Accuracy of the Microlife large–extra large-sized cuff (32–52 cm) coupled to an automatic oscillometric device

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To determine the accuracy of the large–extra large-sized (L–XL) cuff (32–52 cm) coupled to a Microlife WatchBP Office ABI blood pressure measuring device tested according to the requirements of the International Protocol of the European Society of Hypertension. The L–XL cuff tested in this study is designed to provide accurate blood pressure measurements in patients with large arms (arm circumference ≥ 32 cm) over a wide range of arm circumferences using a single 145 ± 1 × 320 ± 1 mm bladder. The evaluation was made in 33 patients with a mean ± standard deviation age of 53 ± 17 years (range: 30–96 years). Their systolic blood pressure (SBP) was 142 ± 21 mmHg (range: 110–180 mmHg), diastolic blood pressure (DBP) was 87 ± 14 mmHg (range: 62–106 mmHg) and arm circumference was 36 ± 5 cm (range: 32–50 cm). Blood pressure measurements were made in the sitting position. The L–XL cuff coupled to the WatchBP Office ABI passed all three phases of the European Society of Hypertension protocol for SBP and DBP. Mean blood pressure differences between device and observer were −1.3 ± 5.1 mmHg for SBP and −1.8 ± 5.8 mmHg for DBP. Similar device–observer differences were observed in patients divided into two subgroups according to whether their arm circumference was above or below the median in the group. These results indicate that the L–XL cuff coupled to the WatchBP Office ABI monitor provides accurate blood pressure readings in patients with large arms over a wide range of arm circumferences. *Blood Press Monit* **16:99–102 © 2011 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

Blood Pressure Monitoring 2011, **16**:99–102

Keywords: cuff, device, hypertension, self-measurement, validation

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Received 9 November 2010 **Revised** 29 December 2010
Accepted 4 January 2011

Introduction

Appropriate cuff size is essential for accurate measurement of blood pressure (BP). However, recent results indicate that more than one-third of the upper arm devices sold in medical markets and electronic stores do not have any information about cuff sizes [1]. Automated sphygmomanometers for self-BP measurement are often purchased without any medical advice and the use of a standard size cuff in people with large arms may lead to inaccurate readings [2,3]. Obesity is an emerging problem in developed countries [4], and overweight and obese patients often require the use of large-sized cuffs [5]. The regular adult cuff size is too short for individuals with an arm circumference of 32 cm or larger, and many patients will have inaccurate measures of BP if BP monitors do not have correct cuff sizes [2–5]. However, even for obese patients the cuff should be tailored according to the arm circumference and several patients will require the use of an extra large-sized cuff. In patients with very large arms, measurement with a cuff of an appropriate size is often difficult in the presence of a short humerus length because the elbow end of the cuff may extend past the elbow by several centimeters. Therefore, there exists a need for a large cuff, which can provide accurate measurements in obese patients over a wide range of arm circumferences of up to 50 cm or more. The Microlife Company recently developed large–extra large-sized cuff (L–XL cuff) intended for self-BP measurement in patients with arm circumferences ranging from 32 to 52 cm. This study reports on the accuracy of this cuff coupled with the WatchBP Office ABI monitor (Microlife AG, Espenstrasse 139, CH 9443, Widnau, Switzerland) validated earlier [6], evaluated according to the 2002 protocol of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) [7].

Participants and methods

Participants were selected from outpatient clinics and wards at the University of Padova, Italy. Forty-five patients were taken into consideration based on the baseline BP until each of the required bins was filled. Twelve patients were excluded because BP ranges were complete ($n = 9$); Korotkoff sounds were of poor quality ($n = 2$) or there was atrial fibrillation ($n = 1$). Thus, the L–XL cuff coupled with the WatchBP Office ABI monitor was evaluated in 33 patients (13 women) with a mean ± standard deviation age of 53 ± 17 years (range: 30–96 years). Their systolic BP (SBP) was 142 ± 21 mmHg (range: 110–180 mmHg), diastolic BP (DBP) was 87 ± 14 mmHg

1359-5237 DOI: 10.1097/MBP.0b013e328344c73c

(range: 62–106 mmHg) and arm circumference was 36 ± 5 cm (range: 32–50 cm). BP measurements were taken in the sitting position. The study was approved by the Ethics Committee of the University of Padova, and a written informed consent was given by all the participants.

Cuff and device

A L–XL (32–52 cm) cuff coupled with a Microlife WatchBP Office ABI monitor was tested. The nylon cuff contained a rectangular $145 \pm 1 \times 320 \pm 1$ mm thermoplastic polyurethane bladder. The WatchBP Office ABI device is an oscillometric automatic device, which proved accurate for BP measurement at the upper arm in earlier studies [6]. It is provided with a novel technology that carries out an analysis of the measurement signal during cuff inflation and adjustment of the device parameters to the individual arm circumference and arm composition for the following deflationary measurement phase [6]. It can therefore measure BP accurately in a wide range of arm sizes with a single size bladder, provided the cuff sleeve assures a firm placement of the cuff on each arm size within the specified range of 32–52 cm arm circumference. This can be also achieved in the largest arms, thanks to the 70.0 cm length of the cuff. More information on the L–XL cuff is reported in the Appendix.

Device validation

The validation team consisted of three persons. The two observers used for the present validation (S.M. and F.S.) had received adequate training by an expert in BP measurement. They were tested according to the suggestions of the ESH protocol and the agreement between these two observers was 0.2 ± 2.7 mmHg for SBP and 0.1 ± 2.1 mmHg for DBP. The two observers were blinded to the measurement values of each other and took BP measurement with a mercury sphygmomanometer at the upper arm using an adult cuff, the bladder of which covered at least 80% of the arm circumference. Thus, for this study a 15×30 cm bladder was used for circumferences ranging from 33 to 37 cm, a 17×34 cm bladder for circumferences ranging from 38 to 43 cm and a 17×40 cm bladder for circumferences of 44 cm or more. The study was initiated on May 2010 and the device evaluation was made according to the 2002 version of the ESH protocol [7]. Using the double-headed stethoscope and the mercury sphygmomanometer (Erka, Bad Tölz, Germany), observers 1 and 2 took four sequential readings (BP1, BP3, BP5 and BP7). The supervisor (P.P.) took three readings with the test instrument (BP2, BP4 and BP6). The discrepancy between the reading provided by the device and the mean of the observers' measurements was allocated in four zones of accuracy following the recommendations of the ESH protocol [7].

Statistical analysis

To compare subgroups, Student's *t*-test for unpaired observations was used. Correlations were made with Pearson's test, and the Bonferroni correction was applied to probability values. Predictors of the discrepancy between observer and device measurements were included in linear multivariable regression analyses. A P value of less than 0.05 was considered statistically significant.

Results

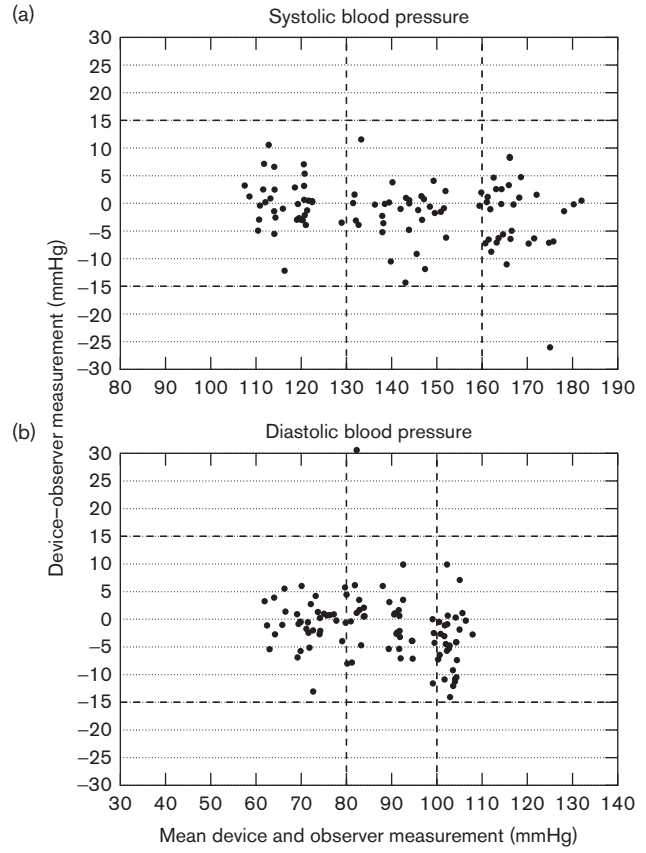
Data from the first 15 recruited participants who fulfilled the International Protocol criteria were included in the analysis of phase 1. In total, 45 measurements (three measurements $\times$ 15 participants) were available for analysis. The L–XL (32–52 cm) cuff coupled with the WatchBP Office ABI monitor passed all three criteria of the International Protocol for the primary phase (Table 1), for both SBP and DBP. In addition, the second phase encompassing 18 participants was successfully completed, including the second part of phase 2 (phase 2.2) of the ESH protocol (Table 1). Mean differences $\pm$ standard deviation between device and observer were -1.3 ± 5.1 mmHg for SBP and -1.8 ± 5.8 mmHg for DBP (Fig. 1). Only two out of 198 differences were more than 15 mmHg. In a 96-year-old woman with an arm circumference of 32 cm, the device underestimated SBP by 26 mmHg and in a 79-year-old man with an arm circumference of 33.5 cm, the device overestimated DBP by 30 mmHg. The predictive value of several clinical variables for the device–observer discrepancy was tested in univariate and multivariable regression analyses. For both SBP and DBP, no relationship of the device–observer BP difference was found with age, sex, entry SBP and DBP and arm circumference. When the participants were divided into two subgroups according to whether their arm circumference was below or above the median in the group, the device–observer differences did not significantly differ between the subgroups ($P = 0.52$ for SBP and $P = 0.18$ for DBP).

Table 1 Device validation table for the large–extra large cuff coupled to a Microlife WatchBP Office ABI monitor

Phase 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade
Required				
One of	25	35	40	
Achieved				
SBP	35	42	45	Passed
DBP	32	41	44	Passed
Phase 2.1	**≤ 5 mmHg**	**≤ 10 mmHg**	**≤ 15 mmHg**	**Grade**
Required				
All of	60	75	90	
Achieved				
SBP	72	92	98	Passed
DBP	70	91	98	Passed
Phase 2.2	**2/3 ≤ 5 mmHg**	**0/3 ≤ 5 mmHg**		**Grade**
Required	≥ 22	≤ 3		
Achieved				
SBP	25	3		Passed
DBP	22	3		Passed

DBP, diastolic blood pressure; SBP, systolic blood pressure.

Fig. 1



Plot of the (a) systolic (upper plot) and (b) diastolic (lower plot) device–observer blood pressure differences. The *x*-axis represents the mean of the device and observer measurements. The *y*-axis represents the difference between the device and observer measurements. A positive value indicates that the device measurement is greater than the observer's measurement.

Discussion

The use of cuffs containing bladders of inappropriate dimensions may be the source of substantial error, which leads to erroneous conclusions in clinical practice [1–5]. Four out of every five people are able to use the standard size cuff that comes with the monitor and get accurate readings. However, some people have large arms and a standard size cuff may produce inaccurate readings. Measuring BP with a 12×24 cm cuff in people with arm circumference of 32 cm or more spuriously elevates the recorded BP leading to overdiagnosis of hypertension. Although most obese people will be served by an 'adult large' cuff, some will need an even larger cuff. According to some investigators [8], 'large' cuffs should work for most mid-sized fat people (35–44 cm) and 'thigh' cuff for supersized people (45–52 cm). However, exact sizing for cuffs is not well standardized and some companies make large adult cuffs that go much higher than 44 cm, whereas other large adult cuffs tend to run smaller. In addition, the use of an appropriate cuff in participants with very large arms is often difficult because in participants with short humerus length the elbow end of a thigh-sized cuff may extend past the elbow. For the above-mentioned reasons, special cuffs that can accommodate a wide range of arm sizes from medium to very large are needed. In this study, we tested the accuracy of a single cuff provided with a 145×320 mm bladder that may fit arms 32–52 cm in circumference. Our results indicate that this cuff coupled with an oscillometric device can also measure BP accurately in patients with very large arms for whom a thigh cuff should be used. Within our sample, we did not find any relationship between the device–observer SBP and DBP discrepancies and the circumference of the arm. In addition, in the participants divided into two subgroups with smaller and larger arms, the mean device–observer discrepancies did not differ between the subgroups. In particular, no BP overestimation was observed in the subgroup with very large arms. This indicates the effective function of the device algorithm and cuff for the claimed purpose.

In conclusion, these results show that the L–XL (32-52 cm) cuff coupled with the WatchBP Office ABI monitor can provide accurate BP measurements in patients with large arms over a wide range of arm circumferences.

Acknowledgement

This study was funded by a Grant from Microlife AG and by the University of Padova, Padua, Italy.

References

1 Akpolat T. Obesity, hypertension and home sphygmomanometer cuffs. *Eur J Int Med* 2010; **21**:338–340.
2 O'Brien E. Review: a century of confusion; which bladder for accurate blood pressure measurement? *J Hum Hypertens* 1996; **10**:565–572.
3 Alpert BS. Cuff width and accuracy of measurement of blood pressure. *Blood Press Monit* 2000; **5**:151–152.
4 Graves JW, Bailey KR, Sheps SG. The changing distribution of arm circumferences in NHANES III and NHANES 2000 and its impact on the utility of the 'standard adult' blood pressure cuff. *Blood Press Monit* 2003; **8**:223–227.
5 Oliveira SM, Arcuri EA, Santos JL. Cuff width influence on blood pressure measurement during the pregnant-puerperal cycle. *J Adv Nurs* 2002; **38**:180–189.
6 Stergiou GS, Tzamouranis D, Protogerou A, Nasothimiou E, Kapralos C. Validation of the Microlife Watch BP Office professional device for office blood pressure measurement according to the International protocol. *Blood Press Monit* 2008; **13**:299–303.
7 O'Brien E, Pickering T, Staessen J, Mengden T, Imai Y, Asmar R, *et al.* European Society of Hypertension International protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; **7**:3–17.
8 Perloff D, Grim C, Flack J, Frohlich ED, Hill M, McDonald M, *et al.* Human blood pressure determination by sphygmomanometry. *Circulation* 1993; **88**:2460–2467.

Appendix

In this appendix the basic information of the L–XL cuff (32–52 cm) is reported.

Cuff identification: Microlife L–XL cuff (32–52 cm).

Microlife AG.

The cuff is suitable for upper arm circumferences ranging from 32 to 52 cm.

Dimensions: 145 ± 1 × 320 ± 1 mm.

The characteristics of the Microlife WatchBP Office ABI device were reported elsewhere (Ref. [6]).

Costs: retail price of L–XL cuff + WatchBP Office ABI device was around α890, in Europe. The L–XL cuff is also applicable in combination with home BPM devices from Microlife (see *www.dableducational.org/*).

Compliance with standard: class IIa Medical Device after European MDD 93/43 EEC + Amendments.

Applicable standards for performance and safety.

Instructions for use, care and maintenance: these are reported in detail in the instruction manual.

Service facilities: for Microlife distributors refer to *www.microlife.com* or Microlife European Headquarter: Microlife AG.

Method of BP measurement: oscillometric, corresponding to Korotkoff method: phase I systolic, phase V diastolic.

Factors affecting accuracy: movement artefacts, arrhythmias.

Operator training requirements: users should follow the recommendations and instructions in the supplied manual. The monitor does not require specific expertise because it is very easy to operate.