apo norm®
die marke der apotheke

Blutdruckmessgeräte vom Marktführer[1]

[1]Quelle: IQVIA; OTC® Report, Umsatz und Absatz; Markt: Digitale Blutdruckmessgeräte Oberarm und Handgelenk aus der Apotheke, 2010 - 06/2023, Stand Juli 2023

Nr.1[1]
in der Apotheke

Klinische Studien
(Auszug)

technology by microlife®

Eine Qualitätsmarke von WEPA
DIE APOTHEKENMARKE

INHALTSVERZEICHNIS

KLINISCHE VALIDIERUNGEN VON BLUTDRUCKMESSGERÄTEN – EINE ÜBERSICHT

Klinische Validierung – Was heißt das?

Grundsätzlich müssen Blutdruckmessgeräte mindestens eine klinische Basisvalidierung vorweisen können, um auf dem europäischen Markt verkauft werden zu dürfen.

Bei einer klinischen Validierung wird anhand einer Testgruppe von Personen, die bestimmte Merkmale aufweisen müssen (Blutdruck-Einstufung, Alter, Geschlecht, Vorerkrankungen etc.), die Messgenauigkeit des Geräts, der Manschette oder/und besonderer Zusatzfunktionen überprüft.

Auf Grundlage der europäischen Medizinprodukteverordnung, die seit 2021 in Kraft ist, werden die Standards für Blutdruckmessgeräte-Validierungen unter neuen ISO-Normen zukünftig weiter vereinheitlicht, um großen qualitativen Unterschieden bei den Geräten noch besser vorzubeugen und die Sicherheit für Nutzer zu erhöhen.

Basisvalidierungen

Als Basis-Validierung werden Prüfungen bezeichnet, die anhand einer Testgruppe von Menschen durchgeführt werden, die einer „Durchschnittsbevölkerung ohne diagnostizierte Vorerkrankungen“ entspricht.

Basis-Validierungen können auf Grundlage der Prüfprotokolle z. B. folgender Institutionen vorliegen:

International

ESH European Society of Hypertension

BIHS British and Irish Hypertension Society
Committed to preventing cardiovascular disease

AAMI Celebrating Fifty Years of Building Tomorrows

Deutschlandweit

PRÜFSIEGEL Hochdruckliga Messgenauigkeit klinisch validiert

Dabei gibt es zwischen den Prüfprotokollen der Institutionen Unterschiede, z. B. die **Gruppengröße.**

- Je größer die Probandenanzahl, desto statistisch aussagekräftiger ist der Validierungstest:

ESH European Society of Hypertension

mind. 33
Probanden

BIHS British and Irish Hypertension Society
Committed to preventing cardiovascular disease

AAMI Celebrating Fifty Years of Building Tomorrows

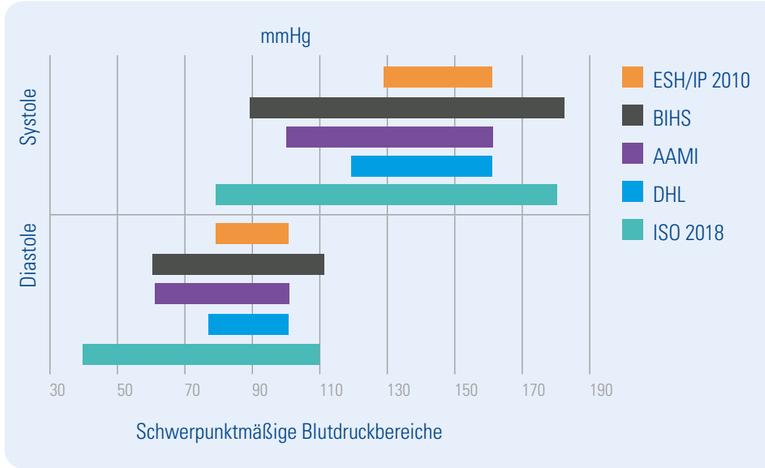
mind. 85-86
Probanden

PRÜFSIEGEL Hochdruckliga Messgenauigkeit klinisch validiert

mind. 96
Probanden

Ein weiteres Unterscheidungsmerkmal sind die **überprüften Blutdruckbereiche:**

- Je nach Protokoll ist die Spanne der Blutdruckbereiche, in der die Blutdruckmessgeräte schwerpunktmäßig und in statistisch valider Testgruppengröße auf Messgenauigkeit überprüft werden, unterschiedlich breit (siehe Grafik). Je weitgefächerter, desto sicherer sind Sie, dass die Geräte auch in niedrigeren bzw. höheren Blutdruckbereichen immer noch korrekt messen.



Hinweis: ESH & BIHS/AAMI-Protokolle wurden 2018 durch ein „AAMI/ESH/ISO Collaboration Statement - ISO 81060-2:2018“ ersetzt, um Qualitätsstandards zu vereinheitlichen. Das neuere Protokoll sieht 85 Probanden als Basis-Testgröße vor und wird laufend weiterentwickelt. Es erlaubt neben Basisvalidierungen auch Validierungen in speziellen Probandengruppen (siehe Seite 9).

aponorm® Blutdruckmessgeräte – Klinische Validierungen

Handgelenkmodelle

Mobil Basis
DHL| AAMI ✓

Mobil Slim
DHL | AAMI | ISO 81060-2:2013 ✓

Oberarmmodelle

Basis Control
DHL | BIHS | ISO 81060-2:2018 ✓

Basis Control PLUS
DHL | BIHS | ISO 81060-2:2018 ✓

Professional Control
DHL | BIHS | ISO 81060-2:2018 ✓

Basis Plus Bluetooth
DHL | BIHS | ISO 81060-2:2013 ✓

Professional Touch
DHL | BIHS | ISO 81060-2:2013 ✓

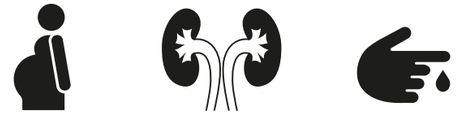
Spezialvalidierungen für bestimmte Personengruppen

Neben den Basisvalidierungen gibt es darüber hinaus noch gesonderte Spezialvalidierungen **für z. B. Personen mit Vorerkrankungen wie Diabetes und Niereninsuffizienz oder Schwangere mit Bluthochdruck.**

Bei diesen Personen können krankheits- bzw. schwangerschaftsbedingte Veränderungen der Gewebs- und Arterienstrukturen dazu führen, dass nicht für diese Risikogruppen ausgelegte Blutdruckmessgeräte abweichende Messwerte anzeigen. Diese Blutdruckmessgeräte tendieren dann dazu, den Blutdruck nach oben oder unten deutlich abzufälschen.

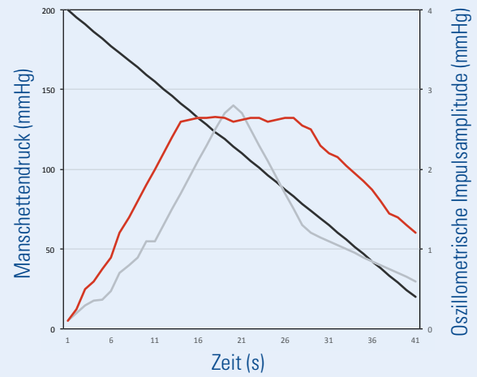
Daher ist es für Risikopatienten besonders wichtig, ein Blutdruckmessgerät zu nutzen, für das im Rahmen einer Spezialvalidierung die Messgenauigkeit trotz veränderter Umstände bestätigt wurde.

Die Oberarm-Blutdruckmessgeräte von aponorm® (alle Modelle) sind hier immer eine gute Wahl. Diese sind unter anderem speziell validiert für:



Schwangere | Nierenkranke | Diabetiker

Doch auch andere Anwender können mit speziell validierten Blutdruckmessgeräten auf Nummer sicher gehen, denn selbst ohne offiziell diagnostizierte Vorerkrankung können Veränderungen an den Arterien vorliegen. Dies gilt insbesondere bei Patienten auf die folgende Risikofaktoren zutreffen:



Vergleich normale Druckkurve (grau)
mit Druckkurve bei veränderten Gefäßstrukturen (rot)
▶ übliche Algorithmusberechnung funktioniert nicht mehr
(schwarze Linie = Manschettendruck)

Manschettenvalidierungen

Basisvalidierungen werden in der Regel mit der Standard-Manschettengröße des jeweiligen Gerätemodells durchgeführt. Darüber hinaus gibt es jedoch **noch Spezialvalidierungen für bestimmte Manschettengrößen und/oder -arten** (Softbügelmanschette, Schalenmanschette, Universalgrößen etc.).

Durch den steigenden Anteil (stark) übergewichtiger Personen werden z. B. auch XL-Manschetten-Validierungen immer relevanter, um garantieren zu können, dass auch bei Verwendung einer extragroßen Manschette korrekte Werte ermittelt werden.

aponorm® ist hier einer der wenigen Anbieter am deutschen Markt mit einer expliziten Validierung für die erhältliche XL-Manschette und daher auch für Patienten mit Übergewicht eine gute Empfehlung.

▶ aponorm® bietet für alle Oberarme die passende Manschettengröße an.

Manschettengröße	Armumfang	PZN
S (Bügelmanschette)	17-22 cm	15423752
M (Bügelmanschette)	22-32 cm	15423769
M-L (Bügelmanschette)	22-42 cm	15423775
M-L (Komfort-Schalenmanschette)	22-42 cm	15423806
L-XL (Bügelmanschette)	32-52 cm	15423781

Validierungen von Zusatzfunktionen

Über die bisher genannten Validierungen hinaus gibt es auch immer wieder Praxisstudien anderer medizinischer Forschungsanstalten. **Diese beschäftigen sich z. B. mit neuen Technologien oder Messverfahren,** die in Blutdruckmessgeräten zum Einsatz kommen.

So haben etwa bekannte Einrichtungen wie die Oxford- und Maastricher Universität sowie das Karolinksa Institut in Stockholm oder medizinische Fachjournale wie das „Journal of Human Hypertension" klinische Studien zur sogenannten Afib$_{sens}$-Technologie veröffentlicht, die in Deutschland ausschließlich in den aponorm® Professional-Blutdruckmessmodellen zum Einsatz kommt. Diese Technologie kann laut diesen Studien mit sehr hoher Trefferquote gefährliches Vorhofflimmern erkennen, welches die häufigste Ursache für einen Schlaganfall ist. Damit ist sie deutschlandweit die einzige mit CE-Zeichen zugelassene Technologie für die Manschetten-Heimmessung, die Vorhofflimmern tatsächlich studienbelegt erkennen kann.

Darüber hinaus gibt es auch Studien, die sich mit automatischen Mehrfachmessungen beschäftigen – eine Technik, wie sie etwa auch in den aponorm® Modellen zum Einsatz kommt (sog. 3MAM-Technologie). In diesen Studien wurde überprüft, welche Pausenzeiten zwischen den einzelnen Messungen eingehalten werden müssen, um am Ende valide Messergebnisse zu erhalten. Als Referenzwert wurde eine Pausenzeit von 15 Sekunden ermittelt.

AFIB sens
Vorhoffflimmern-Erkennung

3 MAM
Dreifach-Messung 15 Sek.

Hinweis: Gilt nur für ozsillometrisch messende Blutdruckmessgeräte. Für manuelle Blutdruckmessungen liegt der Standard bei 60 Sekunden.).

▶ **Tipp:** Achten Sie darauf, ob die in den Geräten verwendeten Funktionen (z. B. auch Pulsanomalie-Erkennungstechniken) ausreichend auf Genauigkeit getestet wurden. Die Qualitätsunterschiede sind hier meist nicht auf den ersten Blick zu erkennen.

STUDIEN ZU SPEZIALPATIENTEN & -TECHNOLOGIEN

Validation of the Microlife BP A3 PC upper arm blood pressure monitor in patients with diabetes mellitus according to the ANSI/AAMI/ISO 81060-2:2013 protocol

Beate Beime[a], Ralf Krüger[a], Gertrud Hammel[b], Peter Bramlage[a] and Cornelia Deutsch[a]

Objective The aim of the present study was to validate the blood pressure (BP) measurement device, Microlife BP A3 PC, in patients with diabetes mellitus, according to the ANSI/AAMI/ISO 81060-2:2013 protocol.

Patients and methods In 85 individuals aged 56–88 years, with predefined criteria for diabetes mellitus, BP measurements on the upper arm were performed alternately using the Microlife BP A3 PC and a standard mercury reference sphygmomanometer. A total of 333 comparisons were included for analysis.

Results The mean difference between the Microlife BP A3 PC and the reference was –1.5± 6.3 mmHg for systolic BP (SBP) and –1.3± 5.2 mmHg for diastolic BP (DBP) according to criterion 1 of the protocol. For SBP, a total of 209 of the 333 measurements were within the range of 5 mmHg (62.8%), whereas the corresponding numbers for DBP were 232 of 333 (69.7%). For criterion 2, the intraindividual differences for the test device and the reference were –1.50± 4.73 mmHg for SBP and –1.30 ± 4.55 mmHg for DBP, thus being within the defined ranges provided by the protocol.

Conclusion The Microlife BP A3 PC fulfilled the requirements of criteria 1 and 2 of the ANSI/AAMI/ISO 81060-2:2013 protocol and can also be recommended for BP measurement in diabetic patients. Blood Press Monit 00:000–000
Blood Pressure Monitoring 2017, 00:000–000

Keywords: Association for the Advancement of Medical Instrumentation, American National Standards Institute, blood pressure-measuring device, diabetes mellitus, ISO 81060-2:2013, Microlife BP A3 PC, validation

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Validation of an oscillometric home blood pressure monitor in an end-stage renal disease population and the effect of arterial stiffness on its accuracy

Aliza M. Thompson, Kazuo Eguchi, Michael E. Reznik, Samir S. Shah and Thomas G. Pickering

Objectives Increased arterial stiffness, common in end-stage renal disease patients, has been shown to affect the correspondence between oscillometric and mercury sphygmomanometer blood pressure readings. The purpose of this study was to validate an oscillometric home blood pressure monitor in an end-stage renal disease population and to determine the effect of arterial stiffness on its accuracy.

Methods Blood pressure measurements were taken with the Microlife 3AC1-1PC (Microlife; Taipei, Taiwan), an oscillometric home blood pressure monitor, and a mercury sphygmomanometer in 33 patients as specified by the European Society of Hypertension Validation Protocol. Radial pulse wave analyses were also performed.

Results On the basis of European Society of Hypertension criteria, the Microlife 3AC1-1PC received a passing score for systolic and diastolic blood pressures. On average, the oscillometric monitor overestimated diastolic blood pressure by 2.4mmHg (P = 0.005, SD= 4.5mmHg) and there was a trend towards overestimation of systolic blood pressure as well (1.3 mmHg, P =0.09, SD= 4.4 mmHg). A positive correlation was found between arterial stiffness, as assessed by augmentation index and pulse pressure, and the diastolic blood pressure difference between the device and the mercury sphygmomanometer (r =0.54, P = 0.003; and r = 0.65, P =0.001, respectively). Diastolic blood pressure was negatively correlated with the diastolic blood pressure difference (r= –0.49, P =0.003). No significant relationship was found between the systolic blood pressure difference and augmentation index, pulse pressure or systolic blood pressure.

Conclusion The Microlife 3AC1-1PC was shown to accurately measure blood pressure in patients with endstage renal disease. As arterial stiffness increased and diastolic blood pressure fell, diastolic blood pressure was increasingly overestimated. Blood Press Monit 12:227–232

Blood Pressure Monitoring 2007, 12:227–232

Keywords: arterial stiffness, chronic kidney failure, dialysis, home blood pressure monitoring, hypertension Department of Medicine, Behavioral Cardiovascular Health and Hypertension Program and Division of Nephrology, Columbia University, New York, New York, USA

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An accurate automated blood pressure device for use in pregnancy and pre-eclampsia: the Microlife 3BTO-A

A. Reinders, A.C. Cuckson, J.T.M. Lee, A.H. Shennan

Objective To assess the accuracy of an automated blood pressure device (Microlife 3BTO-A) in pregnancy and pre-eclampsia according to the British Hypertension Society (BHS) protocol.

Design Prospective observational study.

Setting Antenatal ward and clinics at Guy's and St Thomas' Hospital, London, UK.

Population One hundred and five pregnant women including 35 women with non-proteinuric hypertension and 35 with pre-eclampsia.

Methods Two trained observers took nine sequential same-arm measurements from each woman. Measurements alternated between a mercury sphygmomanometer and the device.

Main outcome measures Grading criteria of the BHS protocol (A/B grade = pass; C/D grade = fail).

Results The device passed the BHS protocol by achieving an A/B grade. It also achieved criteria of the Association for the Advancement of Medical Instrumentation for systolic and diastolic pressures respectively, in normotensive [– 0.5 (5.7) mmHg; – 0.07 (7.7) mmHg], non-proteinuric hypertensive [– 3.3 (6.9) mmHg; – 2.4 (6.6) mmHg] and pre-eclamptic pregnancy [– 4.1 (6.4) mmHg; – 1.3 (7.9) mmHg].

Conclusion The Microlife 3BTO-A can be recommended for use in a pregnant population, including preeclampsia, according to the BHS protocol.

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Introduction

Intracranial haemorrhage is the leading cause of maternal mortality in women with pre-eclampsia.[1] Severe hypertension is likely to be the most significant aetiological factor related to this cause and effective anti-hypertensive treatment is crucial. It is not known if inaccurate blood pressure measurement contributes to maternal mortality, but it is well recognised that automated devices systematically underestimate both systolic and diastolic blood pressure in preeclampsia and often by clinically significant amounts.

The 'gold standard' (mercury sphygmomanometer) has been criticised for its associated observer errors and environmental safety groups have concerns about mercury toxicity. Over the past 20 years various mercury-independent alternatives (aneroid and automated) have been introduced, the majority of which do not use auscultation to determine blood pressure. It is imperative that these devices be assessed according to recognised protocols to determine their accuracy compared with the mercury sphygmomanometer. The Association for the Advancement of Medical Instrumentation (AAMI),[2] the British Hypertension Society (BHS)[3] and most recently the European Society for Hypertension (ESH)[4] have all published protocols with a view to standardise both the method of assessment and the level of accuracy required of a device in order to be recommended for clinical use.

Only one automated device, the Omron MIT,[5] has demonstrated sufficient accuracy to be appropriate for clinical use in pre-eclampsia and there is an urgent need for more accurate devices. Of the eight other devices[6–11]—deemed accurate in adults—that were evaluated in hypertensive pregnancy, the vast majority under-read in pre-eclampsia by clinically significant amounts (i.e. by a mean of more than 5 mmHg). It is therefore important for devices intended for use in an obstetric population to be assessed in this group specifically.

The Microlife 3BTO-A (Microlife, Taipei, Taiwan) is a compact device suitable for self-measurement. The device previously achieved the highest possible grade for accuracy (A/A) in an adult population[12] according to the BHS protocol. In this study we evaluated its accuracy in a pregnant population, including women with non-proteinuric hypertension and pre-eclampsia.

Methods

The study was performed by two observers, trained in blood pressure measurement (BHS specifications). Women were recruited from the antenatal ward and clinics at two large teaching hospitals in London, UK (Guy's and St Thomas' Hospitals). Ethical approval was obtained and participants were asked to give written informed consent.

One hundred and five women were recruited to the study, including 35 women with non-proteinuric hypertension and 35 women with pre-eclampsia. Only women over the age of 18 years and with a gestation greater than 22 weeks were approached to take part in the study. Women with any arrhythmia or those in which Korotkoff sounds did not disappear, or with a diastolic <40 mmHg, were excluded. Korotkoff 5 was used to identify the diastolic pressure.

Pre-eclampsia was defined as a diastolic blood pressure of ≥ 90 mmHg on two separate occasions more than 4 hours apart or a single reading >110 mmHg accompanied by proteinuria of >0.3 g on a 24-hour sample or 2þ on reagent strip.[13] Non-proteinuric hypertension was defined as those women who fulfilled only the hypertension criteria of the above definition.

The study was performed according to guidelines of the 1993 BHS protocol. A calibration check was performed according to guidelines in the protocol. The device underwent a minimum of 400 inflations in its intended environment and calibration was rechecked. This part of the protocol was undertaken during the assessment of the same device in an adult population[12] directly preceding this study and therefore not repeated. Calibration was rechecked before the start of this study and the device achieved targets as outlined in the protocol.

Table 1. BHS grading criteria

Grade	Absolute difference between standard and test device (mmHg)		
	≤5	≤10	≤15
Cumulative percentage of readings (%)			
A	60	85	95
B	50	75	90
C	40	65	85
D		Worse than C	

Demographic information such as age, height and gestation was obtained from each patient. Blood pressure measurements were taken in a quiet room with the subject seated and the arm supported at heart level. Arm circumference was measured at the approximate midpoint of the upper arm to determine the appropriate cuff size to be used.

Two cuff sizes were available: normal adult (22–32 cm) and large adult (32–42 cm). The device was connected to a laptop computer with recording software (LabView) to facilitate additional ongoing analysis not described in this paper.

Nine sequential same arm measurements were takenalternating between the reference (mercury sphygmomanometer) and the test device (Microlife 3BTO-A). Auscultatory readings were taken using an electronic stethoscope (Welch Allyn sensor-based stethoscope model 5079-400) and a distributor box enabled the second observer to listen to Korotkoff sounds. More than 30 seconds but less than 1 minute was allowed between readings to reduce the effect of venous congestion and to limit variability. The patient was advised to relax, avoid talking and to keep the arm as still as possible as the device measurements could be influenced by movement. The patient was also asked to advise us of any discomfort during the procedure.

Of the nine measurements taken, only the last seven were used in analysis. The first manual reading was used to classify the subject in the appropriate category as specified in the protocol and the first device reading was used to 'orientate' the device to the patient. The mean differences and standard deviation between device and observer was calculated and device was graded according to criteria of the BHS protocol (Table 1). The device should achieve percentages greater than or equal to those in the table to achieve a particular grade. Furthermore, a visual representation of the accuracy of the device is provided using Bland–Altman plots.[14] This has the benefit of establishing at first glance whether there are any trends (e.g. increased error at increased pressures) or cases of extreme inaccuracy.

Results

The Microlife 3BTO-A achieved an overall grade A for systolic pressures and grade B for diastolic pressures (Table 2). Results for normotensive, hypertensive and pre-eclamptic pregnancies are shown in Table 3. AAMI criteria (mean <5 mmHg [<8]) were met overall and in all groups individually.

Bland–Altman plots[14] show the difference in blood pressure between the test device and the better observer plotted against the mean pressure of the device and the observer. Results are shown for normotensive, non-proteinuric hypertensive and pre-eclamptic pregnancy. Figures 1 and 2 indicate the results for systolic and diastolic pressures, respectively. Demographic information is displayed in Table 4.

Table 2. Grading, cumulative percentage of differences between mercury sphygmomanometer and test device that varied by 5, 10 and 15 mmHg, mean pressure and mean difference of the pressure between observer and test device.

	Grade	Difference between standard and test device (mmHg)			Mean [SD] (mmHg)	Mean [SD] of differences (mmHg)
		≤5	≤10	≤15		
Adult population (n = 255)*						
SBP	A	64	87	96	134.9 [28.1]	– 1.7 [7.4]
DBP	A	68	89	97	84 [19.7]	– 2.1 [6.3]
Pregnant population (n = 315)**						
SBP	A	63	87	97	125 [17.5]	– 2.7 [6.3]
DBP	B	57	83	97	79.2 [12.6]	– 1.3 [7.4]

SBP = systolic blood pressure; DBP = diastolic blood pressure; SD = standard deviation.
* Previously published data in non-pregnant adults.[17]
** Including hypertensive pregnancy.

Table 3. Grading, cumulative percentage of differences between mercury sphygmomanometer and test device that varied by 5, 10 and 15 mmHg, mean pressure and mean difference of the pressure between observer and test device for normotensive and hypertensive pregnancy.

	Grade	Difference between standard and test device (mmHg)			Mean [SD] (mmHg)	Mean [SD] of differences (mmHg)
		≤5	≤10	≤15		
Normotensive (n = 105)						
SBP	A	69	95	99	108 [11]	– 0.5 [5.7]
DBP	B	55	82	97	66 [12]	– 0.07 [7.7]
Non-proteinuric hypertension (n = 105)						
SBP	B	60	80	95	132 [16]	– 3.3 [6.9]
DBP	B	58	85	100	85 [12]	– 2.4 [6.6]
Pre-eclampsia (n = 105)						
SBP	A	62	86	96	137 [26]	– 4.1 [6.4]
DBP	B	59	82	93	87 [14]	– 1.3 [7.9]

SD = standard deviation.

Table 4. Demographic information. Values are presented as mean [SD].

	Normotensive	Non-proteinuric hypertensive	Pre-eclampsia
Age (years)	31 [5.6]	33 [5.3]	33 [5.7]
CI (age)	28.6 – 32.4	30.9 – 34.6	31.3 – 35.2
Gestation (weeks)	32 [5.1]	35 [4.6]	35 [4.7]
CI (gestation)	31 – 34	33 – 36	33 – 36
Second trimester	8	3	6
Third trimester	27	32	29
Primips	16	22	18

CI = 95% confidence intervals.

There were no statistically significant differences between the groups (P > 0.1). Fourteen pre-eclamptic women and six women who had non-proteinuric hypertension had an arm circumference greater than 32 cm. All the women in the normotensive group had an arm circumference <32 cm. The range of proteinuria (24-hour collection) was 0.3–15.52 g/dL for women with pre-eclampsia. Thirteen women with non-proteinuric hypertension and 20 women with pre-eclampsia were receiving anti-hypertensive treatment at the time of recruitment.

Comment

The Microlife 3BTO-A can be used clinically for BP assessment in pregnancy and is one of only two devices recommended in pre-eclampsia.

Various devices, recommended in an adult and pregnant population according to the BHS criteria, under-estimated quite significantly when assessed in pre-eclampsia. Mean differences reported have been as great as 15 mmHg when compared with mercury sphygmomanometry[8] and 25 mmHg when compared with intra-arterial measurements7 and individual readings have been far greater.

To our knowledge only one device, the Omron MIT (self-measurement), has achieved the BHS criteria in preeclampsia. [5] This device uses inflationary oscillometry (i.e. it determines the blood pressure while the cuff is inflating and then rapidly deflates). This is contrary to most oscillometric devices, which measure blood pressure during deflation of the cuff. As pre-eclampsia is associated with decreased arterial compliance and an increase in interstitial tissue oedema, it was thought that transmission of the pressure wave could be delayed using a deflation method (thereby under-estimating true blood pressure). Using an inflationary method would allow immediate detection of the signal and therefore be more accurate.

Our study using the Microlife 3BTO-A has reconfirmed that a good algorithm is vital (using a deflationary method), but as no other inflationary device has been assessed according to a recognised protocol, it is uncertain whether the accuracy of the Omron MIT can be attributed to inflationary oscillometry or simply a good algorithm (or a combination of both).

It is well known that automated devices tend to show increased error at higher pressures. In the assessment of the Microlife 3BTO-A, the device shows greater error in preeclampsia compared with normo-

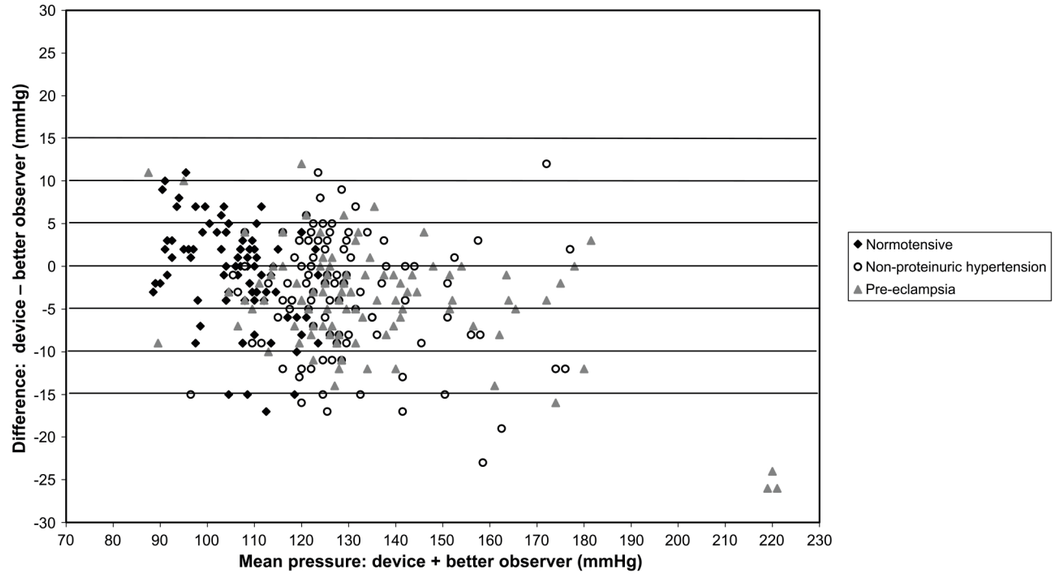

Fig. 1. Plot of the pressure difference between the better observer and the test device and the mean pressure of that observer and the device for systolic pressure, in normotensive and hypertensive pregnancy.

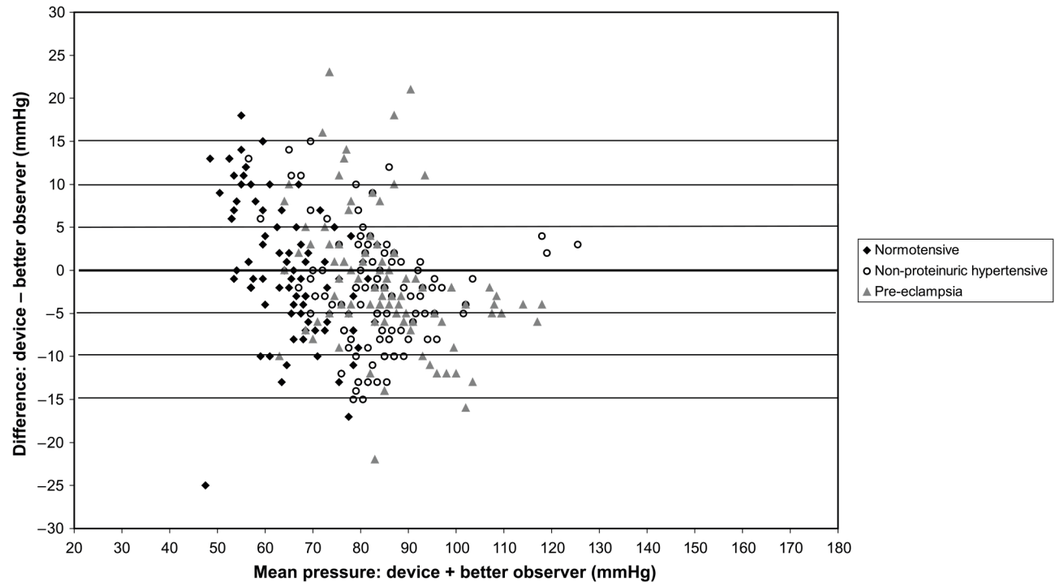

Fig. 2. Plot of the pressure difference between the better observer and the test device and the mean pressure of that observer and the device for diastolic pressure in normotensive and hypertensive pregnancy.

tensive pregnancy [SBP 4.1 (6.4) vs 0.5 (5.7); DBP 1.3 (7.9) vs 0.1 (7.7)]. Whether using inflationary methods could possibly rectify or reduce this error needs further investigation.

Another factor contributing to device accuracy is the use of an appropriately sized cuff. Pre-eclampsia is associated with oedema due to increased interstitial permeability and it is thought that women with a BMI >30 are at an increased risk for pre-eclampsia. In this study almost half of all pre-eclamptic women and a fifth of women with non-proteinuric hypertension had an arm circumference >32 cm.

Devices intended for self-measurement, like the Microlife 3BTO-A, can also be used by patients to measure their blood pressure in their home environment. It reduces/eliminates the white coat effect and could impact on the cost and effort involved for women who have to come to hospital just to have their blood pressure checked. Results from studies done in both a non-pregnant population[15] and a pregnant population[16] have been encouraging. Patient compliance and reporting of device measurements are enhanced as most of these devices now either have a memory facility or the capability to connect to a PC or printer to obtain a printout of readings.

Home monitoring by the patient using new technologies seems feasible and beneficial to both the patient and the clinician. Waugh et al.[17] did a small study investigating the use of home blood pressure monitoring in combination with urinalysis. Results were very positive and low risk as well as high risk populations are currently being assessed to determine the application of this point-of-care technology.

Only one robust device is currently recommended for use in pregnancy, although it did not achieve BHS criteria when assessed in pre-eclampsia.[9] As we have no robust device suitable for use in the clinical setting (with regard to pre-eclampsia) and there is pressure to phase out the mercury sphygmomanometer, would it be feasible to use a device intended for self-measurement?

We are only aware of one study in which a self-measurement device was assessed in the clinical setting. Lo et al.18 used the Omron HEM 705-CP to compare blood pressure readings to that obtained by mercury sphygmomanometry in pre-eclamptic women on the antenatal ward. The methodology of the study was ad hoc and the Omron device used failed BHS criteria when assessed in preeclampsia in a previous study.[5]

If self-measurement devices are to be used in the clinical setting, then consideration should be given to issues like accuracy, lifespan, cost and monitoring facilities. Devices intended for use in a pregnant population should be assessed according to a recognised protocol in a pregnant population and accuracy should not be assumed from a validation conducted in an adult population. Currently, only the BHS protocol and AAMI make provision for the assessment of a blood pressure measuring device in pregnancy. However, it does not make specific provision for women with pre-eclampsia.

Furthermore, the lifespan of any blood pressure measuring device greatly depends on the capacitive sensor. This sensor consists of two round copper plates that press against each other with pressure changes in the cuff. These pressures are translated to a digital chip and then converted to a digital signal. The lifespan of these sensors can vary from 10,000 to 30,000 measurements. The longer the lifespan, the more expensive the sensor. Most devices for self-measurement are therefore likely to have a capacitive sensor with a shorter lifespan in order to keep the cost down, whereas robust devices are likely to have a more expensive sensor with a longer lifespan. However, robust devices are often capable of more intensive monitoring facilities (i.e. temperature, saturation, etc.) and these parameters will also influence the lifespan and cost of the device.

As no other robust device can currently be recommended for use in pre-eclampsia, it might be feasible to use a selfmeasurement device, depending on the level of monitoring required and the frequency of use. The Microlife 3BTO-A can be recommended for use in pregnancy, including those women who have non-proteinuric hypertension and preeclampsia. The role of self-measurement devices in the clinical setting warrants further investigation.

Acknowledgments

The authors would like to thank staff and patients at Guy's and St Thomas' Hospitals for their help. Our thanks also extend to the Charitable Foundation of Guy's and St Thomas' Hospital for funding this study and to Microlife for providing financial support for previous validation work.

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Validation of the Microlife WatchBP Home blood pressure device in pregnancy for medium and large arm circumferences

Katherine Clark[a], Olivia Snowball[a], Diane Nzelu[a], Polly Kay[a] and Nikos A. Kametas[a,b]

Objective The Microlife WatchBP Home automated blood pressure device was assessed for accuracy in pregnant women of medium (<32 cm) and large (≥32 cm) arm circumference.

Materials and methods The British Hypertension Society validation protocol was modified for the purpose of this study to include women with arm circumference of less than 32 cm (N=51) and greater than or equal to 32 cm (N=46)
as two separate arms.

Results The device achieved an overall A/A grade for medium arm circumference and B/A grade for large arm circumference. The mean ± SD device-observer difference was 1.7± 6.2 and –0.4± 4.4 for systolic and diastolic blood pressure, respectively, for medium arm circumference and 3.0± 8.5 and 1.5± 5.1, respectively, for large arm circumference. When all women with pre-eclampsia from both groups were pooled (N=23), the device achieved an overall grade of A/A with mean differences of 2.1± 7.2 for systolic blood pressure and 1.0± 5.6 for diastolic blood pressure.

Conclusion The Microlife WatchBP Home automated blood pressure device can be recommended for use in pregnant women of all gestations, including those with preeclampsia. However, caution is needed for women with large arm circumferences. Blood Press Monit 00:000–000

Blood Pressure Monitoring 2018, 00:000–000

Keywords: automated device, hypertension, Microlife WatchBP Home, oscillometric, pre-eclampsia, pregnancy, validation

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Rapid assessment of blood pressure in the obstetric day unit using Microlife MAM technology

Anja Wilton[1], Annemarie De Greef, Andrew Shennan

Objective: To compare MAM technology with current methods of assessing blood pressure (BP) over time on the obstetric day unit.

Background It is recommended that the average of repeated measures is used to confirm hypertension in pregnancy. The Microlife 3AC1 is a validated oscillometric device featuring „MAM" mode using the average of at least 3 BP readings 15 seconds apart. This allows rapid assessment of BP. The difference between each measurement is calculated and influences the percentage contribution to the final average reading. We compared MAM with readings taken in a conventional manner.

Methods Blood pressure was measured in 30 hypertensive pregnant patients recruited from the obstetric day unit of a large teaching hospital. Single BP measurements were taken at 0, 15, 30, 60, and 90 minutes using the Microlife BP 3BT0-A[2]. Simultaneous measurements (in the opposite arm) were also taken at 0 and 90 minutes using MAM technology.

Results Systolic BP fell over 90 minutes (p = 0.035) compared with the first single reading, but diastolic BP did not (p = 0.54). The difference between the first MAM and the first single reading was significantly different for systolic BP (5.6 mm Hg, p = 0.017), but not for diastolic (0.6 mm Hg, p = 0.39). The mean of all single readings and the first MAM reading were similar for both systolic and diastolic BP (SBP:0.3 mm Hg, p = 0.75, DBP: 0.2 mm Hg, p = 0.87).

Conclusions White-coat hypertension exists for systolic BP in the obstetric day unit. The MAM technology allows rapid and accurate characterization of blood pressure equivalent to repeated measures over 90 minutes.

Quelle: https://pubmed.ncbi.nlm.nih.gov/17454216

Rapid oscillometric blood pressure measurement compared to conventional oscillometric measurement

Steven A. Yarows[a], Ketul Patel[b] and Robert Brook[a]

Background There have been few reports studying the necessary interval between blood pressure measurements, after the initial rest period.

Methods Blood pressure was measured in 50 patients using the conventional oscillometric technique (COT) and the rapid oscillometric technique (ROT).

Results The difference between COT and ROT was –1.1/–0.1mmHg, which was not significantly different (p = 0.8/1.0) and the pulse difference was –0.8 beats per minute (p = 0.8).

Conclusions It is concluded that a 15-second interval between blood pressure readings is as accurate as a one-minute interval providing that these measurements are started after a 5-minute rest period. Blood Press Monit 6:145–147 2001 Lippincott Williams & Wilkins.

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Keywords: blood pressure determination, hypertension, oscillometry

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STUDIEN ZU VORHOFFLIMMERN & $AFIB_{SENS}$-TECHNOLOGIE

aponorm® Professional-Modelle – Das Vorhofflimmern-Warnsystem für zuhause

Jedes Jahr erleiden allein in Deutschland ca. 260.000 Menschen einen Schlaganfall. Jeder Dritte davon zieht dauerhafte Schäden bis hin zum Tod nach sich. Schlaganfälle rangieren dadurch gleich nach Herzschwäche und Herzinfarkt auf Platz 3 der Todesursachen in Deutschland.
Eine der häufigsten Ursachen für einen Schlaganfall ist dabei das Vorhofflimmern, eine gefährliche Form der Herzrhythmusstörung. Bei dieser kann sich das Blut in den Vorhöfen des Herzens stauen, verklumpen und Blutgerinnsel bilden. Später können diese durch den Blutstrom bis zum Gehirn wandern, dort die Blutgefäße verstopfen und zum Schlaganfall führen.

Das Heimtückische an Vorhofflimmern:
Es verläuft gerade im Anfangsstadium meist symptomlos und tritt nur unregelmäßig auf, sodass es selbst bei sporadischen Arztbesuchen oftmals unentdeckt bleibt.
Die aponorm® Professional-Blutdruckmessgeräte ermöglichen es durch die integrierte Afib$_{sens}$-Technologie (Afib = engl. Atrial Fibrillation = dt: Vorhofflimmern), dass Patienten sich selbst verlässlich und engmaschig auf Vorhofflimmern screenen können.

Vorteile der Heimmessgeräte mit Vorhofflimmern-Erkennungsfunktion:
- Jederzeit verfügbar (nicht an Arztpraxis oder Krankenhaus gebunden)
- Regelmäßigkeit der Kontrolle
  (erhöht Chance, sporadisch auftretende Vorhofflimmern-Attacken zu detektieren)
- Einfach in der Handhabung (während der normalen Blutdruckmessung ohne weitere Vorkenntnisse)
- Niedriger Anschaffungspreis (anteilig erstattungsfähig auf Rezept)
- Sicher in der Diagnostik (siehe nachfolgende Studienauszüge)
- Doppelnutzen (gleichzeitig Dokumentation der Blutdruckdaten)

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PZN: 12393720
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positionsnummer:
21.28.01.2130

Die Vorhofflimmern-Spezialisten unter den Blutdruckmessgeräten

AFIB sens

The Epidemiology of Atrial Fibrillation and Stroke

Francesca Pistoia[1], Simona Sacco[2], Cindy Tiseo[2], Diana Degan[2], Raffaele Ornello[2], Antonio Carolei[2]

Abstract
The burden of stroke is increasing due to aging population and unhealthy lifestyle habits. The considerable rise in atrial fibrillation (AF) is due to greater diffusion of risk factors and screening programs. The link between AF and ischemic stroke is strong. The subtype most commonly associated with AF is cardioembolic stroke, which is particularly severe and shows the highest rates of mortality and permanent disability. A trend toward a higher prevalence of cardioembolic stroke in high-income countries is probably due to the greater diffusion of AF and the control of atherosclerotic of risk factors.

Keywords: Atrial fibrillation; Cardioembolic stroke; Cryptogenic stroke; Epidemiology; Stroke.

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Accuracy of oscillometric blood pressure monitors for the detection of atrial fibrillation: a systematic review

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Atrial fibrillation (AF) is a significant risk factor for stroke and early detection of AF may help to identify patients in need of treatment. Automated blood pressure (BP) monitors with implemented AF or arrhythmia detection systems may be a useful tool for early diagnosis of AF. A systematic review (Medline/PubMed, Embase, Cochrane) of studies was performed to assess the accuracy of modified BP monitors (for diagnosing AF). A total of five studies (four tests in the physician's office and one at home) were selected. For the most accurate AF detection, three sequential BP measurements should be performed. Direct comparison against a 12-lead ECG showed that the highest sensitivity, 97% (95% CI: 94–100%), for detecting AF was obtained when three readings were assessed with two or three AF-positive readings. The highest specificity (97%) was obtained when performing three measurements, of which all three must be AF positive. The modified BP monitor (Microlife Corporation, Taipei, Taiwan) has high potential in improving AF screening.

Keywords: arrhythmia • atrial fibrillation • blood pressure measurement • oscillometric blood pressure monitor • primary care • screening • stroke

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, occurring in 1–2% of the general population [1,2]. Its prevalence increases with age from 0.5% at 40–50 years to 5% in subjects over 65 years, to 14% among those over 85 years old [3,4]. In 2006, there were approximately 639,000 people with AF in the UK [101]. However, the number of newly diagnosed patients with AF is rising to approximately 5% per year [5]. Presently, the most common method used to detect AF is by means of opportunistic screening, that is, during pulse palpation [102]. However, this method has limited accuracy and is highly liable to observer bias [6].
Recently, a number of automated oscillometric blood pressure (BP) monitors have been developed that are equipped with an AF detection system that allows AF screening during routine BP measurement. The present paper aims to provide an overview of all studies of the diagnostic accuracy of this modified automated oscillometric BP monitor for diagnosing AF.

Methods

Identification of papers

For the present review, we systematically searched Pubmed, Medline, EMBASE and the Cochrane databases using the following keywords: atrial fibrillation, or arrhythmia, or irregular, in combination with blood pressure, or oscillometric, or automatic. In addition, we searched the internet (e.g., clinical trial registration sites) and references from considered papers for additional studies that did not deliver any new results. This led to a combined finding of 212 abstracts, which were screened by two persons (WJ verberk and PW de Leeuw). All studies that investigated the accuracy for diagnosing AF or arrhythmia using automated oscillometric blood pressure monitors with an implemented AF detection or arrhythmia detection system were included, except one. This study was excluded because of the limited number of patients and lack of study details [7].

Statistical analysis

As all except one of the papers that were selected dealt with the AF detection system of Microlife corporation (Taipei, Taiwan) only, no statistical comparison was performed. For calculating averages of specificity and sensitivity, we weighted with inverse variances (direct pooling) [8] using aggregate-level data ('metareg') in Stata version 9.2 Texas.

Results

Altogether, five studies were found, of which four were tested in the physician's office [9–12]. In one study, the feasibility of the modified sphygmomanometer for home use was assessed [13]. We analyzed the accuracy of the AF detector of Microlife only, as this is the only system that has been investigated in more than one study. The one paper that provided the results of the arrhythmia detection system of the Omron device was discussed separately.

Working of the AF detection system of the Microlife BP monitors

The automated BP monitor measures the last ten pulse intervals during the cuff deflation phase of a regular BP measurement and calculates the mean and SD of the time intervals. In order to reduce the influence of premature beats on the results, a cut-off value of 25% was chosen so that each interval greater or less than 25% of the mean time interval is deleted. Then an irregularity index, which is defined as the SD divided by the mean of the time intervals, is calculated from the remaining data. If the irregularity index exceeds a threshold value of 0.06 the rhythm is considered irregular [10–12].

Table 1. Studies performed to determine the accuracy of the modified oscillometric Microlife blood pressure monitor (Microlife Corporation, Taipei, Taiwan) for detecting atrial fibrillation compared with a 12-lead electrocardiography.

Study (year)	Patients (n)	Age (years)	Men (%)	AF, n (%)	Non-AF arrhyth n (%)	Readings used (n)	Readings needed for diagnosis (n)	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (%)	κ (95% CI)	Ref.
Wiesel *et al.* (2004)†	450	69	59	53 (12)	(±25)	1	1	1	0.84	86		[9]
						2	2	1	0.92	92		
Stergiou *et al.* (2009)	72	71	66	27 (37)	23 (31)	1	1	0.93 (0.74–0.99)	0.89 (0.76–0.96)	90	0.80 (0.65–0.94)	[10]
						2	1	1 (0.84–1.00)	0.76 (0.60–0.87)	85	0.70 (0.54–0.85)	
						3	2	1.00 (0.84–1.00)	0.89 (0.75–0.96)	93	0.86 (0.74–0.98)	
Wiesel *et al.* (2009)	405	73	51	93 (23)	64 (14)	1	1	0.95 (0.93–0.98)	0.86 (0.84–0.89)	87		[11]
						3	2	0.97 (0.91–0.99)	0.89 (0.85–0.92)	89		
Marazzi *et al.* (2011)	503	67	54	101 (20)		3	3	0.92	0.97	96		[12]

†The Microlife AF detection system (Microlife Corporation, Taipei, Taiwan) was implemented in a different blood pressure device.
AF: Atrial fibrillation.

Performance of the modified blood pressure monitor in the office

The four studies that investigated the modified sphygmomanometer in the physician's office for accuracy in diagnosing AF involved 1430 subjects in who all were recruited from outpatient hypertension clinics or a cardiology practice. The average age of the participants was (mean ± SD) 70 ± 2.4 years with 55 ± 4% males. The prevalence of AF averaged 20 ± 7% and the prevalence of non-AF arrhythmias was 10 ± 11%. All studies indicated that the measurements were performed at only one clinic visit. A 12-lead ECG measurement that was either taken simultaneously with [10,12] or within 2 [11] or 5 [9] min from the measurements with the modified sphygmomanometer (two [9] or three [10–12] measurements) served as gold standard. All 12-lead ECG's were evaluated by an experienced cardiovascular consultant.

Table 1 provides an overview of the studies and shows that sensitivity and specificity values differed slightly between and within studies, and were mainly dependent upon the number of measurements (readings) and the algorithm, that is, the number of AF-positive readings used for classifying a patient as AF positive.

There were three studies [9–11] that investigated the 1 out of 1 algorithm that led to an average sensitivity of 97% (95% CI: 94–100%) and specificity 84% (95% CI: 83–86%). There were two studies [10,11] that investigated the ≥2 out of 3 algorithm and showed an average sensitivity of 97% (95% CI: 94–100%) and a specificity of 89% (95% CI: 86–92%). The algorithm 1 out of 2 and 2 out of 2, investigated in different studies, both obtained 100% sensitivity with specificity levels of 76 and 92%, respectively [9,10]. The highest specificity (97%) was obtained from three measurements, of which all three must be AF positive for classifying a patient as being AF positive (Figure 1). As a reference, two commonly used methods for diagnosing AF in the GP's practice have been added to (figure 1): 12-lead ECG diagnosed by a GP and pulse palpation.

Performance of the modified blood pressure monitor at home

Wiesel et al. investigated the feasibility of the AF detection system for detecting recurrent AF at home [13]. A total of 19 cardiac outpatients (average age: 74 years; 59% men) who were in sinus rhythm but had at least one documented episode of AF during a previous office visit or during the index hospitalization were studied. Patients were first measured in the office with the modified sphygmomanometer in order to exclude the presence of AF at that moment. The patient then had to measure his or her BP on a once-daily basis. If, at any time, the patient found an irregularity, a second measurement was required; if this was also positive then the patient needed to perform a third measurement 1 h later. If patients had found irregularities, they were asked to go to the hospital for a 12-lead ECG to document the rhythm before its duration exceeded 24 h. Results showed that with the modified sphygmomanometer seven patients could be detected who had recurrent AF. Three patients had false-positive readings that were the result of sinus arrhythmia or ectopy, and nine patients had no irregular measurements during the study period.

Conclusion

Overall, the AF detector of the modified Microlife BP monitor shows high accuracy for detecting AF compared with the 12-lead ECG diagnosed by a cardiovascular consultant. Sensitivity and specificity values are dependent upon the number of readings and the algorithm used. The highest sensitivity is obtained with two readings, of which at least one must be AF positive or with three measurements with at least two AF-positive readings. The highest specificity is obtained when taking three readings all three of which must be AF positive.

The most important question with regard to the modified oscillometric BP monitor is what would be the best algorithm to serve its purpose. Although the present review indicates that high sensitivity and specificity levels can be obtained with two measurements, the performance of one extra measurement in combination with the right algorithm should improve the screening accuracy. For this reason, three measurements should be preferred over two. Comparing the studies from both Stergiou et al. [10] and Wiesel et al. [11] with the study of Marazzi et al. [12] shows that changing the ≥2 out of 3 algorithm to a 3 out of 3 algorithm decreases sensitivity and increases specificity.

Since clinical measurements are usually performed at one occasion (clinical visit) at a certain time point, a higher sensitivity would be more useful than a higher specificity in order to increase the chance of diagnosing AF-positive patients. Generally, when people measure their BP at home or when they would be asked to screen for AF at home they should measure themselves on multiple occasions [14]. Therefore, a relatively low specificity would lead to many false-positive results. This may cause anxiety to the patients and may lead to unnecessary visits to the doctor. Lower sensitivity, on the other hand, increases the chance of false-negative readings. However, owing to the frequent number of measurements, the chance of missing (paroxysmal) AF, when present, becomes very small. Based on the above-described arguments, Microlife corporation has chosen to use different algorithms for evaluation at home (3 out of 3) and at the office (≥2 out of 3).

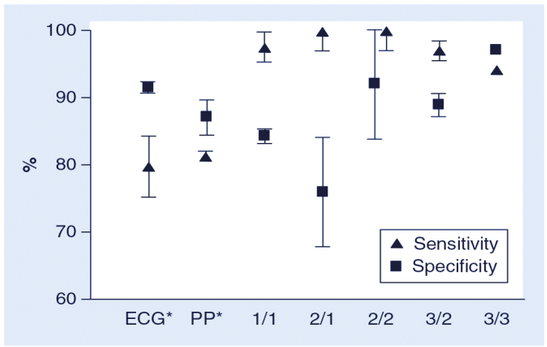

Figure 1. Sensitivity and specificity values for diagnosing atrial fibrillation. (1) The remaining results are obtained with the modified oscillometric blood pressure monitors. 1/1 means one measurement is performed and one atrial fibrillation (AF)-positive reading is required for classifying a patient as having AF; 2/1, two measurements are performed, of which at least one AF-positive is required, and so on. All values are the result of comparison with a 12-lead ECG as diagnosed by a cardiovascular consultant (2). ECG: Indicates 12-lead ECG as diagnosed by a GP; PP: Pulse palpation.
The results from both ECG and PP are obtained from the SAFE trial [15].

Marazzi et al. assessed two automated BP devices for their accuracy in detecting AF: the Omron M6 with implemented irregular heartbeat detector and the Microlife BPA 200 plus for detecting AF [12]. The authors compared three measurements of the Microlife device against one measurement of the Omron device among 503 patients who were referred to a hypertension clinic. They found that the Omron device had higher sensitivity than the Microlife device (100 vs 92%) but lower specificity (94 vs 97%, respectively), and concluded that the Omron device was more accurate. However, the paper contains some serious flaws, indicating that the author's conclusion is not supported by the data as presented in their paper. First, the conclusion that the Omron device is more accurate is not supported by statistical evidence. Second, accuracy should not be based on sensitivity only as the specificity becomes at least as important when considering a population that has a relatively low AF prevalence. In practice, this would mean that at a regular screening session with approximately 2% of all patients having AF, the Omron device leads to significantly more erroneous measurements than the Microlife device. Moreover, one should realize that both devices are primarily designed for self-measurement of BP. When subjects measure their BP regularly, specificity should be high in order not to cause anxiety due to false-positive readings, and to avoid unnecessary consultation of the GP. This, together with the need to order unnecessary ECGs for confirmation, may lead to increased healthcare costs. Third, based on the data as provided by Marazzi et al., the authors appear to have made a calculation error: the study consisted of 503 patients, 101 of which have AF [12]. The patients who were correctly diagnosed by the Microlife device were, based on the values as provided by the authors, 93 patients with AF (true positives) and 390 without AF (true negatives). This means that, in total, 483 out of 503 patients were correctly diagnosed by the Microlife device, which is an agreement of 96.4% instead of 94%, as stated by the authors. The Omron device diagnosed 479 (101 with AF and 378 without AF) patients correctly, which is 95.2%, as was stated. This means that in contradiction to the statement from the authors, the Microlife device appears to have a higher calculated accuracy than the Omron device.

In a small study Huang et al. compared the potential of wrist (Omron HEM609, HL868BA) and upper-arm BP monitors (Omron HEM780 and HL868BA) to detect arrhythmia [7]. They performed ten measurements among six patients (two with AF, two non-AF arrhythmia and two with sinus rhythm) and found that the upper-arm devices from Omron and Health and Life Company had sensitivity values of 53 and 74%, and specificity values of 100 and 90%, respectively. The wrist monitors of Omron and Health and Life Company showed sensitivity values of 42 and 97%, and specificity values of 100 and 97%, respectively. The authors concluded that the sensitivity of all devices was insufficient and that these only had some clinical relevance with positive reporting. In addition, the fact that the wrist monitor of the Health And Life Company showed higher accuracy for detecting AF may, according to the authors, be related to the fact that the radial pulse is usually stronger than the brachial pulse. However, the conclusions and findings should be seen within the serious limitation of this study, namely that there were only six subjects tested, of which only two had AF.

Pulse palpation versus modified sphygmomanometer
According to amount others, the NICE Guidelines for Hypertension [102], AF should be screened for by means of pulse palpation before routine BP measurement. A systematic review (three studies, 2385 patients) on the accuracy of pulse palpation to detect AF showed a pooled sensitivity of 94% (95% CI: 84–97%) and a pooled specificity of 72% (95% CI: 69–75% [6]). In addition, Hobbs et al. found in the SAFE trial among 4933 GP patients of 65 years and older a sensitivity of 87% (95% CI: 82–91%) and a specificity of 81% (80–83% [15]). Although studies that directly compared the AF detection capability of the modified BP monitor with pulse palpation have not yet been performed, it seems that the modified BP monitor is more accurate. In addition, pulse palpation is liable to observer bias and adherence to guidelines among healthcare workers can be poor [16,17].

Strengths & limitations
The strong part of the studies on accuracy of the AF detection system of the modified oscillometric BP monitor in the physician's office is that a 12-lead ECG diagnosed by a cardiovascular consultant (gold standard) was used as a comparator. In addition, all selected studies were performed with a sufficient number of patients and all studies compared more than one measurement. A weakness might be that the population studied had a relatively high AF prevalence (±20%). Since the modified oscillometric BP monitor is mentioned for screening, the performance and diagnostic ability should be verified in the environment in which it will be used. Therefore, it deserves recommendation to perform a study among a regular GP population with an AF prevalence of approximately 2.5%. A weakness of the device could be that, since the device works according to the principle of calculating the pulse interval times, subjects with some other arrhythmia may have a higher chance of having false-positive measurements than subjects in sinus rhythm. However, the algorithm adjusts for premature beats and showed that it is still accurate when 10% of all patients to be measured have non-AF arrhythmias.

Expert commentary
The modified BP monitor of Microlife can help to improve AF screening in regular clinical practice, without any extra efforts. Although a direct comparison is lacking, it seems that the device is more accurate and less liable to observer bias than pulse palpation. For the most accurate AF detection, three sequential BP measurements, should be performed. For office measurements, two or three measurements should be AF positive for classifying a patient as AF positive. For using the device at home, all readings need to detect AF before a patient is diagnosed with AF. When patients use the device at home for self-measurement of BP it may lead to increased detection of AF, mainly among those who have no symptoms. The device may be promising for the detection of paroxysmal AF for patients at home, although a study performed among a general GP population is desired. Using the device in a regular GP's practice might lead to more AF patients being diagnosed and to a lower number of subjects erroneously suspected of having AF, and thus to a decrease in unnecessary ECGs for confirmation.

Five-year view
It is expected that the number of patients with AF will increase over the coming 5 years by approximately 0.11–0.16% [18]. This increase, mainly due to demographic aging and a Western lifestyle, indicates that AF will have a bigger impact on overall healthcare expenditure in future. If the modified oscillometric blood pressure monitor is used during routine blood pressure measurement at the GP's practice, more patients with (asymptotic) AF may be detected and at an early stage. This means that treatment could start early, which would significantly diminish the number of AF-related strokes. As a side effect, routine use of the modified oscillometric device may create more awareness about AF for both physicians and patients with positive effects (e.g., improved treatment strategies, high adherence to treatment and lifestyle improvement). If patients start to use the device at home, it may lead to improved detection of paroxysmal AF and may provide an insight into the prevalence of paroxysmal AF.

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WJ Verberk is an employee of Microlife Corporation. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.
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Key issues
- Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, occurring in 1–2% of the general population. Its prevalence increases with age to 5% in subjects over 65 years of age.
- AF is often without symptoms and, therefore, remains undetected, whereas when detected at an early stage followed by adequate treatment, the risk of stroke can be reduced by approximately two-thirds.
- One in five of all strokes is attributed to AF.
- Hypertension is a risk factor for AF.
- Currently, it is advised to screen for AF by means of pulse palpation before routine blood pressure measurement in the GP's practice.
- Pulse palpation generally, shows moderate accuracy

and is dependent on observer bias. In addition, currently the detection of AF often depends on the clinicians willingness and awareness to perform pulse palpation.

- With the modified oscillometric blood pressure monitor, AF can be screened during routine BP measurement with high accuracy and without extra effort.
- Routine use of the modified oscillometric blood pressure monitor may lead to more patients being diagnosed with AF at an earlier stage.

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Quelle: https://pubmed.ncbi.nlm.nih.gov/23249156/

Diagnostic performance of an automatic blood pressure measurement device, Microlife WatchBP Home A, for atrial fibrillation screening in a real-world primary care setting

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Objective To evaluate the diagnostic performance of a UK National Institute for Health and Care Excellence-recommended automatic oscillometric blood pressure (BP) measurement device incorporated with an atrial fibrillation (AF) detection algorithm (Microlife WatchBP Home A) for real-world AF screening in a primary healthcare setting.

Setting Primary healthcare setting in Hong Kong.

Interventions This was a prospective AF screening study carried out between 1 September 2014 and 14 January 2015. The Microlife device was evaluated for AF detection and compared with a reference standard of lead-I ECG.

Primary outcome measures Diagnostic performance of Microlife for AF detection.

Results 5969 patients (mean age: 67.2±11.0 years; 53.9% female) were recruited. The mean CHA2DS2-VASc (C : congestive heart failure [1 point]; H : hypertension [1 point]; A_2 : age 65-74 years [1 point] and age ≥75 years [2 points]; D : diabetes mellitus [1 point]; S : prior stroke or transient ischemic attack [2 points]; VA : vascular disease [1 point]; and Sc : sex category [female] [1 point])score was 2.8±1.3. AF was diagnosed in 72 patients (1.21%) and confirmed by a 12-lead ECG. The Microlife device correctly identified AF in 58 patients and produced 79 false-positives. The corresponding sensitivity and specificity for AF detection were 80.6% (95% CI 69.5 to 88.9) and 98.7% (95% CI 98.3 to 98.9), respectively. Among patients with a false-positive by the Microlife device, 30.4% had sinus rhythm, 35.4% had sinus arrhythmia and 29.1% exhibited premature atrial complexes. With the low prevalence of AF in this population, the positive and negative predictive values of Microlife device for AF detection were 42.4% (95% CI 34.0 to 51.2) and 99.8% (95% CI 99.6 to 99.9), respectively. The overall diagnostic performance of Microlife device to detect AF as determined by area under the curves was 0.90 (95% CI 0.89 to 0.90).

Conclusions In the primary care setting, Microlife WatchBP Home was an effective means to screen for AF, with a reasonable sensitivity of 80.6% and a high negative predictive value of 99.8%, in addition to its routine function of BP measurement. In a younger patient population aged <65 years with a lower prevalence of AF, Microlife WatchBP Home A demonstrated a similar diagnostic accuracy.

Keywords: Atrial fibrillation; microlife; screening.

Quelle: https://pubmed.ncbi.nlm.nih.gov/28619766

Detection of atrial fibrillation using a modified microlife blood pressure monitor

Joseph Wiesel[1], Lorenzo Fitzig, Yehuda Herschman, Frank C Messine

Background Hypertension is a major risk factor for the development of atrial fibrillation (AF) and for stroke due to AF. Asymptomatic AF can result in a stroke, in patients with risk factors, if it is not detected and treated appropriately. This study evaluated the sensitivity and specificity of an automatic oscillometric sphygmomanometer designed to detect AF.

Methods The sphygmomanometer incorporates an algorithm for detecting AF while reducing false positive readings due to premature beats. A total of 405 unselected outpatients seen in two cardiology offices were evaluated by taking three sequential device readings and one electrocardiogram (EKG) on each patient.

Results For detecting AF, the sensitivity was 95% and the specificity 86% with a positive predictive value of 68% and a negative predictive value of 98% for single device readings. For the three sequential device readings grouped together, the sensitivity was 97% and the specificity was 89%. The device correctly categorized most of the non-AF, abnormal rhythms. The specificity for those in sinus rhythm was 97%.

Conclusions This device is able to detect AF with high sensitivity and specificity. Use of this device by patients who monitor their blood pressure at home may help detect asymptomatic AF and allow for treatment prior to the development of a stroke.

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Diagnostic accuracy of a home blood pressure monitor to detect atrial fibrillation

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Atrial fibrillation (AF) is the most common sustained arrhythmia and is associated with an increased longterm risk of stroke. A screening test for early diagnosis has the potential to prevent AF-related strokes. This study assessed the diagnostic accuracy of an automated device for self-home blood pressure (BP) monitoring, which implements an algorithm for AF detection. A modified, automated oscillometric device for selfhome BP monitoring (Microlife BPA100 Plus, Microlife, Heerbrugg, Switzerland) with an AF detector was used to carry out triplicate BP measurements in subjects with sinus rhythm, AF and non-AF arrhythmias. During each BP measurement, the electrocardiogram (ECG) was recorded simultaneously. A total of 217 simultaneous BP measurements and ECG recordings were obtained from 73 subjects. Twenty-seven subjects (37%) had AF, 23 (31%) non-AF arrhythmias and 23 (31%) had sinus rhythm. A single measurement had 93% sensitivity and 89% specificity for detecting AF. For two measurements, in which one of them was required to detect AF, the sensitivity was 100% and specificity 76%, whereas for three measurements, in which two of them were required to detect AF, the sensitivity was 100% and specificity 89% (j¼0.86 for an agreement with ECG). Using the latter approach, there were five false positive cases all having irregularities in B50% of the heartbeats. In patients with tachyarrhythmia, the device underestimated heart rate. These data suggest that an electronic device for self-home BP monitoring, which implements an algorithm for AF diagnosis has an excellent diagnostic accuracy and might, therefore, be used as a reliable screening test for the early diagnosis.

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Keywords: atrial fiblillation; diagnosis; screening; blood pressure measurement; self-home monitoring

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Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia in clinical practice.[1,2] In the last two decades, the prevalence of AF has increased considerably[1,2] and has been described as a 'growing epidemic'.[3] In the general population, the prevalence of AF is 0.5–1%, yet it is clearly related to age with ~5% of subjects over the age of 65 suffering from AF in which ~10% of subjects over 80.[1,2] Approximately, 70% of AF patients are older than 65 years.[1,2] Atrial fibrillation is associated with an increased long-term risk of stroke with one in every six strokes occurring in relation with it.[1,2] As AF is frequently asymptomatic, stroke is often the initial presentation that leads to AF detection. Therefore, screening programmes have attempted to address this important issue.[4] With early diagnosis and effective anticoagulation, many AF-related strokes could be prevented.

Approximately 25–30% of the adults in the general population and more than 50% of those older than 65 years are hypertensives.[5,6] Devices for self-monitoring blood pressure (BP) by patients at home are used widely in the community in several countries, and numerous hypertensive societies have endorsed the use of this method for long-term follow-up of treated hypertension.[7,8] An algorithm that assesses pulse irregularity and applies a threshold for detecting AF, during routine BP measurement, has been integrated in a home BP monitor.[9] Preliminary evidence shows that this method has a good diagnostic ability for AF detection.[9,10] Such a screening tool for AF, in the population, has considerable potential for the early detection and management of AF and thereby for stroke prevention.

This study was designed to assess the diagnostic accuracy of an automated device for self-home BP monitoring for detecting AF among subjects with sinus rhythm, sustained AF and other non-AF arrhythmias.

Subjects and methods

Participants

Subjects with known sustained AF, or other non-AF arrhythmias, and controls with sinus rhythm were recruited among those attending an Outpatients Hypertension Clinic, patients admitted in a University Department of Medicine wards and healthy volunteers. Exclusion criteria were age <35 years, presence of a pacemaker, and/or an implanted defibrillator and refusal to participate.

Device

An automated oscillometric device for self-home BP monitoring, which has been validated earlier for BP measurement accuracy,[11] and an additional function, which allows AF detection during routine BP measurement, has been developed (Microlife BPA100 Plus, Microlife, Heerbrugg, Switzerland). Atrial fibrillation is detected during the usual BP recording by the application of an in-built algorithm, which analyses the irregularity of the pulse rate.[9] The average time interval of the last 10 beats, during deflation, is calculated and intervals that are 25% shorter or longer than that of the average are discarded. The mean of the remaining intervals is calculated with its s.d., and an AF diagnosis is made, if the s.d. per mean ratio is >0.06.[9] Four devices were donated by the manufacturer for carrying out this study.

Procedure

A medical history and a baseline 12-lead electrocardiogram (ECG) were obtained from each participant. Triplicate BP measurements were then taken after at least a 5-min rest in the lying position and with at least 30 s between measurements, using the tested home BP monitor with the AF detector. Simultaneously during the deflation phase of each BP measurement (when the AF detector of the device operates), the ECG was recorded continuously (one lead with a clear appearance of p-waves selected from the individual's baseline ECG). When an error occurred in BP measurement, this was repeated in order to obtain three sets of measurements with the corresponding ECGs per participant. The systolic and diastolic BP values and pulse rates measured by the device and the AF diagnosis carried out (AF, yes/no), were recorded for each measurement. The ECG heart rate and diagnosis of AF or other arrhythmias at baseline, and during each measurement, were made by one of the investigators and verified by an expert cardiologist. The protocol was approved by the hospital scientific committee and signed informed consent was obtained from all participants.

Analysis

The sensitivity, specificity and kappa-statistic for the AF diagnosis, carried out using the tested device and taking the ECG diagnosis of AF as reference method, were assessed for individual measurements and also for duplicate or triplicate measurements. Student's t-tests and one-way analysis of variance were used for the comparison of continuous variables in two or more groups of subjects, respectively, and the chi-squared tests were used for categorical variables. Paired t-tests were used to compare continuous variables in the same subjects. Statistical analysis was carried out using the MINITAB INC Statistical Software (Release 13.31). A probability value of $P<0.05$ was considered statistically significant.

Results

A total of 73 subjects were recruited and all were included in the analysis. Twenty-seven (37%) had AF, 23 (31%) non-AF arrhythmias and 23 had (31%) sinus rhythm (Table 1). The ECG showed AF during all three BP measurements in 27 subjects (two subjects had two measurements), sinus rhythm during all three measurements in 23 subjects and non-AF arrhythmias during all three measurements in 16 subjects. Seven subjects (10%) had a change in the ECG rhythm during their three BP measurements. Four subjects had non-AF arrhythmia during two BP measurements and sinus rhythm during the third one; two subjects had sinus rhythm during two measurements and non-AF arrhythmia during the third; and one subject had non-AF arrhythmia during two measurements and AF during the third one (the latter subject was excluded from 'cases' analysis because of intermittent AF).

Overall, 217 simultaneous BP measurements and ECG recordings were obtained (two subjects had two readings instead of three). The ECG showed sinus rhythm during 77 BP measurements, AF during 80 and non-AF arrhythmia during 60 measurements. With regard to the AF diagnosis, 77 of the 80 BP measurements obtained while the ECG showed AF, were effectively detected as AF by the tested device (three were missed). Furthermore, 76 of the 77 BP measurements obtained while ECG showed sinus rhythm, were correctly diagnosed by the tested device (no AF), and one was misdiagnosed as AF. Finally, of the 60 measurements obtained, while the ECG showed non-AF arrhythmia, 21 (35%) were misdiagnosed as AF by the tested device.

The evaluation of the diagnostic value of the AF detector is presented in Table 2. When the diagnosis was based on a single measurement (all individual readings, n=217 or only the first one of each subject, n=72), the sensitivity of the device for diagnosing AF was >90% and the specificity >80% with the kappa-statistic suggesting a substantial agreement (Table 2). When the first two or all three measurements were taken into account and only one measurement was needed to diagnose AF, the sensitivity was 100% but the specificity <80%. Finally, when all three measurements were taken into account and two of them were required to diagnose AF, the sensitivity was 100% and specificity 89% with the kappa-statistic suggesting an almost perfect agreement (Table 2). Applying the optimal diagnostic approach (three measurements taken and at least two of them needed to diagnose AF), five cases were misdiagnosed as AF by the tested device. All these patients had non-AF arrhythmias in all their three measurements, which were misdiagnosed by the device as AF in all their three measurements (three subjects) or in two of their three measurements (two subjects). In these cases, the ECG during the BP measurements showed irregular RR intervals in B50% of the beats (range:24–72%).

Table 1. Characteristics of participants with atrial fibrillation, other arrhythmias and sinus rhythm

	All subjects (n=73)	Atrial fibrillation (n=27)	Other arrhythmia (n=23)	Sinus rhythm (n=23)	P-value
Age (years)	70.5±10.6	75.7±6.3	70.1±10.4	64.0±11.6	<0.001
Men (%)	65.8	67.9	63.6	65.2	NS
BMI (kgm^{-2})	27.0±4.3	26.3±3.3	28.4±4.9	26.7±4.5	NS
Arm circ (cm)	28.2±3.4	28.0±3.3	28.7±3.9	28.0±3.0	NS
Smokers (%)	5.5	7.1	4.5	4.3	NS
CVD (%)	39.7	60.7	27.3	26.1	<0.01
Diabetes mellitus (%)	15.1	25.0	13.6	4.3	NS
Hypertension (%)	63.0	60.7	72.7	56.5	NS
Number of drugs[a]	1.8±1.5	1.8±1.6	2.0±1.3	1.6±1.7	NS
Systolic BP (mmHg)	138±19	141±21	135±16	137±19	NS
Diastolic BP (mmHg)	80±12	79±14	77±11	82±10	NS
Pulse rate (b.p.m)	74±17**	78±16*	68±14**	75±19	<0.01
ECG heart rate (b.p.m)	78±21	84±24	74±16	75±20	<0.01

Abbreviations: BMI, body mass index; BP, blood pressure; b.p.m., beats per minute; CVD, cardiovascular disease; ECG, electrocardiogram; NS, non-significant.
[a]For hypertension; *Po0.01, **Po0.001 versus ECG heart rate.

Table 2. Diagnostic value of the atrial fibrillation detector by basing the diagnosis on different measurements and taking ECG diagnosis as reference

	N	Readings used	Readings needed for diagnosis[a]	ECG (AF +/–)	BP monitor (AF +/–)	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (%)	Kappa (95% CI)
Readings	217	1 (any)	1	80/137	100/117	0.96 (0.89–0.99)	0.83 (0.76–0.89)	88	0.76 (0.67–0.84)
Subjects	72	1 (first)	1	27/45	30/42	0.93 (0.74–0.99)	0.89 (0.76–0.96)	90	0.80 (0.65–0.94)
Subjects	72	2 (first)	1	27/45	38/34	1.00 (0.84–1.00)	0.76 (0.60–0.87)	85	0.70 (0.54–0.85)
Subjects	72	3	1	27/45	41/31	1.00 (0.84–1.00)	0.69 (0.53–0.81)	81	0.62 (0.46–0.79)
Subjects	72	3	2	27/45	32/40	1.00 (0.84–1.00)	0.89 (0.75–0.96)	93	0.86 (0.74–0.98)

Abbreviations: AF, atrial fibrillation; (+/), atrial fibrillation diagnosis (yes/no); BP, blood pressure; CI, confidence interval; ECG, electrocardiogram.
[a]Number of readings that should indicate AF in order to make an AF diagnosis.

The ECG-calculated heart rate was on average 6 b.p.m. (beats per minute) higher than the pulse rate measured using the tested device in subjects with AF and in those with non-AF arrhythmia, but not in those with sinus rhythm (Table 2). Among subjects with AF or non-AF arrhythmia, those with a ≥10-b.p.m. pulse rate, underestimation by the tested device had a faster ECG heart rate (97.0±28.3 (s.d.) b.p.m.) compared with those with <10-b.p.m. difference (74.8±17.4 b.p.m., $P<0.001$).

Discussion

This prospective study assessed the diagnostic accuracy of an automated device for self-home BP monitoring in detecting AF. Overall, the device appeared to have a good diagnostic value, and even a single measurement achieved agreement with ECG diagnosis in more than 80% of the cases. For triplicate BP measurements, in which two of them were required to make the diagnosis of AF, the device has an almost perfect agreement with ECG diagnosis (93%) with 100% sensitivity and 89% specificity.

Until recently, the diagnosis of AF was only made on the basis of an ECG. This method was regarded as a very accurate one, but proved to be so only when carried out by a specialist. This is shown clearly in a study that compared the AF diagnosis, made by general practitioners, and a computer software algorithm using a 12-lead ECG, versus a reference diagnosis made by two cardiologists.[12] The general practitioners' diagnosis proved to be imperfect with a sensitivity of 80% and specificity of 92%. When taking into account the general practitioner's diagnosis together with the interpretative software (either or both positive), the diagnostic performance was improved, but only reached a sensitivity of 92% and specificity of 91%.[12] The investigators concluded that many primary care professionals cannot accurately detect AF on an ECG, even when helped by an interpretative software.[12] Self-diagnosis by patients of the pulse irregularity as a screening test for the detection of AF has been evaluated in a community education program with 6203 participants.[13] Unfortunately, 27% of the trained participants could not find their pulse, and of those who did, 9% could not tell whether it was irregular.[13]

Owing to the widespread devices for self-home BP monitoring in the community, the idea that such devices also monitor pulse rate by implementing specific algorithms that are able to screen for arrhythmias is challenging. Early arrhythmia detectors integrated in home BP monitors picked up any pulse rate irregularity (even occasional ectopic beats) and could not distinguish between AF and other arrhythmias. Thus, their specificity for AF diagnosis is unacceptably low. Wiesel et al.[9] developed an algorithm for AF detection during routine BP measurement, which has been integrated in the home BP monitor tested in this study. The first study that assessed the diagnostic accuracy of an AF-detecting home BP monitor (modified Omron 712C) included 450 subjects, of whom 54 had AF on ECG.[9] When single BP readings were used, the sensitivity of the device for diagnosing AF was 100% and the specificity 84%, whereas for two readings (diagnosis made only if both were positive), the sensitivity and specificity were 100 and 91%, respectively.[9] A recent study by the same group tested the same device as in this study in 205 subjects, of whom 52 had AF on ECG.[10] The sensitivity and specificity of a single measurement for detecting AF was 98 and 88%, respectively. For three measurements, in which two of them were required to diagnose AF, the diagnostic accuracy was improved (sensitivity, 100%; specificity, 89%),[10] that is identical with the finding of this study (Table 2). The feasibility of using the device by patients at home for detecting intermittent AF has been tested in a small study of 19 patients with a history of AF.[14] Selfmonitoring at home, once per day for a period from 5 days to 5 months, seven patients with recurrent AF were identified by the monitor.[14]

The important features of this study that ensured a comprehensive assessment of the diagnostic accuracy of the AF detector are, first, that all BP measurements (and AF detector operation) were carried out simultaneously with continuous ECG recording, and, second, that three distinct groups of subjects (sinus

rhythm, AF and non-AF arrhythmia) were investigated. This study design allowed the detection of changes in rhythm during the triplicate BP measurements, which actually occurred in 10% of the participants. In addition, the performance of the AF detector was tested in rather difficult diagnostic conditions, because of the inclusion of a group of subjects with non-AF arrhythmias. We hypothesized that a false positive diagnosis of AF might be common in the latter group. Such a drawback (poor specificity) of this screening method would often cause the users to be alarmed unnecessarily.

Interestingly, even in these more complex diagnostic conditions, the device proved to have a good diagnostic value. In line with the findings of Wiesel et al.,[10] and after testing several approaches including single, duplicate and triplicate measurements, and one of two, one of three and two of three positive measurements needed for diagnosis, these data confirmed that triplicate measurements, in which two of them were required to make an AF diagnosis, is the optimal approach in terms of diagnostic accuracy (Table 2). In fact this screening tool appears to be more accurate in diagnosing AF than the general practitioners' diagnosis carried out by ECG together with an interpretative software.[12]

Even after applying the optimal diagnostic approach (two of the three measurements needed for diagnosis), the tested device overdiagnosed AF in five patients. All these subjects had non-AF arrhythmias with irregular RR intervals in ~50% of the beats, which were regarded as clinically important non-AF arrhythmias. Thus, even in these cases with a false positive AF diagnosis, patients are not alarmed unnecessarily by the device because they may benefit from medical consultation.

As this device is designed to detect AF by assessing the consistency of pulse rate irregularity, it cannot detect atrial flutter. On the other hand, the device will not alert patients with sporadic ectopic beats, which is a considerable improvement compared with that of other arrhythmia detectors implemented in the current oscillometric manometers. At present, and based on the prevalence of these arrhythmias and the associated cardiovascular risk, this technology seems to offer the optimal screening method.

Another issue raised by this study is that in case of arrhythmia (AF or other), heart rate is underestimated by the device, particularly in cases with tachyarrhythmia. Given the recent evidence that validated, automated BP monitors give accurate BP measurements in patients with AF and can be used in everyday clinical practice,[15,16] this issue deserves special attention.

In conclusion, this study showed that a home BP monitor with an integrated algorithm for AF diagnosis appears to have a very good diagnostic accuracy, which might be superior to that of a general practitioner. The widespread application of this technology in devices for routine home BP monitoring in the community appears to be an excellent screening test, yet its ability to detect intermittent AF requires further investigation.[14] Subjects with AF, detected by the device, should consult their physician as soon as possible in order to confirm the AF diagnosis by ECG before a decision for pharmacologic intervention is made.

What is known about this topic

- Atrial fibrillation is the most common sustained arrhythmia in clinical practice and is associated with an increased long-term risk of stroke.
- Atrial fibrillation is often asymptomatic and remains undiagnosed until a stroke has occurred. A screening method for early diagnosis has the potential to prevent strokes.
- Devices for routine monitoring of blood pressure at home can detect arrhythmias by assessing pulse irregularity. An algorithm specific for atrial fibrillation detection has been developed. What this study adds.
- Triplicate blood pressure measurements taken using a home monitor with integrated algorithm for atrial fibrillation, gives an almost perfect agreement with ECG diagnosis of atrial fibrillation.
- False negative diagnosis appears to be very unlikely. However, false positive diagnosis is not uncommon among patients with other significant arrhythmias, which may also benefit from medical consultation.
- The widespread application of this technology might be an excellent screening test for early diagnosis of atrial fibrillation and thereby for more effective stroke prevention.

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Conflict of interest

The Hypertension Center has received grants from the manufacturer of the tested device (Microlife) for other research activities. GSS was a consultant to Microlife for the design of other blood pressure monitors. Microlife was not involved in the design of this study.

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Triage tests for identifying atrial fibrillation in primary care: a diagnostic accuracy study comparing single-lead ECG and modified BP monitors

Karen Kearley[1], Mary Selwood, Ann Van den Bruel, Matthew Thompson, David Mant, Fd Richard Hobbs, David Fitzmaurice, Carl Heneghan

Objective New electronic devices offer an opportunity within routine primary care settings for improving the detection of atrial fibrillation (AF), which is a common cardiac arrhythmia and a modifiable risk factor for stroke. We aimed to assess the performance of a modified blood pressure (BP) monitor and two single-lead ECG devices, as diagnostic triage tests for the detection of AF.

Setting 6 General Practices in the UK.

Participants 1000 ambulatory patients aged 75 years and over.

Primary and secondary outcome measures Comparative diagnostic accuracy of modified BP monitor and single-lead ECG devices, compared to reference standard of 12-lead ECG, independently interpreted by cardiologists.

Results A total of 79 participants (7.9%) had AF diagnosed by 12-lead ECG. All three devices had a high sensitivity (93.9-98.7%) and are useful for ruling out AF. WatchBP is a better triage test than Omron autoanalysis because it is more specific-89.7% (95% CI 87.5% to 91.6%) compared to 78.3% (95% CI 73.0% to 82.9%), respectively. This would translate into a lower follow-on ECG rate of 17% to rule in/rule out AF compared to 29.7% with the Omron text message in the study population. The overall specificity of single-lead ECGs analysed by a cardiologist was 94.6% for Omron and 90.1% for Merlin.

Conclusions WatchBP performs better as a triage test for identifying AF in primary care than the single-lead ECG monitors as it does not require expertise for interpretation and its diagnostic performance is comparable to single-lead ECG analysis by cardiologists. It could be used opportunistically to screen elderly patients for undiagnosed AF at regular intervals and/or during BP measurement.

Keywords Primary Care; Stroke Medicine.

Quelle: https://pubmed.ncbi.nlm.nih.gov/24793250/

Automated blood pressuremeasurement in atrial fibrillation: validation processmodification and evaluation of a novel professional device which detects atrial fibrillation and adapts its blood pressure measurement algorithm

George S. Stergiou, Konstantinos G. Kyriakoulis, Ioanna Bountzona, Ariadni Menti, Antonios Destounis, Petros Kalogeropoulos, and Anastasios Kollias

Objectives Blood pressure (BP) measurement in atrial fibrillation (AF) patients is problematic and automated monitors are regarded as inaccurate. The optimal procedure for validating BP monitors in AF is questionable. This study evaluated the accuracy of a novel professional oscillometric upper-arm cuff device (Microlife WatchBP Office), which has an algorithm for detecting AF and then applies an AF-specific BP measurement algorithm. BP variability, which is inherently increased in AF patients, was considered in the analysis.

Methods Subjects with sustained AF were included in a validation study using the same arm sequential measurement method of the Universal Standard (ISO 81060-2:2018) for special populations. Analysis was performed in all subjects and separately in those with and without high reference BP variability (>12/8mmHg SBP/DBP).

Results Thirty-five subjects with 105 paired test/reference BP measurements were included (mean age 76.38.4 years, reference SBP/DBP 128.219.5/72.512.1mmHg, pulse rate 68.314.9 bpm). Validation Criterion 1 (mean differenceSD) was 0.07.7/0.27.0mmHg in all 105 BP pairs (threshold 58 mmHg). Criterion 1 was 0.56.1/<?>0.26.8mmHg in 18 subjects (54 BP pairs) with low reference BP variability and <?>0.69.2/ 0.67.3mmHg in 17 (51 pairs) with high variability. Criterion 1 did not differ in pulse rate < 70 vs. 70 bpm Validation Criterion 2 (SD of differences for 35 individuals) was 5.38/6.20mmHg (SBP/DBP; threshold 6.95/6.95).

Conclusion A technology which detects AF and activates an AF-specific BP measurement algorithm introduces a challenging solution for clinical practice. Validation of BP monitors in AF patients should not ignore their inherently high BP variability.

Keywords arrhythmia, automatic, blood pressure monitoring, diagnosis, electronic, performance
Abbreviations: AAMI, American Association for the Advancement of Medical Instrumentation; AF, atrial fibrillation; BP, blood pressure; ESH, European Society of Hypertension; ISO, International Organization for Standardization.

Quelle: https://pubmed.ncbi.nlm.nih.gov/33060450/

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