Criteria for a suitable reference cuff for validation studies of blood pressure measuring devices in people with arm circumference between 43 and 50 cm

Paolo Palatini, Claudio Fania, Elisabetta Benetti, Francesca Saladini, Francesca Battista and Andrea Ermolao

Objective Recommendations about the dimensions of the reference cuff for device validations in people with arm size >42 cm are still unavailable. The aim of this study was to identify the criteria for an appropriate reference cuff for validation studies in people with upper arm circumference between 43 and 50 cm.

Methods In 20 adults with upper arm circumference between 43 and 50 cm (X-large group), 34 subjects with arm circumference between 37 and 42 cm and 78 subjects with arm circumference <37 cm cylindrical and tronco-conical cuffs were compared. In all participants, the pressure transmitted to the arm under the two cuffs was measured using a paper-thin pressure sensor.

Results In the X-large group, all participants had an arm slant angle <86.0°. In this group, the difference between the pressure detected on the arm surface with the sensor using the cylindrical versus the tronco-conical cuff (13.5 mmHg) was larger than in the group with an arm circumference of 37–to 42 cm and the group with a circumference <37 cm (3.7 and 0.6 mmHg, respectively, $P<0.001$ versus both). In the whole sample, the between-cuff pressure difference was proportional to the conical shape of the arm ($P<0.001$).

Conclusions These data suggest that in people with arm size between 43 and 50 cm the reference cuff for validation studies should have a conical shape with an 84–85° slant angle. To comply with current guidelines, an 18.5 × 37.0 cm bladder should be used which would allow proper cuffing in the large majority of subjects. *Blood Press Monit* 28: 67–72 Copyright © 2022 Wolters Kluwer Health, Inc. All rights reserved.

Blood Pressure Monitoring 2023, **28**:67–72

Keywords: cuff, obesity, pressure sensor, tronco-conical, upper arm

Department of Medicine, University of Padova, Padua, Italy

Correspondence to Paolo Palatini, Department of Medicine, Studium Patavinum, Università di Padova, via Giustiniani, 2 - 35128 Padua, Italy
Tel: +39 049 821 2378; fax: +39 049 875 4179; e-mail: palatini@unipd.it

Received 11 August 2022 **Accepted** 13 October 2022.

Introduction

A large number of epidemiological data have documented an increasing prevalence of obesity among adult individuals with a rapid increase also of morbid obesity [1,2]. In recent years, despite the important technological advances in blood pressure (BP) measurement equipment, little attention has been paid to the performance of cuffs in the very obese [3]. In particular, little or no information is available for arm circumferences above 42 cm. The Association for Advancement of Medical Instrumentation/European Society of Hypertension/International Organisation for Standardisation (AAMI/ESH/ISO) organization provides recommendations for reference cuffs to be used in validation studies including subjects with arm size ranging up to 42 cm [4]. People with an arm circumference of 43 cm or larger are considered a special population by the AAMI/ESH/ISO but recommendations about the dimensions and shape of the reference cuff for this arm size class are still unavailable. One aspect often neglected by manufacturers and clinicians is that in these individuals conically shaped arms are almost always encountered, so the use of a cylindrical cuff, even of adequate size, can lead to unreliable BP measurements [5,6]. In fact, in a conical arm, a cylindrical (rectangular) cuff will expand irregularly on the lower part of the upper arm leading to an uneven pressure distribution along the cuffed arm [5–7]. Thus, the aim of this study was to investigate the effect of the shape of the cuff in a group of very obese subjects with arm circumference between 43 and 50 cm by comparing a cylindrical cuff and a tronco-conical cuff of appropriate size and having the same length and width on the midpoint. Using a pressure sensor applied on the center of the cuffs, we wanted to check the effect of the shape of the cuff on the pressure transmission to the arm in this special population.

Methods

Subjects

Twenty adults with upper arm circumference between 43 and 50 cm, 34 subjects with arm circumference between 37 and 42 cm, and 78 subjects with arm circumference <37 cm were enrolled. No people with circumferential skin folds around the upper arm were encountered. The 37–42 cm category was chosen based on previous data from our laboratory which showed that a small drop in pressure was achieved with the cylindrical cuff in this arm size range [7]. All participants were patients attending outpatient clinics at the Padova University Hospital.

 DOI: 10.1097/MBP.0000000000000630

Measurements

Information on anthropometric measurements was published previously [8]. Briefly, measurements of arm dimensions were made with the subjects in the supine position with arms resting comfortably at the sides. The upper arm proximal, middle and distal circumferences were measured to the nearest 0.5 cm with a measuring tape. The proximal circumference was measured just below the axilla and the distal circumference was just above the antecubital fossa. Middle circumference was measured at the midpoint from the acromion to the olecranon. Upper arm length was measured from the axilla to the antecubital fossa. The proximal and distal circumferences and the upper arm length were used to calculate the slant angle of the truncated cone according to the formula [9]:

$$SA = \text{arccosine}\ [(C_1 - C_2)/(2\pi \times L)] \times (360/2\pi),$$

where SA is the slant angle in degrees, 'C_1' is the arm proximal circumference in cm, 'C_2' is the arm distal circumference in cm and 'L' is the arm length in cm (Fig. 1). Skinfold thickness was measured in triplicate with a manual caliper at the triceps and biceps, and the average of the six measurements was defined as upper arm skinfold thickness. Based on the slant angle, the participants were divided into five conicity classes with a slant angle of ≥88°, 86–87.9°, 84–85.9°, 82–83.9° and <82°.

Cuffs

In all participants, tronco-conical and cylindrical cuffs and bladders were used having a length that was at least 80% and a width that was at least 40% of arm circumference at the midpoint (for the 43–50 cm group both cuffs were 40 × 20 cm on the center) (El. Med Garda S.r.l, Costermano, Italy). The tronco-conical cuff had an 85.0° slant angle (its bladder had a proximal and distal length of 45 and 35 cm, respectively). This shape was based on previous anthropometric data obtained in our laboratory [5]. Also for the other two groups, tronco-conical and cylindrical cuffs and bladders of appropriate size were used, using slant angles derived from anthropometric measures previously obtained in our laboratory [5].

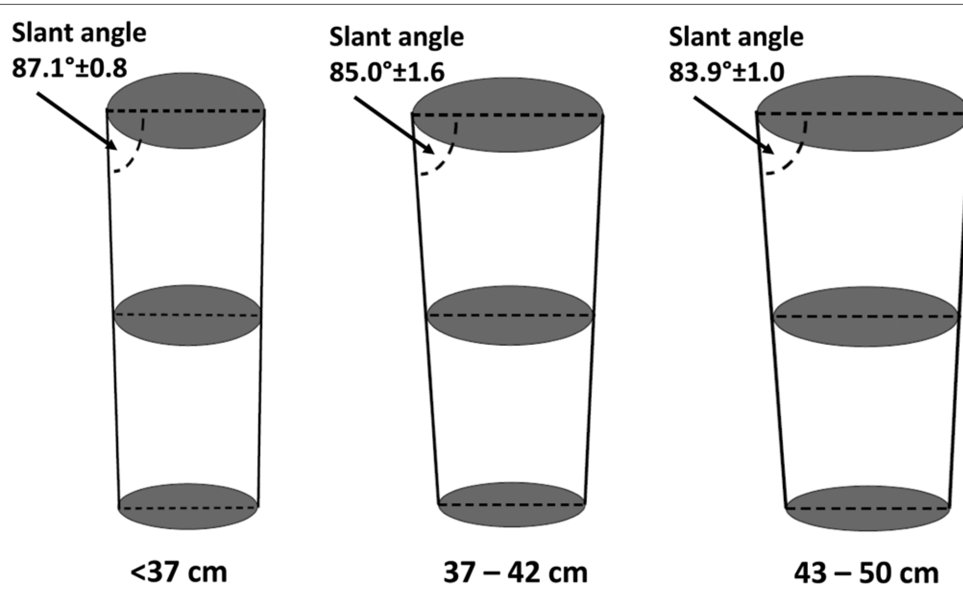
Procedures

The procedures followed were in accordance with institutional guidelines and were approved by the clinical study review board of our department. All participants gave their written informed consent.

Measurement of the pressure under the cuffs

The pressure present on the arm surface under the cuff was measured at five different in-cuff pressure levels (60, 90, 120, 150 and 180 mmHg) using a paper-thin pressure sensor attached to the central point of the cuffs and placed over the brachial artery, which was connected to a pressure transducer (Microlab, Padua, Italy). Air was pumped into the cuff until the desired pressure level was reached. After a steady-state pressure condition was achieved, three pressure readings were collected and averaged with both the cylindrical and the tronco-conical cuffs. Thus, in each participant, 15 readings with the tronco-conical cuff and 15 readings with the cylindrical cuff were obtained. Other details on the procedures used have been reported elsewhere [7,10–12].

Fig. 1



Upper arm shape in 132 subjects divided into three groups according to their arm circumference. The arm slant angle (mean ± SD) progressively decreased on going from the <37 cm to the 43–50 cm group attesting to a more pronounced conical shape in the latter.

Statistics

The primary dependent variable was the difference between the pressures measured on the arm surface by the pressure transducer using the tronco-conical and the cylindrical cuff. For comparisons between the three arm-circumference groups, an ANCOVA test was used adjusting for age and sex. Tukey's test was used to compare between-group BP differences and Bonferroni corrected *P* values were provided. Data are presented as mean ± SD unless specified. A $P < 0.05$ or less was considered as statistically significant.

Results

Subjects

The clinical characteristics and the anthropometric measures of the three groups of subjects are reported in Table 1. As expected, BMI and arm skinfold thickness, were greater in the subjects with an arm circumference of 43–50 cm (X-large) than in the other two groups. Arm length was also greater in the X-large group. The arm slant angle decreased on going from the <37 cm to the 43–50 cm group ($P < 0.001$) (Fig. 1).

Shape of the arm

The conical shape of the arm progressively increased across the three groups (Table 1). In the X-large group, no participant had a slant angle >86.0°, and most had a slant angle between 82.0° and 85.9° (Fig. 2).

Pressure transmission to the arm with the cylindrical versus the tronco-conical cuff

In the X-large group, the pressure measured on the arm surface with the sensor was similar to the in-cuff pressure when the tronco-conical cuff was used and was lower than the in-cuff pressure when the cylindrical cuff was used. The difference between the pressures measured with the cylindrical and the tronco-conical cuffs was much higher in the X-large group (−13.5 mmHg) than in the two groups with smaller arm size ($P < 0.001$ versus both groups) (Table 1 and Fig. 3). The between-cuff pressure difference was proportional to the conical shape of the arm (Fig. 4, $P < 0.001$).

Discussion

The main finding of the present study is that in the group of obese subjects with arm circumference between 43 and 50 cm, the pressure transmitted to the arm by the cylindrical cuff was much lower than that transmitted by the tronco-conical cuff (−13.5 mmHg) indicating a loss of transmission pressure when the cylindrical cuff was used. A smaller loss of pressure was found in the 37–42 cm group and virtually no difference in the <37 cm group, in keeping with our previous results [7,12]. The pressure difference between the cylindrical and tronco-conical cuff was assessed at five different pressure levels over a 60–180 mmHg range and was proportional to the arm circumference and to the conical shape of the arm.

In previous studies, we found that in subjects with arm size >37 cm a cylindrical cuff overestimated SBP and DBP compared to BP measured with a tronco-conical cuff, an error which was proportional to the arm circumference and the conical shape of the arm and was explained by the loss of transmission pressure when using the cylindrical cuff [7].

The present results in the 43–50 cm arm size group may have an impact on the future validation of automatic monitors intended for BP measurement in obese subjects with X-large arms. The AAMI/ESH/ISO, which is internationally recognized as the leading organization for establishing standards for device validation studies [4], recently published a protocol for the validation of BP measuring monitors using cuffs for arms up to 42 cm circumference. People with arm size >42 cm are considered a special population by AAMI/ESH/ISO and thus, after a successful validation in an 85-subject general population study, BP measuring devices need an additional validation in 35 subjects. However, there is still no agreement as to the properties of the reference cuff that should be used by the investigators in individuals with X-large arm [13].

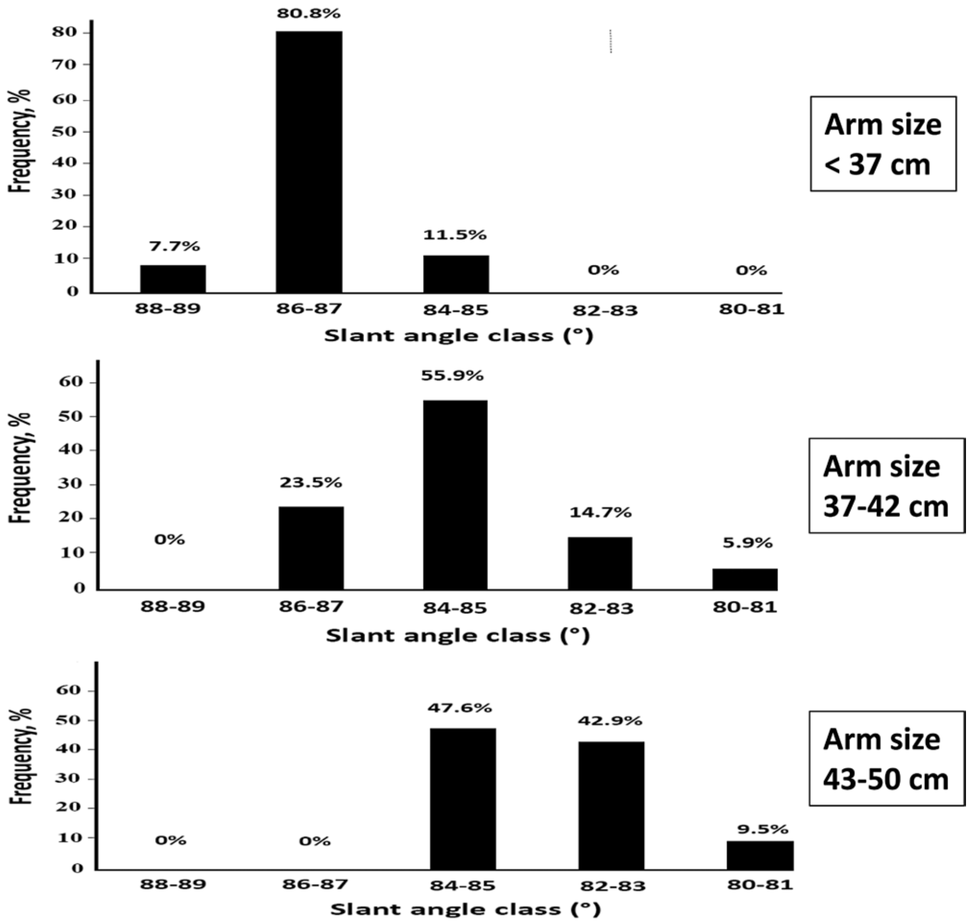
There is a general consensus that the reference cuff and bladder in validation studies should have at least a 37% width and a 75% length of arm circumference

Table 1 Clinical and anthropometric characteristics of the participants with 43–50 cm upper arm circumference (X-large) and of the two groups of control

	Group 1	Group 2	Group 3	
Variable	<37 cm	37–42 cm	43–50 cm	*P* value
Age (years)	52.0 ± 1.8	44.9 ± 2.7	52.2 ± 3.6	0.087a
Sex (female)	35.9%	50.0%	50.0%	0.27a
Body mass index (Kg/m^2)	27.9 ± 0.9	43.4 ± 1.4	44.7 ± 1.9	<0.001
Arm length (cm)	20.9 ± 0.2	20.9 ± 0.2	22.8 ± 0.3	<0.001
Arm middle circumference (cm)	30.3 ± 0.3	40.3 ± 0.5	44.4 ± 0.6	<0.001
Arm skinfold thickness (cm)	1.5 ± 0.06	2.9 ± 0.09	3.0 ± 0.11	<0.001
Upper arm slant angle (°)	87.1 ± 0.1	85.0 ± 0.2	83.9 ± 0.2	<0.001
Between-cuff pressure difference (mmHg)b	−0.6 ± 0.5	−3.7 ± 0.8	−13.5 ± 1.0	<0.001

Data are mean ± ESM. *P*-values are adjusted for age and sex.
[a]Unadjusted.
[b]Cylindrical cuff pressure − tronco-conical cuff pressure.

Fig. 2



Distribution of the conicity classes in the three arm circumference groups.

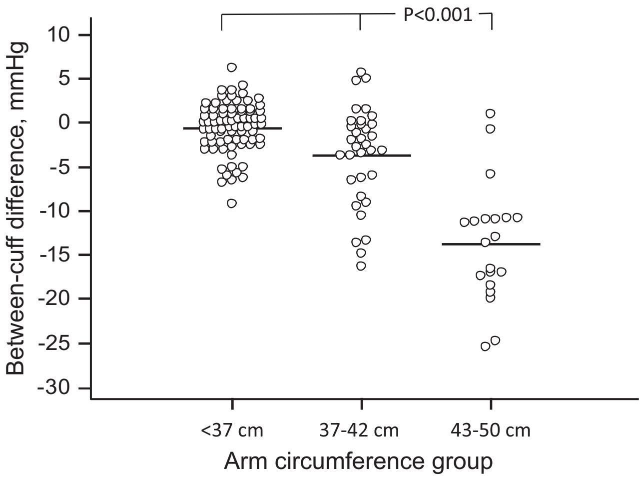
[4,14,15]. Thus, for the 43–50 cm arm size range the bladder width should be at least 18.5 cm. Considering that to allow room for proper placement of the stethoscope, the lower end of the cuff should be at least 2 cm above the antecubital fossa when an auscultatory measurement is being taken [15], an 18.5 cm wide cuff can not be used in people with arm length <20 cm (distance from axilla to antecubital fossa). According to our unpublished results in 74 obese people with 43–50 cm arm size, 5.5% had arm length <20 cm (four women) and 21% had arm length <21 cm.

An important feature of our 43–50 cm arm size participants was that all had a conically shaped arm with a slant angle <86° which likely accounted for the loss of transmission pressure when the cylindrical cuff was used. This indicates that a tronco-conical cuff can fit better on these arms ensuring proper and consistent cuff placement and should thus be used in X-large arms. Both the upper arm size and slant angle are independent predictors of the between-cuff pressure difference [7,12]. However, given the close relationship between the arm size and conical shape, for practical purposes, the arm circumference can be used to predict the measurement error.

Limitations

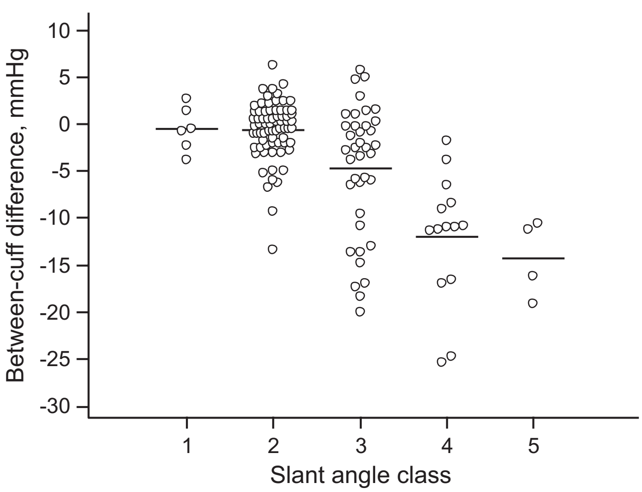
A limitation of the present study is the small number of subjects in the X-large arm group and thus our data need to be confirmed in larger samples. However, the much larger between-cuff pressure difference in the X-large arm group compared to both groups of control ($P < 0.001$) makes it unlikely that the present results were obtained by chance. Another limitation of our approach is that the use of a cuff of appropriate width was impossible in subjects with upper arm length <20 cm who had to be excluded. The longer arm span in the X-large participants can actually be due to the exclusion of people with short arms in this group. However, according to our recent results, only 5.5% of X-large people have an arm length <20 cm. These data, however, may not be fully representative of real-world people with very large arms especially if women, older individuals and short people are considered. For these individuals (the majority are

Fig. 3



Pressure difference detected by the sensor under the cuff using the cylindrical and the tronco-conical cuffs in the three arm circumference groups. The procedure was repeated five times at incremental pressure levels and the mean difference was used for the comparisons. *P* from age-and-sex-adjusted ANCOVA<0.001.

Fig. 4



Pressure difference detected by the sensor under the cuff using the cylindrical and the tronco-conical cuffs according to arm conicity class. The procedure was repeated five times at incremental pressure levels and the mean difference was used for the comparisons. Based on the arm slant angle, the participants were divided into five conicity classes with slant angles of ≥88° (class 1), 86–87.9° (class 2), 84–85.9° (class 3), 82–83.9° (class 4) and <82° (class 5). *P* from age-and-sex-adjusted ANCOVA<0.001.

women) other methods of BP measurement should be sought.

Suggestions for the reference cuff to be used in people with 43–50 cm arm circumference

Based on the above considerations, we can formulate some criteria to identify a suitable reference cuff for device validation studies in people with arm size between 43 and 50 cm.

Dimensions

An 18.5×37.0 cm bladder should be used which would allow proper cuffing in the large majority of subjects. Extending the arm size range up to 52 cm would require the use of a 19.2 cm wide cuff increasing the number of excluded people to 21%.

Shape

With the limitation of the small sample size, our data suggest that a tronco-conical cuff should be used with a slant angle of 84–85°. This shape would allow the cuff to be pulled taut with a comparable tightness at the top and bottom edges in most subjects in agreement with current recommendations [15]. There is little information about whether a rectangular bladder inside a tronco-conical cuff could work equally well as a tronco-conical bladder. Thus, in the absence of specific information, we recommend the use of a tronco-conical bladder. Although we provided helpful suggestions for the use of an appropriate cuff in people with very large arms, the validation of BP measuring devices in these subjects will remain a problematic and challenging issue due to the low Korotkoff sound intensity of reference auscultatory measurement often encountered in this segment of the population.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

References

1 Leggio M, Lombardi M, Caldarone E, Severi P, D'Emidio S, Armeni M, *et al*. The relationship between obesity and hypertension: an updated comprehensive overview on vicious twins. *Hypertens Res* 2017; **40**:947–963.
2 Ostchega Y, Dillon C, Carroll M, Prineas RJ, McDowell M. US demographic trends in mid-arm circumference and recommended blood pressure cuffs: 1988-2002. *J Hum Hypertens* 2005; **19**:885–891.
3 Palatini P, Parati G. Blood pressure measurement in very obese patients: a challenging problem. *J Hypertens* 2011; **29**:425–429.
4 Stergiou GS, Alpert B, Mieke S, Asmar R, Atkins N, Eckert S, *et al*. A universal standard for the validation of blood pressure measuring devices: association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) collaboration statement. *J Hypertens* 2018; **36**:472–478.
5 Bonso E, Saladini F, Zanier A, Benetti E, Dorigatti F, Palatini P. Accuracy of a single rigid conical cuff with standard-size bladder coupled to an automatic oscillometric device over a wide range of arm circumferences. *Hypertens Res* 2010; **33**:1186–1191.
6 Maxwell GF, Pruijt JF, Arntzenius AC. Comparison of the conical cuff and the standard rectangular cuffs. *Int J Epidemiol* 1985; **14**:468–472.
7 Palatini P, Benetti E, Fania C, Malipiero G, Saladini F. Rectangular cuffs may overestimate blood pressure in individuals with large conical arms. *J Hypertens* 2012; **30**:530–536.
8 Palatini P, Fania C, Ermolao A, Battista F, Saladini F. Use of anthropometric indices to identify appropriate cuff shapes for blood pressure measurement: normative data for adults. *Am J Hypertens* 2022; **35**:526–532.
9 Varona JL. Rational values of the arccosine function. *Centr Eur J Math* 2006; **4**:319–322.
10 Benetti E, Fania C, Palatini P. Validation of the A&D BP UA-651 device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010. *Blood Press Monit* 2014; **19**:50–53.

11 Benetti E, Fania C, Márquez Hernández V, Palatini P. Validation of the Thermor BIOS BD215 device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010. *Blood Press Monit* 2014; **19**:176–179.
12 Palatini P, Benetti E, Fania C, Saladini F. Only troncoconical cuffs can provide accurate blood pressure measurements in people with severe obesity. *J Hypertens* 2019; **37**:37–41.
13 Palatini P, Asmar R, O'Brien E, Padwal R, Parati G, Sarkis J, *et al*.; European Society of Hypertension Working Group on Blood Pressure Monitoring, Cardiovascular Variability, the International Standardisation Organisation (ISO) Cuff Working GroupEuropean Society of Hypertension Working Group on Blood Pressure Monitoring, Cardiovascular Variability, the International Standardisation Organisation (ISO) Cuff Working Group. Recommendations for blood pressure measurement in large arms in research and clinical practice: position paper of the European Society of Hypertension Working Group on blood pressure monitoring and cardiovascular variability. *J Hypertens* 2020; **38**:1244–1250.
14 Geddes LA, Tivey R. The importance of cuff width in measurement of blood pressure indirectly. *Cardiovasc Res Cent Bull* 1976; **14**:69–79.
15 Muntner P, Shimbo D, Carey RM, Charleston JB, Gaillard T, Misra S, *et al*. Measurement of blood pressure in humans: a scientific statement from the American Heart Association. *Hypertension* 2019; **73**:e35–e66.