Need for Re-validation of Automated Blood Pressure Devices for use in Unstable Conditions

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Abstract

The current validation of non-invasive blood pressure (NIBP) device is performed under resting conditon. However, NIBPs are often used without giving much consideration about the measurement conditions. This study aimed to provide scientific data on the use of BP devices in unstable conditions.

BP measurements were performed on 20 healthy subjects under both resting and regular deep breathing conditions. During the measurement the oscillometric cuff pressure waveforms were recorded digitally. They were then regenerated by a specially designed BP simulator and presented to two clinically validated hospital grade automatic NIBP devices to obtain automated BPs. Automated BPs obtained from the two conditions were finally compared between the two devices.

Under resting condition, there was no significant difference in both automated SBP and DBP between the two devices. However, under regular deep breathing condition, significant SBP and DBP differences were observed between the two devices (both $P<0.01$; mean±SD: 118.8±10.6 vs 115.1±11.6 mmHg for SBP; 68.5±8.6 vs 65.3±8.9 mmHg for DBP). For the effect of deep breathing on BP measurement, significant SBP decrease was observed only from device 2 ($P<0.05$, with a mean difference±SD of 3.8±6.2 mmHg), indicating inconsistent measurements between the two devices under unstable conditions.

Our results provide scientific evidence that automated BP devices can be used only under the condition for which the validation was performed.

1. Introduction

Automatic non-invasive blood pressure (NIBP) measurement devices are widely used in many health care institutions or at home because they are easy to operate [1]. Before these NIBP devices can be sold on market, it is required by the International Organization for Standardization that they should be validated clinically to confirm their accuracy by comparing with either directly measured invasive pressures or with manual auscultatory measurements [2]. The current validation of NIBP device is performed under resting conditon.

In clinical practice and research studies, NIBP devices are often used without giving much consideration about the conditions in which BP measurements are taken. It has been reported that measurement inaccuracies are associated with incorrect patient posture, incorrect arm position, incorrect cuff position and size, patient movement, coughing and talking [3-9]. However, in the majority of published studies, the automated BP values used for analysis were from NIBP devices validated under resting condition, and there was no validation of the devices used for non-resting conditions.

This leads us to question whether the current validated NIBP devices can achieve accurate BP measurement under non-resting conditions. This study aimed to provide scientific data on the use of NIBP devices under unstable conditions.

2. Methods

2.1. Subjects

Twenty healthy normotensive subjects (aged from 28 to 61 years) were studied. This study received ethical permission from the Newcastle & North Tyneside Research Ethics Committee, and all subjects gave their written informed consent to participate in the study.

2.2. Manual auscultatory blood pressure measurement

Manual BP measurements were performed by a trained observer under both resting and regular deep breathing conditions using a clinically validated manual electronic sphygmomanometer (Accoson Greenlight 300 from AC Cossor & Son (Surgical) Ltd) [10]. All BP measurements were performed in a quiet clinical measurement room while the subjects were seated on a chair. The whole BP measurement procedure followed the guidelines recommended by the American Heart Association and British Hypertension Society [11].

During the manual measurement, the oscillometric cuff pressure was deflated linearly at a recommended rate of 2-3 mmHg/s, and was recorded digitally to a computer. In total, 40 oscillometric cuff pressure waveforms were obtained from the two measurement conditions.

2.3. Automated blood pressure measurement using simulator

A BP simulator, designed and construcsted at the Physikalisch-Technische Bundesanstalt (PTB) and capable of generating previously recorded oscillometric wavfroms [12, 13], was used to regenerate the 40 oscillometric waveforms. It has been reported that this BP simulator could reliably regenerate unstable physiological oscillometric waveforms [14]. The set-up of BP simulator connented to a NIBP device is shown in Figure 1. Each regenerated oscillometric wavefrom was then presented to two clinically validated hospital grade automatic NIBP devices to obtain automated BPs.

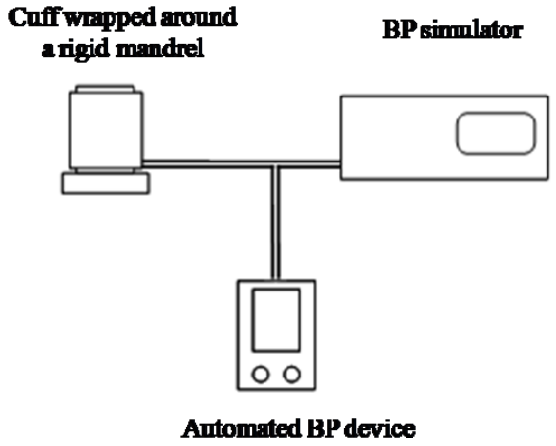

Figure 1. Schematic set-up of BP simulator connected to an automated BP device.

2.4. Data and statistical analysis

The mean and standard deviation (SD) of the manual and auto BPs from the two devices were calculated across all subjects for the two measurement conditions (resting and regular deep breathing). Automated SBP and DBP from both resting and regular deep breathing conditions were then compared between the two devices. The effect of regular deep breathing on automated SBP and DBP was then investigated with BP changes induced by deep breathing compared between the two devices. The SPSS Statistics 19 software package (SPSS Inc, USA) was employed for the data analysis. A P value below 0.05 was considered statistically significant.

3. Results

3.1. Comparison of automated blood pressures between the two devices

Under resting condition, there was no significant difference in both automated SBP and DBP between the two devices (mean±SD: 119.1±10.1 vs 118.9±10.6 mmHg for SBP; 72.2±8.5 vs 71.2±8.8 mmHg for DBP). However, as shown in Figure 1, under regular deep breathing condition, significant SBP and DBP differences were observed between the two devices (both P<0.01; mean±SD: 118.8±10.6 vs 115.1±11.6 mmHg for SBP; 68.5±8.6 vs 65.3±8.9 mmHg for DBP).

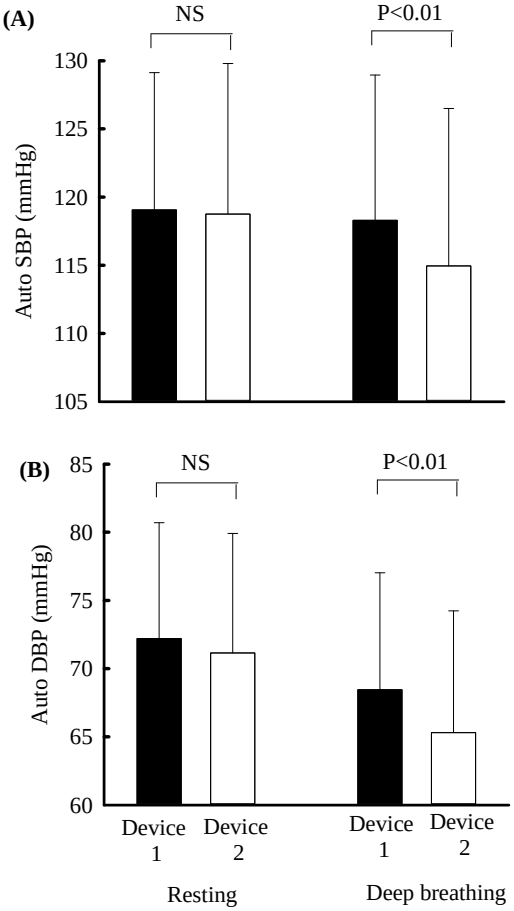

Figure 2. Comparison of auto SBP and DBP obtained from regular deep breathing condition between the two devices. The data are presented as overall mean+SD.

3.2. Effect of deep breathing on automated blood pressures

From figure 2, it can also be seen that, with the effect of deep breathing, significant automated SBP decrease was observed from device 2 ($P<0.05$, with a mean difference±SD of 3.8±6.2 mmHg), but not from device 1 (mean difference±SD of 0.8±7.2 mmHg).

For the effect of deep breathing on automated DBP, significant decrease was observed from both devices (both $P<0.05$, with a mean difference±SD of 3.8±6.4 mmHg for device 1 and 5.9±5.4 mmHg for device 2).

3.3. Comparison of BP changes induced by deep breathing between the two devices

As shown in Figure 3, the auto SBP decrease induced by deep breathing was significantly different between the two devices ($P<0.5$), indicating inconsistent measurements between the two devices under unstable conditions.

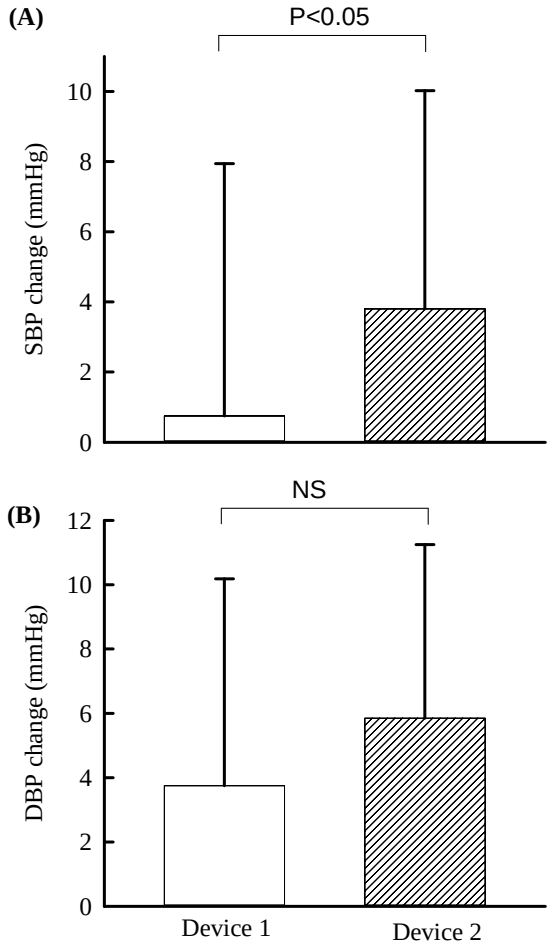

Figure 3. Comparison of automated SBP (A) and DBP (B) changes induced by regular deep breathing between the two devices.

4. Discussion and conclusion

Our study was conducted to assess whether the current validated NIBP devices can achieve accurate BP measurement under non-resting conditions. With the effect of deep breathing on BP measurement, significant BP decrease is expected. Our published clinical study using the manual auscultatory method has reported that both manual SBP and DBP decreased significantly with deep breathing in comparison with the resting condition [14]. However, the current study showed that significant SBP decrease was only observed from one of the two clinically validated NIBP devices, indicating that there is potential measurement inaccuracy from that device.

In summary, our results provide scientific evidence that automated NIBP devices can be used only under the condition for which the validation was performed, and also confirm that a separate validation should be perfomed in order for the devices to be used under different conditions.

Acknowledgements

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