Evaluation of an automated sphygmomanometer for use in the office setting

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Objective **To determine whether the WatchBP Office sphygmomanometer can be used to obtain automated office blood pressure (AOBP) readings that are similar to the awake ambulatory BP.**

Methods **One hundred patients referred for 24 h ambulatory BP monitoring had BP recorded three times using the WatchBP Office fully automated sphygmomanometer in accordance with standard AOBP measurement guidelines. The mean AOBP was compared with the mean awake ambulatory BP.**

Results **The mean (± SD) AOBP (138.6 ± 13.7/79.7 ± 9.0 mmHg) was similar to the mean awake ambulatory BP (136.8 ± 12.4/79.0 ± 10.8 mmHg). The small difference in systolic BP (1.8 mmHg) was statistically significant ($P=0.03$), but was within the accepted range (5 mmHg) recommended by guidelines for equivalence between BP readings. There was a strong correlation ($P<0.001$) between the systolic/diastolic AOBP and awake ambulatory BP readings ($r=0.819/0.801$).**

Conclusion **The WatchBP Office produces BP readings that closely approximate the awake ambulatory BP, confirming that this automated sphygmomanometer is suitable for recording AOBP in clinical practice.** ***Blood Press Monit*** **17:116–119 © 2012 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

Recent guidelines for making a diagnosis of hypertension have set 24 h ambulatory blood pressure monitoring (ABPM) as the gold standard for determining an individual's blood pressure (BP) status [1]. Home BP is generally considered to be complementary to ABPM, although it is also recommended for the diagnosis of hypertension when ABPM is not available. The trend away from office BP measurement can be attributed to several new developments. Numerous studies have reported out-of-office BP to be more predictive of future cardiovascular events than manual BP recordings performed in research settings [1–3]. Manual BP in routine clinical practice is a less reliable measure of BP status than a research quality manual BP. Conventional manual BP measurement using a mercury sphygmomanometer is also at variance with recent recommendations that mercury be banned from the workplace because of environmental concerns [4].

As a consequence of these developments, there has been a proposal [5] for an alternative approach to the measurement of BP in the office setting – automated office blood pressure (AOBP). By following the three basic principles of AOBP (multiple BP readings taken using a fully automated recorder with the patient resting alone in a quiet setting), it is possible to obtain office BP readings that are more reliable than routine manual BP and comparable with the awake ambulatory BP and home BP. Until now, almost all of the research into AOBP has used the BpTRU device (BpTRU Medical Devices Inc., Coquitlam, British Columbia, Canada). This automated oscillometric sphygmomanometer records an initial 'test' BP to verify that a valid reading is being obtained, followed by five readings at 1 or 2 min intervals with the patient resting alone.

For AOBP to become more widely accepted as an alternative to manual BP, there should ideally be more than one AOBP recorder available for use in clinical practice. A recently developed oscillometric sphygmomanometer, the WatchBP Office (Microlife Corp., Heerbrugg, Switzerland), is now available for professional use in the office setting and can be used for AOBP measurement. This device has been validated for accuracy independent of the manufacturer in accordance with the criteria of the International Protocol [6]. We undertook the present study to determine whether AOBP readings taken using the WatchBP Office are similar to the awake ambulatory BP to observe whether this automated sphygmomanometer is suitable for recording AOBP in clinical practice.

Methods

Patients referred for 24 h BP monitoring to an ABPM unit were offered participation in the study if they were 18 years of age or older and were capable of performing ABPM. Basic demographic data including sex, age, hypertension treatment status, and presence of concurrent diabetes mellitus

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were documented. AOBP measurements were obtained in accordance with established guidelines [5] with the patient seated comfortably alone in a quiet room. Before the initiation of ABPM, an initial 'test' reading was taken by the technician with the WatchBP Office attached to the same arm to be used for ABPM. The device was then activated to take three readings separated by 1 min, with the technician immediately leaving the room after the completion of the 'test' reading to allow the patient to rest alone. Different cuff sizes were available to match the circumference of the patient's upper arm. All valid readings were included in the estimation of the AOBP.

Upon completion of the AOBP readings, the patient underwent 24 h ABPM using a Spacelabs model 90207 device (Spacelabs Healthcare Inc., Issaquah, Washington, USA) set to record BP at 15-min intervals between 06:00 and 22:00 h and every 30 min at night. Patients were asked to maintain a diary that included the time of actual sleep. The awake period as reported in the patient's diary was used to determine the readings for inclusion in the calculation of the mean awake ambulatory BP. Patients were instructed to engage in normal daily activities during ABPM. All valid ambulatory BP readings were included in the data analysis.

The study was approved by the Ethics Review Board of Sunnybrook Health Sciences Centre.

The primary outcome measure was the difference between the awake ambulatory BP and the AOBP. Mean ± SD values were computed for descriptive variables. Differences between the mean BP values and 95% confidence intervals were computed and compared using Student's paired *t*-test. Pearson's correlation coefficients were obtained for the mean AOBP versus awake ambulatory BP for individual patients.

Results

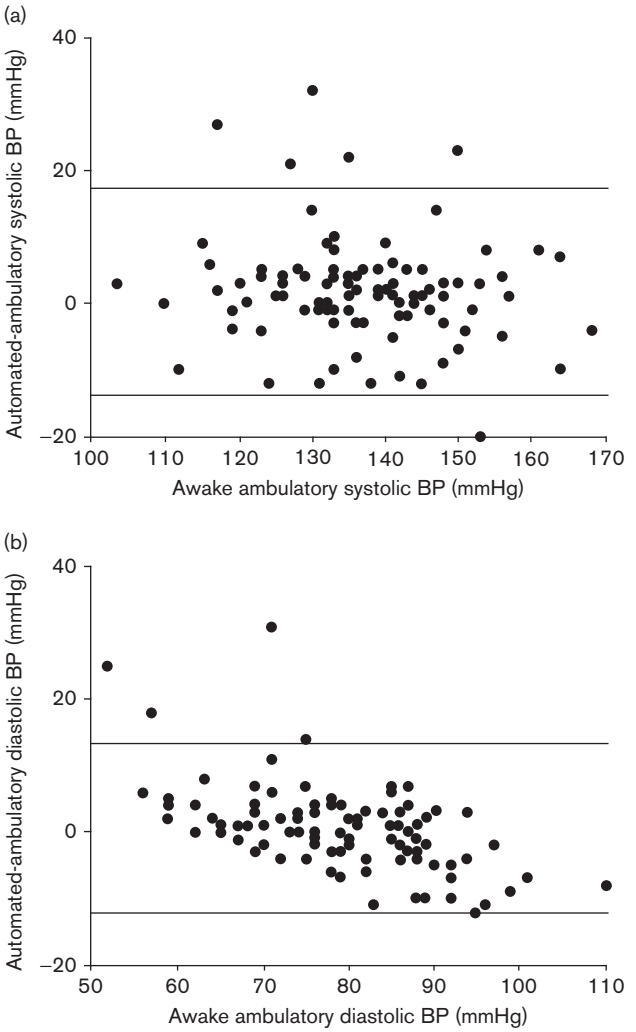
The study population included 100 consecutive patients referred for 24 h ABPM who agreed to participate in the study. The mean age of the patients was 61.8 ± 12.2 years and included 44 men, 51 patients receiving antihypertensive drug therapy, and 20 patients with a diagnosis of diabetes mellitus. The initial BP reading taken by the technician using the AOBP device was 149.4 ± 14.1/84.5 ± 9.2 mmHg (Table 1). Following the departure of the technician from the room, the mean AOBP decreased within 1 min and decreased progressively with each successive reading to a final BP of 132.5 ± 12.2/76.4 ± 9.2 mmHg. The mean (95% confidence interval) systolic/diastolic AOBP was only 1.8 (2.21, 3.35)/0.7 (0.60, 1.98) mmHg higher ($P < 0.03$/$P = 0.29$) than the mean awake ambulatory BP. Figure 1 shows a plot of the awake ambulatory BP against the difference between the AOBP and awake ambulatory BP to show the relationship of the individual AOBP readings with the awake ambulatory BP.

Table 1 Ambulatory blood pressure readings and automated office blood pressure readings preceded by a test blood pressure taken in the presence of the observer

BP reading	BP (mean ± SD; mmHg)
'Test' BP	149.4±14.0/84.5±9.2
Automated office BP	
#1	144.2±15.4/82.7±9.8
#2	139.2±14.6/80.1±9.3
#3	132.5±12.2/76.4±9.2
Mean BP	138.6±13.7/79.7±9.0
Ambulatory BP	
Awake	136.8±12.4/79.0±10.8
24 h	133.4±13.1/76.2±10.7
Asleep	125.1±15.7/69.2±10.5

BP, blood pressure.

Fig. 1



Awake ambulatory systolic (a) and diastolic (b) blood pressure (BP) readings are plotted on the *x*-axis against the differences between the automated office and awake ambulatory BP readings on the *y*-axis. The mean (95% confidence interval) difference was 1.8 (−13.8, 17.3) mmHg for systolic BP and 0.7 (−12.0, 13.4) mmHg for diastolic BP. The horizontal lines represent the 95% confidence intervals.

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Table 2 Coefficients of correlation between individual and mean systolic and diastolic automated office blood pressure readings and the mean awake ambulatory blood pressure

Automated office BP readings	Correlation coefficient (r) Automated office BP vs. awake ambulatory BP
Systolic	
#1	0.752
#2	0.731
#3	0.809
Mean	0.819
Diastolic	
#1	0.697
#2	0.775
#3	0.817
Mean	0.801

BP, blood pressure.

There was a strong and statistically significant ($P < 0.001$) correlation between the individual mean AOBP readings and the corresponding mean awake ambulatory BP (Table 2). The correlation coefficient between the mean of the three systolic/diastolic AOBP readings and the awake ambulatory BP was $r = 0.819/0.801$.

Discussion

In this study, office BP readings taken in accordance with the principles of AOBP using the WatchBP Office were similar to the mean awake ambulatory BP, a gold standard for predicting future cardiovascular risk related to an individual's BP status. Although the slightly higher (1.8 mmHg) systolic AOBP was statistically significant, the difference from the awake ambulatory BP is well within the range generally accepted by validation protocols for equivalence between sphygmomanometers [7,8]. This value is also similar to the differences noted between the awake ambulatory BP and both home BP and AOBP when the latter is recorded using the BpTRU device [9,10]. Moreover, there was also a strong correlation between the AOBP recorded with the WatchBP Office and the awake ambulatory that met or exceeded correlations found between the awake ambulatory BP and either home BP or AOBP taken with the BpTRU [11–13].

Andreadis *et al.* [14] have recently reported on the relationship between AOBP and left ventricular mass, noting that the AOBP taken with the WatchBP Office in a research unit correlated with left ventricular mass ($r = 0.37$) the same as did the awake ambulatory BP. As in previous studies [5,10], BP readings taken in the presence of research staff were higher and correlated relatively poorly ($r = 0.12$) with left ventricular mass. Under the conditions prevailing in this study, the mean AOBP in their patient population was 140/88 mmHg compared with a mean awake ambulatory BP of 136/87 mmHg. As in the present study, the correlation between the systolic/diastolic AOBP and awake ambulatory BP ($r = 0.68/0.78$) was much stronger than with BP readings recorded in the presence of the observer ($r = 0.08/0.01$).

Almost all of the other studies documenting the advantages of AOBP for measurement of BP in the office/clinic setting have used the BpTRU device. In a previous study [15], we sought to broaden the choice of automated sphygmomanometers suitable for AOBP measurement by comparing readings taken with the BpTRU to AOBP readings obtained using another device designed for professional use, the Omron HEM 907 (Omron Healthcare Inc., Bannockburn, Illinois, USA). AOBP readings taken with both devices at either 1 or 2 min intervals in a clinical setting were similar, with the mean BP values being within 1–2 mmHg for each device. The only exception was the Omron HEM 907, which yielded a diastolic BP that was 5 mmHg lower when readings were taken at 2 min intervals. Overall, the Omron HEM 907 appeared to be equivalent to the BpTRU for AOBP measurement, especially using the 1 min setting that is currently recommended for clinical practice. The Omron HEM 907 has also passed a formal validation study [16] and has been shown to yield similar BP readings to the mercury sphygmomanometer when recorded in the presence of a health professional [17].

AOBP was incorporated into the Canadian guidelines for the diagnosis of hypertension in 2010 [18] as an alternative to conventional manual BP measurement. Studies involving AOBP have been reported from the USA and from several countries in Europe, in addition to research conducted in Canada [5,10]. AOBP has also been acknowledged as a potential replacement for manual office BP, to be used in conjunction with ABPM and home BP [5,19,20]. The finding in the present study that the WatchBP Office produces readings that closely approximate the awake ambulatory BP should facilitate more widespread use of AOBP with three devices, the BpTRU, Omron HEM 907, and WatchBP Office, now available for recording AOBP in routine clinical practice.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

References

1 National Institute for Health and Clinical Excellence. *Hypertension NICE Clinical Guidelines 127.* London, UK: National Clinical Guidelines Centre; 2011.
2 Hodgkinson J, Mant J, Martin U, Guo B, Hobbs FDR, Deeks JJ, *et al.* Relative effectiveness of clinic and home blood pressure monitoring compared with ambulatory blood pressure monitoring in diagnosis of hypertension: systematic review. *BMJ* 2011; **342**:d3621.
3 Stegiou GS, Siontis KCM, Ioannidis JPA. Home blood pressure as a cardiovascular outcome predictor: it's time to take this method seriously. *Hypertension* 2010; **55**:1301–1303.
4 Scientific Committee on Emerging and Newly Identified Health Risks. *Mercury sphygmomanometers in healthcare and the feasibility of alternatives.* Brussels, Belgium: SCENIHR; 2009. Available at *http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm#2* [Accessed 4 April 2012].
5 Myers MG, Godwin M, Dawes M, Kiss A, Tobe SW, Kaczorowski J. Measurement of blood pressure in the office – recognizing the problem and proposing the solution. *Hypertension* 2010; **55**:195–200.

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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 American National Standard. *Non-invasive sphygmomanometers – part 2: clinical validation of automated measurement type. ANSI/AAMI/ISO 81060-2:2009*. Arlington, VA: Association for the Advancement of Medical Instrumentation, AAMI; 2009.

8 O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, *et al.* On behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. International protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002 **7**:3–17.

9 Myers MG, Valdivieso M, Chessman M, Kiss A. Can sphygmomanometers designed for self-measurement of blood pressure in the home be used in office practice? *Blood Press Monit* 2010; **15**:300–304.

10 Myers MG, Godwin M. Automated office blood pressure. *Can J Cardiol* 2012; doi:10.1016/j.cja.2011.09.004.

11 Beckett L, Godwin M. The BpTRU automatic blood pressure monitor compared to 24 h ambulatory blood pressure monitoring in the assessment of blood pressure in patients with hypertension. *BMC Cardiovasc Disord* 2005; **5**:18.

12 Myers MG, Valdivieso M, Kiss A. Use of automated office blood pressure measurement to reduce the white coat response. *J Hypertens* 2009; **27**:280–286.

13 Eguchi K, Kuruvilla S, Ishikawa J, Ogedegbe G, Gerin W, Schwartz JE, *et al.* Correlations between different measures of clinic, home, and ambulatory blood pressure in hypertensive patients. *Blood Press Monit* 2011; **16**:142–148.

14 Andreadis EA, Agaliotis GD, Angelopoulos ET, Tsakanikas AP, Chaveles IA, Mousoulis GP. Automated office blood pressure and 24 h ambulatory measurements are equally associated with left ventricular mass index. *Am J Hypertens* 2011; **24**:661–666.

15 Myers MG, Valdivieso M, Kiss A, Tobe SW. Comparison of two automated sphygmomanometers for use in the office setting. *Blood Press Monit* 2009; **14**:45–47.

16 White WG, Anwar YA. Evaluation of the overall efficacy of the Omron office digital blood pressure HEM-907 monitor in adults. *Blood Press Monit* 2001; **6**:107–110.

17 Ostchega Y, Nwankwo T, Sorlie PD, Wolz M, Zipf G. Assessing the validity of the Omron HEM-907XL oscillometric blood pressure measurement device in a national survey environment. *J Clin Hypertens* 2010; **12**:22–29.

18 Quinn RR, Hemmelgarn BR, Padwal RS, Myers MG, Cloutier L, Bolli P, *et al.* The 2010 Canadian Hypertension Education program recommendations for the management of hypertension: part 1 – blood pressure measurement diagnosis and assessment of risk. *Can J Cardiol* 2010; **26**:241–248.

19 Pickering TG. Should doctors still measure blood pressure? *J Clin Hypertens* 2006; **8**:394–396.

20 Myers MG. A proposed algorithm for diagnosing hypertension using automated office blood pressure measurement. *J Hypertens* 2010; **28**:703–708.

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