Accuracy and applicability of the Terumo ES-H55 double-cuff sphygmomanometer for hospital use
Osamu Tochikubo\textsuperscript{a}, Kiyoko Nishijima\textsuperscript{a}, Kenji Ohshige\textsuperscript{a} and Kazuo Kimura\textsuperscript{b}

\textbf{Background} We have developed a new blood pressure (BP)-measuring device with a double-cuff, and evaluated its accuracy and applicability for practical use.

\textbf{Design} The double-cuff method features a small cuff placed in the centre of the compression cuff to detect the oscillation of arterial pulsation, by which algorithms for the determination of systolic BP (SBP) and diastolic BP (DBP) were rendered more objective than with the conventional oscillometric method. Algorithms for automatic BP determination were developed from the oscillation data taken with the small cuff from 217 men and 256 women, and then installed in the Terumo ES-H55 device (length: 17 cm, weight: 120 g). This ES-H55 device was tested on 87 subjects (65 hypertensives and 22 normotensives) to compare its accuracy with that of the auscultatory method according to the AAMI SP-10 protocol.

\textbf{Results} Using Bland and Altman scatter plots, the difference in SBP between the ES-H55 device and the auscultatory method was within \(\pm 5\) mmHg in 88\% of subjects, and within \(\pm 10\) mmHg in 97\% (mean difference \(\pm SD: 0.2 \pm 3.9\) mmHg). The difference in DBP was within \(\pm 5\) mmHg in 80\%, and within \(\pm 10\) mmHg in 97\% (difference: \(-0.1 \pm 4.6\) mmHg). These results satisfied AAMI guidelines, and this device was easy to use.

\textbf{Conclusions} The ES-H55 device is compact and light, with clear algorithms for the determination of BP, and satisfies AAMI criteria, so that it is considered a useful BP-measuring device that could be used instead of a mercury sphygmomanometer by nurses and doctors in hospital wards. \textit{Blood Press Monit} 8:203–209 \copyright 2003 Lippincott Williams & Wilkins.

Blood Pressure Monitoring 2003, 8:203–209

Keywords: blood pressure measurement, oscillometric method, sphygmomanometer, hypertension, arterial blood pressure

\textsuperscript{a}Department of Public Health and \textsuperscript{b}Cardiovascular Centre, Yokohama City University School of Medicine, Yokohama, Japan.

Correspondence and requests for reprints to Osamu Tochikubo, M.D., Department of Public Health, Yokohama City University School of Medicine, 3-9 Fukaura, Kanazawa-ku, Yokohama 226-0004, Japan. Tel: +81 45 787 2610; fax: +81 45 787 2609; e-mail: tocchi@med.yokohama-cu.ac.jp

Received 30 April 2003 Revised 24 July 2003
Accepted 30 July 2003

\textbf{Introduction}

The auscultatory method (the Riva-Rocci and Korotkoff method) using a mercury sphygmomanometer is considered to be the standard method for measurement of blood pressure (BP) in current clinical practice. This method has been used for about 100 years—since it was first devised by Riva-Rocci and Korotkoff [1]. Though it has the advantage of easy measurement with a simple device, the discrimination of Korotkoff sounds (K-sounds) varies among different observers. Besides, the systolic BP (SBP) determined by this method tends to be several mmHg lower than the direct (intra-arterial) BP, while the diastolic BP (DBP) determined by this method tends to be several mmHg higher than the direct BP even if the more appropriate of phase IV or V is used depending on the case [2]. Other problems in performing this method include the auditory acuity of the observer, underestimation of SBP and overestimation of DBP due to an inappropriately rapid cuff deflation rate often seen in busy mass screening and routine medical practice, operator bias for BP values, and digital preference [3]. Moreover, the problem of polluting the environment with mercury has attracted increasing attention recently, and movement toward exclusion of mercury sphygmomanometers is now becoming a global trend, such that the development of a suitable BP-measuring device is now eagerly awaited in clinics [4].

Currently, large automatic BP-measuring devices based on the cuff-oscillometric method are widely used in hospital wards and laboratories throughout the world as well as in Japan. This particular device (oscillometric method) has a simple structure, which includes a compression cuff that lacks a K-sound sensor, but uses pulse waves (oscillations) detected by a pressure-sensor for measurement. This type of device has some fundamental differences when compared to the auscultatory method—principally that of measurement [5,6]. In measurements made using the conventional oscillometric method, the oscillations are always detected from a pressure above SBP to below DBP, so that SBP and DBP cannot be measured by detecting the appearance and disappearance of pulse signals such as K-sounds. Moreover, the inability to detect pulse-wave changes from the central region of the cuff in isolation...
(which is necessary for BP measurement), the conventional oscillometric method has a tendency to detect 'contaminated oscillations' which include pulse waves from both upstream and downstream of the central region. This method therefore cannot help but use contaminated oscillation data in its algorithms when estimating SBP and DBP values, and with each manufacturer of BP devices developing their own algorithms, any clear authorized algorithm criteria has yet to be established.

To rectify the above difficulties and in an effort to overcome the disadvantages of the conventional oscillometric method, we have devised a double-cuff sphygmanometer for use in research [7–9]. In collaboration with the Terumo Corporation, we have developed a practical model using a double-cuff method (the Terumo ES-H55), that can be marketed and used in many medical facilities, and evaluated its accuracy and applicability.

**Methods**

The following factors make it difficult to detect the oscillation changes indicative of SBP and DBP by the conventional oscillometric method: (1) the artery-compressing force of the conventional cuff (large cuff pressure: L-P in Figure 1) for BP measurement is not constant between one end (the upstream side) and the other end (the downstream side) of the cuff; (2) the cuff-compressing pressure is highest in the central cuff region (small cuff pressure: S-P in Figure 1) and decreases gradually towards both ends until it reaches almost zero. Consequently, raising the cuff pressure above the SBP occludes the artery completely under the central cuff region (where there is no oscillation; S-P oscillation in Fig. 1a), but incompletely under the upstream side (where there is oscillation due to pulse pressure). Thus, the oscillation generated by the arterial pulsation under the upstream side contaminates the oscillation of the central cuff region to produce a constant oscillation within the large cuff (L-P oscillation in Fig. 1a). Also, when the cuff pressure is between SBP and DBP, oscillations in the upstream and downstream regions of the cuff are superimposed on the detected pulse oscillations of the central cuff region (where S-P oscillation is greater than L-P oscillation; Fig. 1b and c). Similarly, even when the cuff pressure falls below the DBP, blood influx from the upstream and efflux to the downstream side of the cuff still continues to generate cuff-oscillations in the large cuff (Fig. 1d).

Consequently, the conventional oscillometric method has the following disadvantages: (1) there are no clear targets for detection, such as the appearance and disappearance of K-sounds and (2) it is not possible to detect the pulse-wave change in the central cuff region alone, which is necessary for BP measurement. Therefore, there is no other way but to estimate the pulse wave change in the central cuff region from the contaminated oscillations that include the pulse waves of the upstream and downstream sides. To rectify this, we have previously investigated the liquid-filled cuff method with a double-cuff [8], the photo-oscillometric method [2], where a photo-sensor placed in the central-cuff region detects oscillations in the central-cuff region only, and the double-cuff method [7] which is a simplified version of the photo-oscillometric method. Our findings show that BP values measured by these methods were closer to the values obtained by the direct method in comparison with the auscultatory method [2,7,8].

Recently, we developed the Terumo double-cuff method (TDCM) in collaboration with the Terumo Corporation. The device, the Terumo Electronic Sphygmomanometer ES-H55, is a small, lightweight, high-performance electronic BP-measuring device suitable for hospital use. The TDCM is a newly developed cuff-oscillometric method that overcomes the disadvantages of the conventional cuff-oscillometric method described above. This method
employs a double-cuff, which comprises a large cuff for compression and a small cuff (placed in the centre of the large cuff) for pulse wave detection [7,9].

The specifications of the Terumo Electronic Sphygmomanometer ES-H55 (Figure 2) are as follows:

- It employs the TDCM, which has overcome the disadvantages of the conventional oscillometric method.
- It contains an artifact detection system to exclude arrhythmia and body movement.
- It is a simple all-in-one device with an inflation bulb balloon.
- It is small (overall length including the inflation bulb: 167 mm), light (120 g), and easily portable.
- It can perform more than 1000 measurements with a single alkaline AA cell as the power source.

This sphygmomanometer is intended for use as an alternative to the mercury sphygmomanometer currently used in clinical practice, particularly in routine work in hospital wards and outpatient clinics, home visits and home care. Our aim is to see the use of mercury in clinical practice disappear and to provide healthcare personnel with an excellent source of objective and reproducible BP information through the use of alternative devices like the ES-H55.

In this device a cuff, as used for the conventional oscillometric method incorporating a bladder, was used exclusively as the compression cuff (Figure 3). The size of the large cuff was determined in relation to the arm circumference (small size 11 × 17 cm; medium size 13 × 24 cm; large size 17 × 32 cm). Then a smaller cuff, dedicated to pulsatile oscillation detection is set at the centre of the internal side of the large cuff where the same force as the large cuff pressure is applied. As with the larger cuff, the size of the small cuff was determined in relation to arm circumference (small size 25 × 40 mm; medium size 30 × 60 mm, large size 40 × 80 mm). A buffer sheet is inserted between the small and large cuffs in order to prevent transmission of pulsatile oscillations from the large cuff, and to reduce the compliance of the small cuff. In order to reduce the cost of producing a device with a resistance filter to attenuate contamination due to the pulsatile signals received by the large cuff, a single silicon diaphragm type of piezo-resistive pressure sensor is used to detect both the compression pressure and pulsatile oscillations.

Signals from the pressure sensor are converted from analogue to digital (A/D), then separated into pressure signals and pulsatile signals with a digital filter ready for processing. In order to eliminate external noise, an artifact detection system determines whether the pulse wave is normal or not, based on the degree of noise contamination. Figure 4 (b & c) shows the pulse waveform obtained by filtering the detected pulse waves to emphasize the pulse wave change rate. Compared with the waveform detected by the large cuff in the conventional oscillometric method (Fig. 4c), the waveform detected by the small cuff is characterized by clear detection points for SBP (P_s in Fig. 4b) and DBP (P_d in Fig. 4b). Systolic BP is identified by the detection of a rapid increase in the amplitude due to the start of blood flow into the central cuff region, and DBP by the detection of a rapid decrease in the amplitude due to the disappearance of artery occlusion (Fig. 1d). The
Y-shaped tube. Cuffs of different sizes, small (for arm circumference, 17–26 cm), medium (24–32 cm), and large (32–42 cm), were prepared for this test. The brachial circumference of each subject was measured, and then a cuff of the appropriate size was wrapped around the upper arm. Concurrent with the measurement by the ESH-55 device, two trained observers obtained an auscultatory measurement using a double-headed stethoscope normally for educational use (Littmann 2138, 3 M Health Care, St. Paul, USA), which was applied to the subject's arm with a belt. Systolic BP was determined at Korotkoff phase I, and DBP at phase V. The two observers were placed so that they could not view the readings of the ESH-55 device or each other's measurements. Measurement was performed three times on each subject with an interval of between 1 and 1.5 min between the measurements.

There were 87 subjects (65 hypertensive outpatients and 22 normotensive subjects from the Yokohama City University Cardiovascular Centre, Cardiovascular Medical Outpatient Clinics), from whom a total of 256 measurements were obtained. The mean age of the subjects was 55 years (18–78 years; 36 men and 51 women). The SBP was below 100 mmHg in 32 subjects (13%) and 180 mmHg or higher in 26 subjects (10%), while DBP was below 60 mmHg in 40 subjects (16%) and 100 mmHg or higher in 25 subjects (10%), which satisfied the AAMI guidelines requiring 10% or greater for each. According to the AAMI guidelines, the ratio of subjects with a brachial circumference below 25 cm or greater than 35 cm should both be represented by over 10% of the population being studied. In the present study, 19 subjects had a brachial circumference of 25 cm or less (22%), but no subject had a circumference of 35 cm or greater (the average arm circumference of a Japanese adult is 25.5 cm, and 95% upper range is 33.2 cm, n = 23,172).

The electronic pressure gauge was connected to a computer (PCG-505RX, Sony Co., Tokyo, Japan) to monitor cuff pressure. The measurement data from the ESH-55 device were compared with auscultatory measurements. Measurements were performed by inflating the cuff to a pressure approximately 40 mmHg higher than the predicted SBP. The ESH-55 has a function that automatically recognizes inadequate cuff inflation from the pulse waveform. If the device detects inadequate inflation, it displays the message 'insufficient inflation' and a buzzer sounds. When this message is displayed, inflation is repeated to bring the cuff pressure to 40 mmHg higher than the last value. In this test, the cuff was deflated at about 4 mmHg/sec. The automatic air release function of the ESH-55 after termination of measurement was not activated.

Comparison with auscultatory method
The accuracy characteristics of the device were validated in accordance with the Association for the Advancement of Medical Instrumentation (AAMI) SP-10 (1992) [10]. An electronic standard pressure gauge (pressure accuracy ± 1 mmHg) was connected to the ESH-55 device with a
Measurements were performed three times per subject, who were resting in a sitting position, and finished within 10–15 min according to the AAMI guidelines. In the present study, five data sets were excluded because of unstable BP (with an auscultatory gap), inaudible K-sounds, unstable auscultation due to external noise, inadequate cuff inflation, and an error in data transmission. Prior to the study, all subjects gave their informed consent and the ethical committee of our institute approved the protocol.

Statistical analysis
In addition to standard statistical methods including least-squares linear regression analysis, we used the Bland-Altman scatter plotting method [11]. Values were expressed as mean ± SD. Microsoft Excel was used for calculations.

Results
Comparing the measurements taken by the two observers, the difference in SBP data was ± 5 mmHg in 96% and ± 10 mmHg in 99% of subjects, while the difference in DBP data was ± 5 mmHg in 92% and ± 10 mmHg in 99% of subjects, which satisfied the AAMI guidelines [10] which specify that the differences in values measured by two observers should be ± 5 mmHg in at least 85% and ± 10 mmHg in at least 95% of subjects concerning both SBP and DBP values respectively. Thus, the reliability of the two observers was verified.

The individual differences between BP determined by the auscultatory method and the TDCM with the ES-H55 device are shown in Figure 5 in the form of a Bland-Altman scatter plots. The difference in SBP was 0.2 ± 3.9 mmHg (mean ± SD), and in DBP was −0.1 ± 4.6 mmHg. The difference in SBP between the two methods was within ± 5 mmHg in 87.5%, and ± 10 mmHg in 96.9% of subjects, while the difference in DBP was within ± 5 mmHg in 80.1% and ± 10 mmHg in 95.6% of subjects. The correlation coefficient between measurement data from the auscultatory method and those with the ES-H55 device was 0.992 for SBP and 0.961 for DBP (Table 1).

Discussion
It was verified that absolute errors in measurement by the ES-H55 device compared with the auscultatory method were within 0.2 ± 4.6 mmHg with respect to both SBP and DBP, which satisfied the AAMI guidelines for permissible errors (5 ± 8 mmHg). With respect to SBP, the pulsatile signals from the artery occluded by the cuff were made clearer and detected more distinctly by the TDCM, with the result that the SDs of errors decreased by approximately 30% as compared with the conventional oscillometric method using the Terumo ES-H51 [3].

This test showed that the ES-H55 device was sufficiently accurate for clinical use; however, the SDs of errors with this method were larger than those with the previously reported double-cuff method [8]. This can be attributed
to differences in the population, and simplification of the commercially produced ES-H55, such as elimination of the elastic sheet which cuts out the arterial pulsation from the upstream region of the large cuff. In our previous study, the SDs of differences between double-cuff and photo-oscillometric measurements were smaller than those between double-cuff and auscultatory measurements [8]. Considering that the photo-oscillometric method gave closer values to the direct method compared to the auscultatory method [2], the question of whether or not the auscultatory method should be used for accuracy validation is raised.

There were two limitations to this study. First, in the routine clinical setting, auscultatory measurements are made by means of a mercury sphygmomanometer. However, for this experiment, attaching a mercury manometer to the Y-shaped tube affected the oscillation wave of the ES-H55 device. To avoid this, we used an electronic standard pressure gauge and connected it with a computer to read its pressure values. Naturally, we ascertained that the readings of the mercury manometer and the electronic pressure gauge were the same. The judgements of ES-55 device and those made by other researchers were mutually blind. This method differs from the ordinary auscultatory method, but since one of the goals of this study was to determine the accuracy of the ES-H55 device algorithm, and to avoid errors in mercury-manometer readings, we employed the more accurate electronic pressure gauge.

Second, the Bland-Altman plot (Fig. 5a) shows a downward trend in inter-method differences relative to the inter-method average: the X-axis is \((\text{SPB}_D + \text{SPB}_A)/2\) and the Y-axis is \((\text{SPB}_D - \text{SPB}_A), Y = -0.03 X + 4.3\) \((r = 0.19, p < 0.05)\). In one case, the X-axis is 202 mmHg and the Y-axis is -15 mmHg. The subject in question was a woman demonstrating great BP differences \((\pm 15 \text{mmHg})\), and this discrepancy probably arose because of BP fluctuation at measurement time. Apart from this subject, there was no correlation \((r = -0.12, p > 0.05)\).

Currently, automatic BP measuring devices are widely used in hospitals for monitoring in the ICU, CCU and operating room, but the mercury sphygmomanometer is still the mainstream device for routine measurement in wards and outpatient clinics. The mercury sphygmomanometer is easy to use, but the rate of deflation needs to be controlled to 2-4 mmHg/sec, and errors in visual reading of the mercury column need to be considered. It also requires attention to the performance and placement of the stethoscope, besides a certain level of auditory acuity and training to hear the K-sounds. Daily maintenance to prevent soiling of the wall of the mercury column, oxidization of mercury and clogging of the filter at the top of the mercury column is also necessary. Thus, the mercury sphygmomanometer requires considerable skill to use properly and trouble to maintain. Maintenance is often neglected in a busy clinical practice, and such neglect was the subject of a report discussed in a meeting of the Japanese Society of Hypertension in 2001. The report described a certain medical institution in Japan, where approximately 30% of the devices had errors of 3 mmHg or greater, and only 60% of the devices were free from errors when air leak was included in these errors, and that errors were greater in surgical wards than in medical wards. It was also reported in Brazil that approximately 30% of BP-measuring devices including the aneroid type used in hospitals had accuracy problems [12]. This indicates that the mercury sphygmomanometer requires constant care. Such devices are becoming out of date in medical centres, which must aim at the highest quality with higher efficiency.

Mercury sphygmomanometers contain 50 g mercury if the internal diameter of column is 3 mm, and 120 g mercury if it is 5 mm [13]. If they are broken inside the hospital, a part of the escaping mercury may evaporate into the air and be scattered throughout the hospital through air conditioner ducts. Currently, the mechanical aneroid sphygmomanometer is available as an alternative to mercury sphygmomanometers, but it is easily broken. Moreover, the needle undergoes large swings with the pulse waves, which makes reading difficult. Thus, there is a great demand for an alternative BP-measuring device to these sphygmomanometers.

The Terumo ES-H55 is compact, light at 120 g and easy to use, since it is aimed primarily for use in hospital wards and outpatient clinics where BP-measuring devices are frequently required. It is a simple all-in-one device with a built-in display and inflatable bulb. It costs almost nothing to maintain, and is economical since a single alkaline AA cell will provide more than 1000 measurements. The pressure sensor in this device also showed no deterioration in performance after approximately five years use. The pulse waveform within the small cuff of the ES-H55 device incorporating the TDCM has clearer discrimination points for SBP and DBP compared to the conventional cuff-oscillometric method. Thus, the Terumo ES-H55 can be considered to be useful as a BP-measuring device and capable of replacing the mercury sphygmomanometer.

**Acknowledgements**

The authors wish to thank Takahiro Souma, Yoshiyuki Habu and Kouji Hagij from the Research and Development Section of the Terumo Corporation, Tokyo, Japan, for producing the ES-H55 device. This report is being made with the consent of the Terumo Corporation.
References


5. Gitting JC. Auscultatory blood-pressure determination. *Arch Intern Med* 1910; 6:166-204.


