News Release

Title

Development and validation of a novel cuff-less blood pressure monitoring device

Key Points

○As a joint project between industry and academia, we are developing a cuff-less device (CLB) that enables BP measurement continuously and noninvasively by capturing photoplethysmographical biosignal.

○To validate the estimation of blood pressure (BP) using a cuff-less device (CLB) in accordance with the latest wearable device standard issued by the Institute of Electrical and Electronics Engineers (IEEE1708™-2014).

○The CLB is a novel sensor system for the cuff-less BP estimation, which is technically comparable to the ordinary cuff-based BP measuring device.

Summary

As ambulatory blood pressure (ABP) management becomes more important, ABP monitoring in a variety of situations become necessary. However, an ordinary cuff-based device remains a technical limitation that disturbs activities of daily life, such as sleeping.

As a joint project between industry and academia, we are developing a cuff-less device (CLB) that enables BP measurement continuously and noninvasively by capturing photoplethysmographical biosignal. Here we report a novel system for the cuff-less BP estimation (CLB) that requires only one sensor for PTG and ECG. Our original algorithm enables this simple system and expands the possibility of measuring BP comfortably and flexibly in various settings. The present study is the first report to validate the CLB with a single sensor and to assess the clinical application of the CLB in accordance with the latest wearable device standard issued by the Institute of Electrical and Electronics Engineers (IEEE1708™-2014). We determined whether our new cuff-less sensor and algorithm for BP measurement (i.e., CLB) is qualified to replace a standard cuff-based device. The tested system exhibited high in fidelity that meets the standards for a wearable device issued by IEEE1708™-2014. Our CLB is a flexible and wearable device that permits BP monitoring in a variety of settings.

Research Background

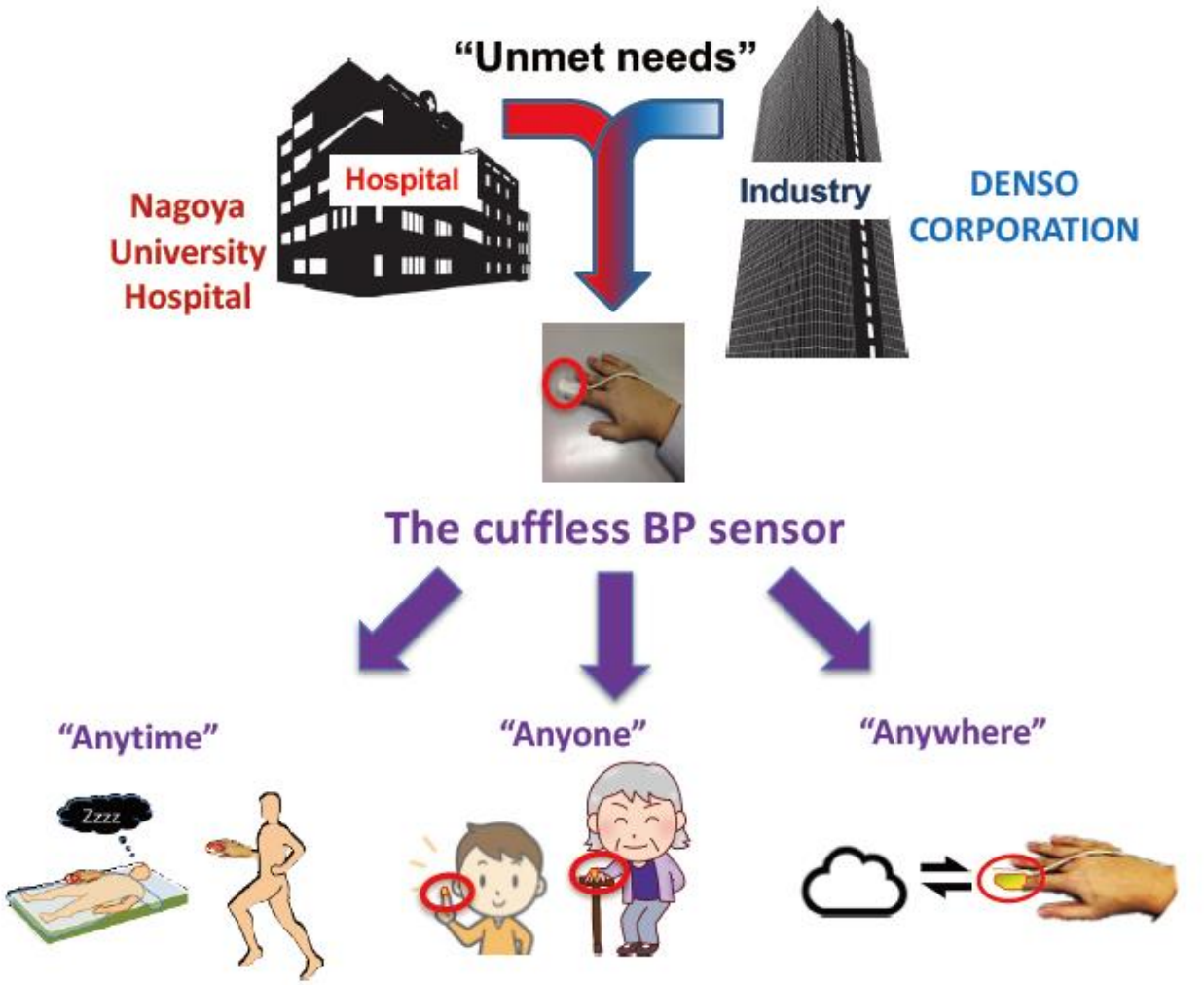
Since the invention of a rubber cuff for the compression of the brachial artery by Dr. Riva-Rocci in 1896 and the development of the auscultatory method of BP reading by Dr. Korotkoff in 1905, cuff-based BP measurement (CB) has been used as the gold standard method for the past 120 years. As ambulatory blood pressure (ABP) management becomes more important, ABP monitoring in a variety of situations become necessary. However, an ordinary cuff-based device remains a technical limitation that disturbs activities of daily life, such as sleeping. Therefore, we aimed to develop a new device for recording BP without a cuff. Here we report a novel system for the cuff-less BP estimation (CLB) that requires only one sensor for PTG

Research Results

Participants (n=172) were consist of volunteers with normotensive, stage 1 and stage 2 hypertension. BP was measured by CLB and by CB either simultaneously or sequentially as appropriate. In accordance with the IEEE1708™-2014, BP validation was performed under static, dynamic (BP rising and falling by provocation), and long-term interval (1 month later) conditions. BP data recorded by CLB were statistically compared to those obtained by CB to assess fidelity (MAD of BP between CLB and CB), agreement (Bland-Altman plot), and reproducibility (ICC). The impact of CLB on wearing comfort during bedtime was evaluated by questionnaire and by changes in autonomic nerve activities (heart rate, high and low and high frequency components of heart rate variability). BP estimation data recorded by CLB were 932 in total and all data were validated by CB. The MAD was less than 7 mmHg, and agreement was within 2 SD for all conditions. The ICC values were greater than 0.8. The CB disturbed sleep in approximately 70% of participants, and this rate was reduced by up to 40% with the use of CLB.

Research Summary and Future Perspective

The present study is the first report to validate the CLB with a single sensor and to assess the clinical application of the CLB in accordance with the latest wearable device standard issued by the IEEE1708™-2014.



Publication

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