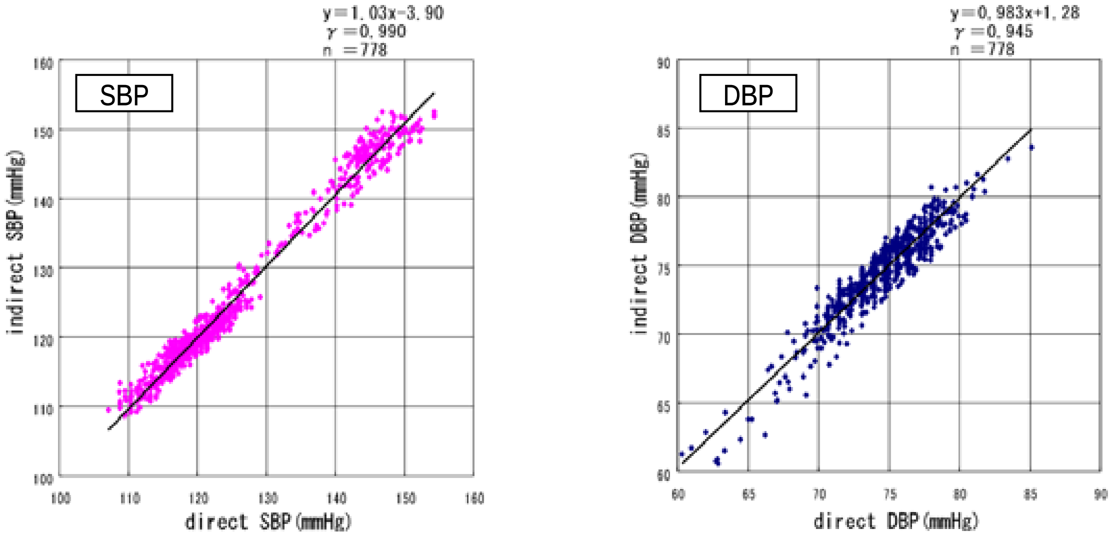

Figure 4: Comparison of direct and indirect simultaneous measurement of SBP (left) and DBP (right).

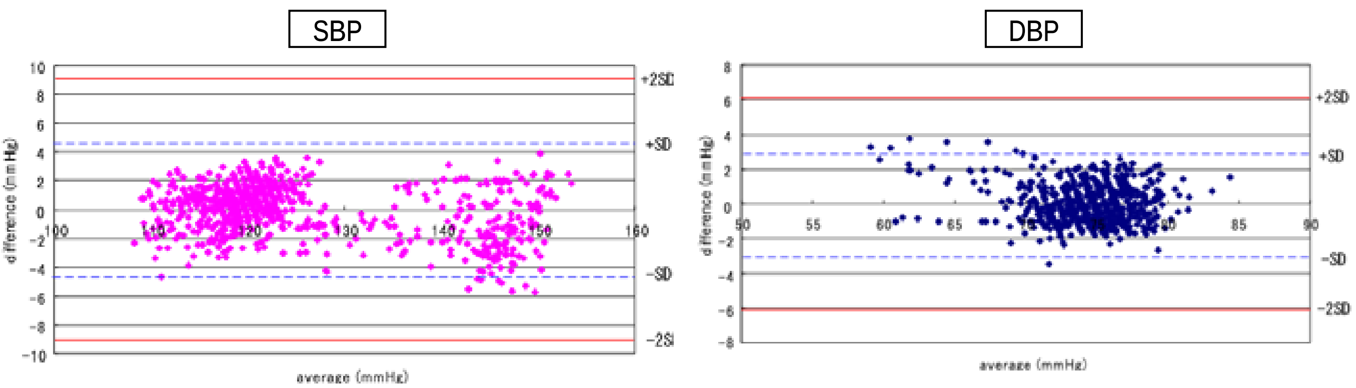

Figure 5: Difference between BP values obtained by the present system and those by direct method plotted against their mean (Bland-Altman plot). [left; SBP, right; DBP]

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the values measured directly (correlation coefficient: SBP; 0.990, DBP; 0.945, slope; SBP; 1.03, DBP; 0.98).

In Figure 5, the Bland-Altman plots of SBP and DBP are shown. Bias and precision calculated for the present system vs. the direct method averaged -0.018 ± 3.16 mmHg and 0.034 ± 4.68 mmHg, for a wide range of SBP and DBP, respectively. This means that beat-by-beat BP in the radial artery could be measured non-invasively with reasonable accuracy using the present system.

Discussion and Conclusion

In order to derive a better understanding of cardiovascular status, there has been a strong requirement for an instrument that can non-invasively measure beat-by-beat BP. To meet this requirement, several devices were developed [4]-[7] and some of those are now commercially available, *e.g.*, the Finapres and the Colin radial tonometer. With these instruments, however, there are practical and/or methodological problems. For example, in the former, blood pooling in the distal segment of the measureing site (finger) is the main problem. In a recent version of this device (Portapres), therefore, both an index finger and a middle finger are used [7]. This may well be a useful idea, however, two cuffs and an additional device constrain the subject more.

The Colin device, which is based on the principle of tonometry, the pressure waveform in a radial artery could be non-invasively measured without blood pooling. However, there is a need to measure BP in the opposite arm by the auscultatory or cuff-oscillometric method in order to calibrate the pressure measurement.

To address these practical and methodological drawbacks, we designed the system capable of mesuring beat-by-beat BP in radial artery with little venous congestion [1]. In this study, accuracy of this system was assessed by the experiments of simultaneous measurement of direct BP. From the results obtaiend, it was clearly demonstrated that, using the system, beat-by-beat BP in radial artery could be non-invasively measured with higy accuracy with wide range of BP level. However, motion artefacts were sometimes observed in BP record when the measured side hand was in flexion-extension movement and/or slippage of the cuff from an original position on the radius occurred. Conclusively, the system using local pressurization technique appears promising as a useful and helpful means for longer durations of instantaneous BP monitoring.

Acknowledgments

This work was partly supported by the Grant-in-Aid for Scientific Research (B)(2), Japan Society for the Promotion of the Science, and by the Knowledge-based Cluster Creation Project (Ishikawa High-tech Sensing Cluster Creation Project), Ministry of Education, Culture, Sports, Science and Technology.

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