Original Article

A New Double Cuff Sphygmomonometer for Accurate Blood Pressure Measurement

Osamu TOCHIKUBO, Junko WATANABE, Kouichi HANADA*, Eiji MIYAJIMA*, and Kazuo KIMURA*

Accurate measurement of blood pressure (BP) is essential in the diagnosis and treatment of hypertension, but neither auscultatory nor oscillometric methods measure intra-arterial BP accurately in all circumstances. Algorithms for automatic BP-measuring devices differ from manufacturer to manufacturer, and no clear authorized algorithm criteria have yet been established. We have devised a double-cuff sphygmononometer to measure BP on the basis of clear algorithms, and investigated the accuracy of this new method by comparing it with the photo-oscillometric method, which is the most accurate method for non-invasive measurement of intra-arterial BP. In the new method, a small cuff (3×6 cm) replaces the photo-sensor in the brachial cuff (13×24 cm) of the photo-oscillometric device, and BP is determined by means of the oscillation within the small cuff. The comparison based on procedures of AAMI-protocol was performed in 136 hypertensive patients and 54 normotensive subjects. The difference in systolic BP between the photo-oscillometric and double-cuff methods was −2.26±2.31 mmHg (89% under 5 mmHg), and the corresponding difference in diastolic BP was 1.9±2.50 mmHg (94% under 5 mmHg). In conclusion, we have devised a new double-cuff method which improves on the photo-oscillometric method, and although it seems to be less accurate than the photo-oscillometric method, the clarity of its algorithm makes it superior to the conventional oscillometric and auscultatory methods employing only one cuff.

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Key Words: blood pressure measurement, hypertension, auscultatory method, oscillometric method

Introduction

Accurate measurement of blood pressure (BP) is essential in the diagnosis and treatment of hypertension. Today, the auscultatory method devised by Riva-Rocci and Korotkoff is the standard method, though automatic BP-measuring devices employing the oscillometric method are also available and used in the clinic and studies (1). Neither auscultatory nor oscillometric methods measure intra-arterial BP accurately in all circumstances. Both tend to overestimate systolic BP (SBP) by a few mmHg and to underestimate diastolic BP (DBP) a few mmHg high (2–4). Algorithms for oscillometric BP-measuring devices differ from manufacturer to manufacturer, and no clear authorized algorithm criteria have yet been established. As O’Brien (5) has pointed out, BP measurement as performed in clinical practice today is a very inaccurate procedure.

We have previously devised a noninvasive BP recorder employing a liquid-filled cuff (6) and a photo-oscillometric method (4) for accurately measuring intra-arterial BP, but because of the complex equipment it involves, these methods have not found wide application. To simplify them, we have devised a double-cuff sphygmononometer to measure BP on the basis of clear algorithms founded on practically the same principles. In the new method, a small cuff replaces the pho-
Fig. 1. New double-cuff method for accurate blood pressure measurement. A computer automatically controls the cuff pressure and air pump, and calculates SBP, DBP and pressure waveforms.

to-sensor in the center of the brachial cuff of the photo-oscillometric device. We investigated the accuracy of our new method by comparing its measurements with auscultatory and photo-oscillometric measurements.

Methods

Double-Cuff Sphygmomonometer

We have previously introduced a photo-oscillometric method employing the delta-algorithm. This method can detect arterial pulsation at the center of the brachial cuff. In the conventional oscillometric method, when cuff pressure greater than SBP is applied, even if the central part of the cuff obstructs the brachial artery, cuff pressure on the upper part — especially at the upper edge of the cuff (Fig. 1; upper part) — is lower than pressure in the central cuff region. For this reason, it is impossible to completely occlude the brachial artery and stop arterial pulsation at the upper part of the cuff; and, since pulsation of the upper part of the cuff contaminates the oscillation in the central part of the cuff, the point of judgment of SBP is unclear (Fig. 2C). When pressure at the center of the cuff drops below DBP, contamination at both edges of the cuff also makes the point of judgment of DBP unclear. To rectify this situation, we positioned a photo-sensor at the central part of the cuff and devised a photo-oscillometric method (4) for detecting arterial pulsation (oscillation) at the cuff center only. With this method, because arterial pulsation is completely eliminated when the cuff pressure is increased above SBP, it is possible to determine SBP clearly. Moreover, when cuff pressure is reduced below DBP, the pulsation amplitude suddenly decreases, making it easy to determine DBP. BP values obtained in this way were close to those obtained by simultaneously conducted direct arterial BP monitoring (4).

Fig. 2. Methods for computer determination of systolic blood pressure (SBP, Ps), and diastolic blood pressure (DBP, Pd). (A) shows small-cuff and large cuff pressure (mmHg), (B) small cuff oscillation, and (C) large cuff oscillation (V: voltage). The conventional oscillometric method uses the large cuff oscillation (C).

This method is considered an ideal way of measuring arterial BP more objectively and accurately than is possible with the auscultatory method (4), but it is not generally used because of the complicated equipment it requires. The present study represents an improvement in that a small cuff replaces the photo-sensor, and BP is determined by means of the pressure oscillation within the small cuff. The use of only one pressure sensor reduces the cost of producing the equipment and simplifies the algorithm.

Like the photo-oscillometric method, the double-cuff oscillation method uses a non-elastic cuff (13×24 cm: large cuff). A small cuff (3×6 cm) is placed on the brachial-artery side of the large cuff. A resistance-mediated tube (cannula)
connects the two cuffs (Fig. 1). A plastic sheet (4×6×10 cm) between them prevents transmission of pulsatory oscillation from the large cuff to the small cuff. We have attempted to minimize contamination of pulsatory oscillation from the upper part by means of this elastic sheet placed at the upper edge of the large cuff (Fig. 1). In addition, to minimize transmission of the large-cuff pulsatory oscillation, we have positioned a Windkessel bag, which planes down large-cuff oscillation, in front of the resistance cannula (Fig. 1). A pressure sensor (PS40-102G-NAM, Copal Electronics, Tokyo, Japan) measures pressure in the small cuff. A computer (Satellite; Toshiba, Tokyo, Japan) reads pressure variation and automatically determines DBP and SBP (P1 and Pi in Fig. 2). In this experiment, large-cuff pressure was also measured, and the two were simultaneously compared.

The computer algorithm (Fig. 2) calls for pressurizing the cuff to 30 mmHg above the predicted SBP value. At depressurization (3 mmHg/s depressurization rate), small-cuff pulsatory oscillation (pressure differential with time constant of 1.5 s) rises 20% above the preceding value, and the cuff pressure from which the continual increase begins is taken as SBP (P1 in Fig. 2B). Similarly, the point at which pulsatory oscillation amplitude decreases suddenly (inflection point in the amplitude envelope curve, P1 in Fig. 2B) is taken as DBP. This algorithm was automatically determined by a computer program. Determination of SBP and DBP in the small cuff was clearer than those determined by large-cuff oscillation (Fig. 2B and C). The conventional oscillometric method determines SBP and DBP by large-cuff oscillation.

**Comparisons between Double-Cuff and Auscultatory or Photo-Oscillometric Methods**

The accuracy of the double-cuff method was determined by comparing it with the auscultatory method and the photo-oscillometric method. Our procedure for comparing the double-cuff method with the auscultatory method was based on procedures of the Association for the Advancement of Medical Instrumentation (AAMI) (7). Concurrent with the double-cuff measurements, two trained observers (doctors) using a double stethoscope auscultated the Korotkoff sounds and recorded their BP values. SBP was determined to be in Korotkoff phase I and DBP in Korotkoff phase V. Measurements were made three times, and mean values obtained by both methods were compared.

To compare the photo-oscillometric and double-cuff methods, auscultation was performed over both the right and left brachial fossae. Subjects in whom the difference between these two was within 5 mmHg were selected. Then the double-cuff method was used to make measurements on their right brachia and the photo-oscillometric method to make measurements on their left brachia. Cuff pressurization and depressurization (~3 mmHg/s) were performed with the same pump. Both sets of values were compared according to the method described above.

![Fig 3. Bland-Altman plots comparing the new double-cuff method and auscultatory method. DBP+, auscultatory diastolic blood pressure (DBP); DBP-, double-cuff DBP; SBP+, auscultatory systolic blood pressure (SBP); SBP-, double-cuff SBP.](image)

Measurements were performed in 136 outpatients with hypertension (70 male, 66 female) and 54 normotensive subjects (28 male, 26 female). Their BP ranges were 95–264 mmHg/53–125 mmHg (SBP/DBP) and their ages were between 20 and 85 years old. We used only subjects whose brachial circumference was between 20 and 35 cm. All subjects gave informed consent to participation in the study, and the protocol was approved by the ethical committee of our institute.

**Statistical Analysis**

In addition to standard statistical methods, including least-squares linear regression analysis, F-test and Student’s paired t-test, we used the Bland-Altman plotting method (8). Values were expressed as the mean±SD, and values of p<0.05 were considered to indicate statistical significance. The multiple Statistical Analysis Program (Social Survey Research Information Co., Ltd., Tokyo, Japan) was used for calculations.
Table 1. Comparisons between Double-Cuff Method and Auscultatory or Photo-Oscillometric Method

<table>
<thead>
<tr>
<th>BP</th>
<th>No. of observations</th>
<th>Range (mmHg)</th>
<th>Mean difference $^1$ (mmHg)</th>
<th>SD of difference (mmHg)</th>
<th>$r$</th>
<th>Percentage exceeding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>5mmHg</td>
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<tr>
<td>Double-cuff–Auscultatory</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>190</td>
<td>95–234</td>
<td>0.42</td>
<td>2.91</td>
<td>0.982</td>
<td>11.6</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>190</td>
<td>53–125</td>
<td>-1.19</td>
<td>3.47</td>
<td>0.982</td>
<td>10.5</td>
</tr>
<tr>
<td>Double-cuff–Photo-oscillometric</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>190</td>
<td>95–264</td>
<td>-2.26*</td>
<td>2.31*</td>
<td>0.996</td>
<td>11.1</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>190</td>
<td>53–118</td>
<td>1.90*</td>
<td>2.50*</td>
<td>0.986</td>
<td>6.3</td>
</tr>
</tbody>
</table>

$^1$ Difference indicates double-cuff BP minus auscultatory BP or photo-oscillometric BP values. $r$, correlation coefficient between two methods; BP, blood pressure. * $p<0.05$ vs. double-cuff auscultatory values.

The SDs (2.3/2.5 mmHg) of differences between double-cuff and photo-oscillometric measurements (SBP/DBP) were smaller than those (2.9/3.5 mmHg) between double-cuff and auscultatory measurements ($p<0.05$, Table 1).

Discussion

The relative simplicity of the equipment and ease with which measurement can be performed account for the superiority of the auscultatory method. It is not, however, perfect (5, 9). Several investigators have compared direct DBP measured at the Korotkoff muffling point (D4) and cessation of Korotkoff sounds (D5). Some investigators (9, 10) noted that the difference between D4 values and direct DBP values was smaller than that between D5 values and direct DBP values. The auscultatory method of measuring BP depends on the judgements of sounds and is therefore likely to involve subjectivity. Moreover, it is very inaccurate compared with direct intra-arterial measurement (2–4). For the sake of obtaining objective values, automatic measurement is desirable, but the algorithm for the oscillometric method is not always clear (11). To deal with this situation, attempts have been made to use a special microphone and the K2-algorithm to measure BP (12). The measurements obtained using the K2-algorithm method were close to those of the direct methods, and the method was considered superior in that it allowed for objective evaluation of the decision algorithm. However, because this method did not include an improvement of the cuff, it has not seen general use.

Our double-cuff method employs a small cuff positioned in the middle of a large cuff. Because the small cuff captures the arterial pressure waveform in the central part of the large cuff, the SBP/DBP discrimination points are clear, and automatic discernment of the algorithm is easy (Fig. 2). Nonetheless, this method tends to measure SBP slightly higher and DBP slightly lower than the auscultatory method. In contrast, it measures SBP slightly lower and DBP slightly higher than the photo-oscillometric method. This may be related to the fact that the auscultatory method measures SBP lower ($-7.4 \pm 5.6$ mmHg) and DBP higher ($3.0 \pm 7.1$ mmHg) than direct arterial BP, whereas the photo-oscillometric method

Results

The difference in SBP between the double-cuff and auscultatory methods was $0.42 \pm 2.9$ mmHg (88% under 5 mmHg). The corresponding difference in DBP was $-1.2 \pm 3.5$ mmHg (89% under 5 mmHg) (Fig. 3 and Table 1).

The difference in SBP between the double-cuff and photo-oscillometric methods was $-2.26 \pm 2.31$ mmHg (89% under 5 mmHg); the corresponding difference in DBP was $1.9 \pm 2.50$ mmHg (94% under 5 mmHg) (Fig. 4 and Table 1).
produces values close to those obtained by direct arterial BP measurement (the SBD/DBP differences between the photoo-oscillometric method and direct method were \(-0.8 \pm 3.1 / 0.6 \pm 2.8 \text{ mmHg}\) (4), and measurements by the double-cuff method produces the middle values between those of the auscultatory method and the photo-oscillometric method. The SDs of differences (Table 1) between the double-cuff and photo-oscillometric measurements were smaller than those between the double-cuff and auscultatory measurements (Table 1). This indicates that the reliability of the double-cuff method is superior to that of the auscultatory method.

A limitation of this study is that we could not compare the measurements of the double cuff method and those of the direct method, for ethical reasons. The automatic double-cuff BP recorder currently under development will differ very little from the standard automatic oscillometric recorder in terms of measurement time and operation. When this new device has been perfected and is being marketed, we will compare the measurements of the marketed device and those of the direct method to investigate its precision in numerous subjects of different age, pulse pressure, heart rate and arm circumference.

In conclusion, we have devised a new double-cuff method that improves on the photo-oscillometric method, and although it seems to be less accurate than the photo-oscillometric method, the clarity of its algorithm makes it superior to the conventional oscillometric and auscultatory methods employing only one large cuff.

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**References**