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See Editorial Commentary, pp 1038–1039

Abstract—The management of high blood pressure (BP) is particularly inadequate in low-income countries, where the unavailability of a reliable, durable, and affordable BP-measurement device is a major obstacle to accurate diagnosis. Recognizing this, a World Health Organization committee was established to correct this deficiency by influencing manufacturers to produce a device according to predetermined criteria and to demonstrate the suitability of the device for low resource settings. A device, which fulfilled stipulated criteria in being inexpensive, semiautomated, and solar powered, was validated according to the International Protocol of the European Society of Hypertension; it was then subjected to field testing in 716 subjects from 2 centers in Uganda and 1 in Zambia. The Omron HEM-SOLAR having previously fulfilled accuracy criteria of the International Protocol for both systolic blood pressure (SBP) and diastolic blood pressure (DBP), fulfilled criteria for SBP, but not for DBP, when revalidated. In field testing, average SBPs and DBPs were 120.5±21.6/74.6±13.8 mm Hg and 122.3±21.8/71.2±14.0 mm Hg, respectively, with the auscultatory technique and the Omron HEM-SOLAR, respectively. Between-device agreement in defining SBP was 93.7%. The Omron HEM-SOLAR was favored over the mercury sphygmomanometer by both patients and investigators. In summary, considering the accuracy, robustness, relatively low cost, operational simplicity, and advantages such as solar power, the Omron HEM-SOLAR is likely to be a valuable device for improving BP measurement in low-resource settings with nonphysician health workers. **(*Hypertension*. 2010;56:1047-1053.) ● Online Data Supplement**

Key Words: Blood pressure measurement device ■ solar power ■ hypertension ■ low-resource settings

Worldwide, there is a progressive increase in the prevalence of cardiovascular diseases, in some locations reaching epidemic levels.[1] Approximately 8 million deaths annually worldwide can be attributed to high blood pressure (BP). Low-income and middle-income countries shoulder approximately 80% of the cardiovascular disease burden, half of which occurs in people of working age.[1] Inadequate BP control is the major contributor to strokes and heart attacks in all parts of the world, including Africa,[2–5] and is responsible for a large and increasing economic and health burden in low-resource settings (LRS).[6] Even in developed countries, the control of BP is at best 20% to 30% in hypertensive patients receiving treatment, but in LRS, the situation is much worse.[2] The World Health Organization (WHO) has identified the reduction of total cardiovascular risk through integrated management of risk factors, including hypertension, as one of the most effective strategies for addressing the global epidemic of cardiovascular disease.[7–10] WHO has also recognized that one of the major causes for poor BP control is the unavailability of reliable, easily obtainable, and affordable devices for BP measurement, a problem that is likely to become greater as mercury sphygmomanometers are phased out. The problem is exacerbated by the marketing of nonvalidated BP measuring devices, the overall high cost of BP devices given limited resources available, and a shortage of nonphysician health workers trained in the technique of conventional BP measurement. To rectify this major deficit, WHO established a committee in 2003 that had 4 objectives: to draw up technical specifications for an accurate and affordable BP-measuring device for clinical use in LRS, to

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engage manufacturers to develop a device according to these specifications, to ensure the bench accuracy of such devices according to the International Protocol of the European Society of Hypertension (ESH), and to determine the field performance of and the acceptability by healthcare providers and patients of devices fulfilling these criteria in conditions found in LRS. The stages in this process, which were fulfilled by the Omron HEM-SOLAR, are described in this article.

Methods

WHO Technical Specifications for BP Device for LRS

In 2005, the WHO committee drew up detailed technical specifications for automated BP-measuring devices for office/clinic use in LRS.[11,12] Briefly, a device must be nonmercury, manual or automated, solar powered, accurate, and robust; it must also meet recommendations regarding transducers, cuff inflation and deflation, cuff size, visibility of digital display, calibration, environmental requirements, memory function, shock, temperature resistance, and low cost.

Engagement of Manufacturers

The major manufacturers of BP-measuring devices were given the specifications and invited to submit devices fulfilling the criteria. Manufacturers were informed that they would be expected to contribute to the costs of bench validation and field testing of any acceptable devices.

Validation of Devices According to the ESH International Protocol

The ESH International Protocol provides for the comparison of a test device with mercury sphygmomanometric measurements, by 2 trained observers, in 33 subjects, 3 comparisons per subject, and covering a wide range of BPs. The number of measurement differences falling within 5 mm Hg, 10 mm Hg, and 15 mm Hg, as well as the number of subjects with at least 2/3 of these differences and with 0/3 of these differences within 5 mm Hg, were calculated. If the device fulfills the criteria for each of these numbers, it is validated and is recommended for clinical use.[13] Validation studies were carried out in the Centre for Epidemiological Studies and Clinical Trials in Ruijin Hospital, Shanghai, China.

Field Testing and Performance

WHO Field-Test Protocol

The field-test protocol, which was drawn up by the WHO committee, provides for an assessment of the accuracy of devices for BP measurement in the field conditions found in LRS. The Omron HEM-SOLAR, which was selected for this stage, was assessed against a mercury sphygmomanometer at the beginning of the study and again after intensive use over a period of time.

Study Coordination and Data Collection

The study was coordinated by the Conway Institute of Biomolecular and Biomedical Research, University College Dublin, Ireland, by the Cardiovascular Research Laboratory of Istituto Auxologico Italiano, Ospedale San Luca, Milano, Italy, and the Department of Clinical Medicine and Prevention, University of Milano-Bicocca, Milano, Italy. These centers were also responsible for data collection and analysis. All data were stored on a dedicated paper case report form and were subsequently digitized to an electronic database in the Milan centers. The study fulfilled the Institute of Medicine recommendations for cardiovascular-disease research and development in LRS countries.[14] The study was approved by relevant national and local hospital authorities, and each subject gave informed consent.

Field-Test Centers

Three centers in Africa were selected because they had the facilities and expertise to carry out the study and, between them, had catchment areas covering of a range of circumstances that prevail in LRS: The Benedict Medical Center in Luzira, Uganda, is a day hospital and medical center on the outskirts of Kampala that receives referrals from a sizable population often living in extremely poor conditions. Lacor Hospital in Gulu, northern Uganda, is a midsized hospital that receives inpatients and outpatients from rural areas and from small urban centers. Mtendere Hospital in Chirundu, Zambia, is an inpatient hospital that serves the surrounding rural area.

Field-Test Observers

Before commencement of the study, each site was visited by 2 of the authors (GP and MO), who trained 2 observers (physicians or nurses) in the auscultatory technique and in the use of the Omron HEM-SOLAR; they were also instructed in the correct completion of the case report forms. At each center, 2 trained physicians or nurses performed device evaluation and BP measurement, and they also collected clinical and demographic data.

Field-Test Subjects

Patients consecutively attending the centers for various medical problems were recruited after obtaining informed consent and, although formal statistical calculation for sample size was not appropriate, it was anticipated that at least 400 subjects would be recruited. A medical history, including a history of hypertension or treatment of hypertension, and family history were recorded. Physical examination included measurement of weight, height, body mass index, arm and waist circumferences, BP, and heart rate.

In 576 of the initial 700 subjects, BP measurements were recorded twice with the mercury sphygmomanometer and twice with the Omron HEM-SOLAR, after 1 month interval, according to the randomized sequential measurement order described below; heart rate was also recorded both at baseline and at final visit 1 month later.

Environmental Variables

Ambient temperature and humidity of the room in which BP measurements were made were recorded.

Field-Test Device

Omron was the only manufacturer that produced a device fulfilling all the requirements of the WHO committee for BP-measuring devices in LRS.[11,12] The device originally submitted by Omron was the Omron M1 Plus, and when solar power was developed and incorporated in the device, it was renamed the Omron HEM-SOLAR. In accordance with the procedure recommended by the ESH Working Group on Blood Pressure Monitoring, a device that has been modified without altering either the measurement algorithm or the measurement mechanisms must satisfy an equivalence procedure to ensure that the modification has had no effect on its accuracy.[15] This procedure was satisfactorily completed for the Omron HEM-SOLAR device. Two HEM-SOLAR devices were made available at each center with backup devices available if needed.

The Omron HEM-SOLAR is a battery-powered device that records brachial BP oscillometrically with a BP measurement range of 0 to 299 mm Hg, and heart rate range of 40 to 180 beats per minute. Systolic BP (SBP), diastolic BP (DBP), and heart rate are displayed on a liquid crystal display. Inflation is manually operated by pumping the inflation bulb; measurement starts automatically after inflation of the arm cuff has ceased. At the end of the measurement, the air release button is pressed to release remaining air in the arm cuff via an automatic pressure release valve. A standard adult cuff for arm circumferences ranging from 220 to 320 mm is provided. After full solar charge at 23°C and 65% room humidity, the battery is capable of 300 inflations. The Omron HEM-SOLAR can also be powered by electrically rechargeable batteries. The wholesale price of the tested device has been set by the manufacturer at €25 (Figure 1).

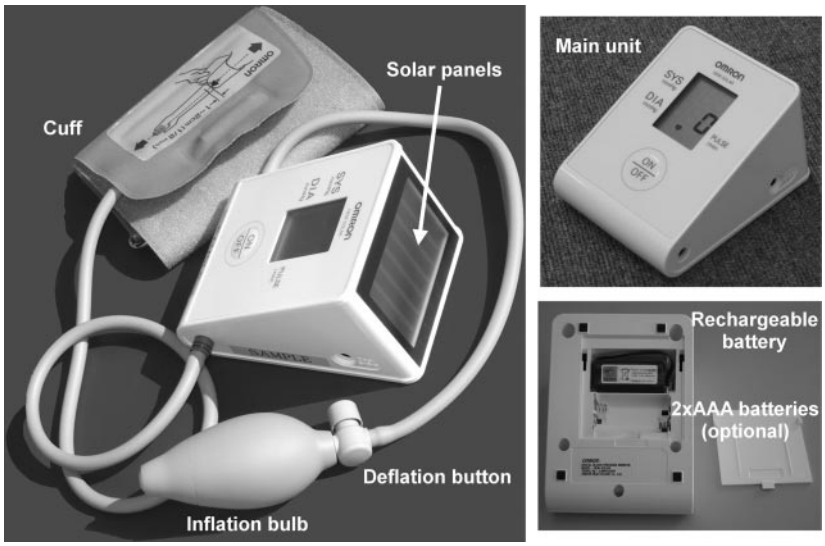

Figure 1. The Omron HEM-SOLAR device.

BP Measurement

Transducer stability of the Omron HEM-SOLAR at baseline and at the end of the study was checked by connecting a mercury sphygmomanometer and the Omron HEM-SOLAR via a Y-tube to a cuff wrapped around a cylinder; then the system was inflated to pressure levels of 0, 50, 100, 150 and 200 mm Hg. BP was measured in both arms with the mercury sphygmomanometer, and the arm with the higher value was used thereafter. In each subject, BP was measured with the Omron HEM-SOLAR and with the mercury sphygmomanometer according to ESH Guidelines.[16] The measurement procedure was as follows: For mercury sphygmomanometer measurements, the cuff was inflated to 30 mm Hg above systolic pressure, palpated at the radial artery, and then deflated at a rate of no more than 2 mm Hg per heart beat (or per second). For Omron HEM-SOLAR measurements, the device was manually inflated (a choice made to save battery power) to 30 mm Hg above systolic pressure, palpated at the radial artery, and then deflated by pressing the deflation button to initiate automatic deflation at a rate of 2 mm Hg per second. BP was measured 4 times within 8 minutes in each subject, twice with the mercury sphygmomanometer (A) and twice with Omron HEM-SOLAR (B); alternating sequences of A-A-B-B and B-B-A-A were used for consecutive patients so that each sequence occurred in 50% of subjects, thus minimizing both time effect and the white coat phenomenon. BP and heart rate measurements were repeated according to the same schedule in subjects who attended the final visit.

Performance of the Omron HEM-SOLAR

The study lasted 6 months in each center and a questionnaire was completed at the beginning and end of the project that investigated details regarding total number of BP measurements made, physical status of the device (intact, deteriorated, broken), and continuing performance (very poor to very good) of the device. The following features were assessed subjectively by healthcare workers via a questionnaire at both the first and final visits. A general rating (very poor to very good) was used to indicate which device was preferred, and which device they would recommend. A 5-point Likert scale rating (1, poor to 5, good) was assigned for each device according to ease of use; patient preference; accuracy; durability; comfort; which features were most liked (automation, size, solar power, ease of use, and time saving); whether the on and off switch worked promptly and/or the device switched off inappropriately; ease and appropriateness of cuff inflation and deflation; clarity of measurement displays; frequency of error messages; and battery longevity.

Statistical Analysis

Comparison between parameters describing the differences between centers was made by ANOVA with Bonferroni post hoc tests. Data from the questionnaire were analyzed using descriptive statistics. Agreement between the Omron HEM-SOLAR and the mercury sphygmomanometer was assessed by calculation of the Cohen's κ coefficient (a value ranging from 0.8 to 1.0 indicates significant agreement). The binary classification test was used to evaluate sensitivity, specificity, and positive and negative predictive values of the Omron HEM-SOLAR as compared with the mercury sphygmomanometer. The McNemar test was used to test comparison between the device evaluation performed at baseline and after 1 month in the 576 subjects. Comparison between the Omron HEM-SOLAR and the mercury sphygmomanometer was made through regression coefficient analysis and Bland-Altman plots.[17] Throughout the study, a $P<0.05$ was used as the minimum level of statistical significance.

Results

Participating Manufacturers

Five manufacturers entered into discussion and 3 manufacturers each submitted a device: the Omron Healthcare Company submitted the M1 Plus (later renamed the Omron HEM-SOLAR); the Microlife Corporation submitted the BP 3AS1-2; and A&D Instruments Ltd, submitted the UA-705.

Validation of Devices According to the International Protocol of the ESH

The Omron M1 Plus (later renamed Omron HEM-SOLAR) fulfilled accuracy criteria of the ESH International Protocol for SBP, but not for DBP. The validation results for the Omron M1 Plus by an earlier validation[18] and the current validation are shown in Table 1. The device fulfilled accuracy criteria for SBP in both validation studies, and it did so for DBP in the first validation, but not in the repeat study. No operational problems were noted during the study. Two other devices tested, the Microlife BP 3AS1–2 and the A&D UA-705, failed to fulfill the criteria of the ESH International Protocol for both SBP and DBP; these devices also developed technical problems during the validation study. Omron completed the equivalence procedure for modified devices,[15] and the Omron HEM-SOLAR is now recommended for clinical use on the http://www.dableducational.org Web site.[19,20]

Table 1. Validation of the Omron M1 Plus

		Phase 2.1				Phase 2.2			
Study	Pressure	n	≤5 mm Hg	≤10 mm Hg	≤15 mm Hg	n	2 or 3/3	0/3	Result
First validation[18]	SBP	99	83	97	99	33	29	0	Pass
	DBP	99	80	93	98	33	27	1	Pass
Second validation	SBP	96	71	88	94	32	27	0	Pass
	DBP	99	46	82	94	33	14	10	Fail

Field Testing and Performance

Field-Test Subjects

Seven-hundred sixteen subjects (age 15–75 years) were recruited after obtaining informed consent. Sixteen subjects were excluded due to data collection violations. Seven hundred subjects, age 35±14 years, who had no violations in data collection at baseline, were included in data analysis. In Uganda, a total of 599 subjects were recruited in the Luzira (464 subjects) and Lacor (135 subjects) centers, while, in Zambia, 117 subjects were recruited at Chirundu hospital. An expanded Results section is available in an online supplement available at http://hyper.ahajournals.org.

BP Measurement

There were no significant differences between the mean SBPs and DBPs recorded by the mercury sphygmomanometer (120.5±21.6/74.6±13.8 mm Hg) and by the Omron HEM-SOLAR (122.3±21.8/71.2±14.0 mm Hg). Twenty percent of subjects were classified as hypertensive (BP≥140/90 mm Hg) with the mercury sphygmomanometer, and 19% were classified as hypertensive with the Omron HEM-SOLAR. The overall between-device agreement in defining the BP status of patients was 94% for systolic BP. Agreement between these approaches was also confirmed by calculation of the Cohen's κ coefficient (κ=0.8, where a value ranging from 0.8 to 1.0 indicates significant agreement).

BP values obtained at baseline in 700 subjects and at final visit in 576 subjects are shown as distribution plots and Bland-Altman plots[17] in Figure 2 for SBP. Plots of DBP are available at http://hyper.ahajournals.org. Agreement between BP values measured by the Omron-HEM-SOLAR device and by the mercury sphygmomanometer was high, particularly for SBP (R2=0.91 for SBP, and 0.77 for DBP at baseline). Linear regression angular coefficients were 0.96 and 0.89,

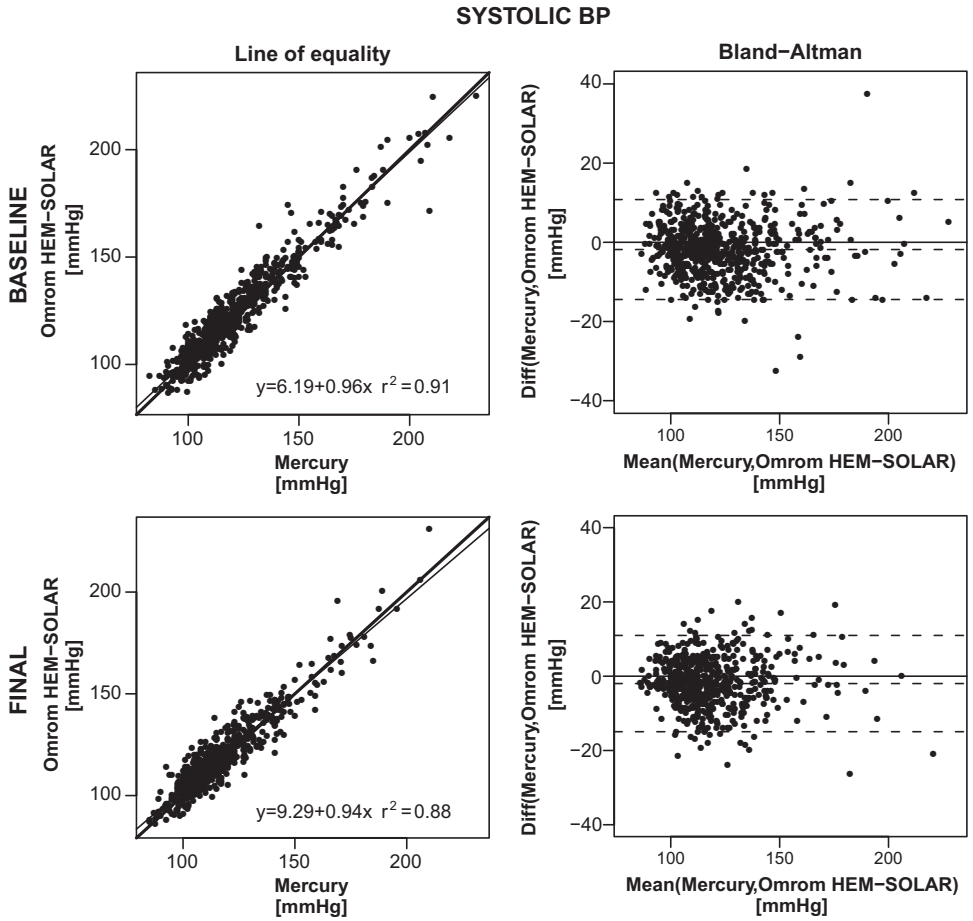

Figure 2. Comparison between the Omron HEM-SOLAR and mercury devices for systolic BP.

Table 2. Comparison of Device Evaluations Given by Healthcare Workers at Baseline and After 1 Month

Appreciation of Omron HEM-SOLAR Features	Baseline (% of 700 Subjects)	Final (% of 576 Subjects)
Features preferred in the Omron HEM-SOLAR		
Automation	85	80
Size	43	44
Solar power	79	81
Easy to use	88	85
Time saving	63	66
Omron HEM-SOLAR performance		
Correct performance switch on/off	98	97
Turning off alone	64 (once 51%)	58 (once 43%)
Correct cuff inflation	97	98
Display clear	98	97
Error message	6	8
Battery replacement	4 (once 4%)	10 (once 10%)
Overall device evaluation		
Omron HEM-SOLAR rated "good" or "very good"	85	95
Omron HEM-SOLAR preferred	95	97
Omron HEM-SOLAR recommended	94	97

respectively; this indicates that the slope of the regression line fitting the values provided by the 2 methods was close to the identify line. Whisker plots showing distribution around the median value (http://hyper.ahajournals.org) are in keeping with the results of regression analysis and with the Bland-Altman plots; these showed similar auscultatory and automated data distribution, particularly for SBP.

Comparison between device assessment at baseline and at final visit in the 576 subjects 1 month later was evaluated by the McNemar test (Table 2). Device evaluation was consistent on both occasions with a nonstatistically significant tendency for the Omron HEM-SOLAR to score better after intensive use than it did at baseline. In the 354 subjects in whom BP measurements were repeated after 2 weeks, the between-method difference in BP levels was similar to that observed at baseline (http://hyper.ahajournals.org).

Performance of the Omron HEM-SOLAR

The general rating of the Omron HEM-SOLAR was marked as "good" or "very good" at baseline by 85% of health workers; it was preferred over the mercury sphygmomanometer in 95% of cases, mainly because of being easy to use (88%), and because of the availability of automated measures (85%). Solar power was considered an advantage by 79% of users (Table 2). The Omron HEM-SOLAR was also rated 5 for comfort by 69% of users, whereas the mercury sphygmomanometer was rated 5 for durability in 30% of cases (Table 3). The Omron HEM-SOLAR display was rated to be clearly legible in 98% of cases, the cuff inflated and deflated appropriately in 97% of cases, and the on/off switch worked correctly in 98% of cases (Table 2).

Device performance evaluation at first and final visits is summarized in Table 2. In summary, at final assessment, 97% of health care users participating in the study favored the Omron HEM-SOLAR device, and when asked to recommend one device over the other, 97% recommended the Omron HEM-SOLAR.

Table 3. Evaluation of Opinion of Healthcare Users on Device Performance and Patient Preference

	Ease of Use		Preference of Patients		Device Accuracy		Device Durability		Device Comfort	
Grade (n=700)	Mercury	Omron HEM-SOLAR	Mercury	Omron HEM-SOLAR	Mercury	Omron HEM-SOLAR	Mercury	Omron HEM-SOLAR	Mercury	Omron HEM-SOLAR
Poor										
1	20	0	18	1	18	1	1	18	19	0
2	1	0	5	1	2	0	1	1	2	0
3	44	0	43	6	29	8	3	2	34	2
4	30	21	21	11	43	20	20	16	36	26
Good										
5	3	77	9	80	5	68	30	7	6	69
No answer	2	2	4	1	3	3	45	56	3	3
Median*	3	5	3	5	3	5	5	4	4	5
Mode	3	5	3	5	4	5	NA	NA	4	5
Mode at final assessment	3	5	3	5	4	5	5†	4†	4	5
% (n=576)	42	74	47	82	41	73	42	32	37	73

All figures are percentages.
Rating from 1 to 5 represents a discrete quantification of users' and/or patients' scores ranging from "poor" (1) to "good" (5).
*Excluding "no answer."
†"No answer" at final assessment: Mercury 29%, Omron HEM-SOLAR 29%.

Discussion

The unsatisfactory control rate of BP worldwide is acknowledged to be one of the major contributing factors of stroke, heart attacks, and heart failure;[1–6] this problem is particularly important in LRS, where detection, monitoring, and control of BP remain inadequate despite a dramatic increase in the prevalence of hypertension. Results from the INTERSTROKE study show that hypertension is the most important risk factor for stroke in developing countries, being accountable for 35% of all strokes.[21] "This finding is particularly relevant because it highlights the need for health authorities in these regions to develop strategies to screen the general population for high blood pressure."[22] This presumes, of course, that a suitable device is available for such screening. Our article addresses an important practical issue that contributes significantly to the failure to detect hypertension and to achieve BP control in LRS, especially in Africa, namely, the unavailability of an accurate, robust, low-cost BP-measuring device suitable for prevailing conditions.

Mercury sphygmomanometers are being phased out of production because of the environmental hazard of mercury.[23] Aneroid sphygmomanometers are often used as replacements but, because these devices become inaccurate with use, they are not recommended.[16] Furthermore, the auscultatory technique requires training in circumstances where the majority of healthcare workers in primary care are not physicians. There is also additional need for a stethoscope, which adds to the total cost of BP measurement. The greatest drawback, however, is that whatever the level of training and quality of the equipment, the auscultatory technique is inaccurate and misleading.[24] Automated devices overcome all these problems provided that the devices are affordable, accurate, and robust.

To our knowledge, we describe for the first time a device that has been designed for the purpose of measuring BP in LRS according to strict criteria drawn up by the WHO.[11,12] The Omron HEM-SOLAR fulfilled bench accuracy criteria of the ESH International Protocol for SBP in 2 studies, and for DBP in 1 study. It performed well during rigorous field-test conditions and was readily acceptable to healthcare workers and patients. In the field-study centers, differences between the mercury sphygmomanometer and the Omron HEM-SOLAR were within the AAMI/ISO recommendations for mean and standard deviations; this confirmed overall accuracy of the device in LRS.[25] Moreover, the Omron HEM-SOLAR, which is affordable at a wholesale cost of €25, is powered primarily by solar energy, but can also use batteries, the energy of which can be conserved by inflating the device manually.

A potential limitation of our study is the selection of the Omron HEM-SOLAR, despite its poorer accuracy for DBP than for SBP. However, the decision to select the device for field testing was justified on 2 counts: first, the device had previously fulfilled accuracy criteria of the ESH International Protocol for both SBP and DBP[18]; second, as SBP is the major contributor to cardiovascular events, especially in LRS, the WHO and the International Society of Hypertension recommendations place more reliance on SBP than on DBP in developing countries.[26]

Our study failed to persuade manufacturers to produce a device costing <€20 as stipulated in the original WHO recommendations.[11,12] We feel justified, however, in allowing a small increase in price because the technology required to provide solar power was not only technically demanding for the manufacturer, it was also expensive. In addition, 7 years have elapsed since the original recommendations, and an allowance for inflation during that time is reasonable. The slightly higher cost is offset by the advantage of having solar power as this greatly increases the capability of measuring BP with an electronic device in LRS where batteries are scarce or are in demand for other devices. Also, the provision of solar energy obviates the need for expensive rechargeable batteries in remote areas where electricity and batteries might be scarce while sunlight is plentiful.

In conclusion, our study provides not only information on field accuracy of the Omron HEM-SOLAR, but also provides very practical data on the usability and durability of a device complying with strict WHO recommendations for the challenging conditions in LRS.

Perspectives

Having identified a serious deficiency in the management of the common condition of hypertension in LRS (namely an inability to measure BP), we provide, for the first time to our knowledge, information on field performance of an accurate, inexpensive, solar powered, automated device that does not require auscultation for BP measurement. The availability of a user-friendly, accurate, and inexpensive device for measuring BP, which does not require observers to be trained in the auscultatory technique, will allow nonphysician health workers (who are the backbone of the primary health care system in rural Africa) to participate in the diagnosis and management of hypertension. It is anticipated that the Omron HEM-SOLAR will help to improve diagnosis and management of hypertension in low- and middle-income countries, and that by achieving better BP control, the global burden of hypertension-related cardiovascular disease will be reduced. We are now embarking on a program to use the device in the diagnosis of hypertension in pregnancy in an effort to reduce the high incidence of maternal mortality in African countries.

Acknowledgements

Appendix

The Appendix, which includes the acknowledgments section, is available in an online supplement available at http://hyper.ahajournals.org.

Sources of Funding

WHO provided €15,795. Three manufacturers, Omron, Microlife, and A&D between them donated €32,990; however, on completion of the study, A&D asked for a refund of €5,500, which was made, leaving a total of €43,285 for the project. The laboratory validation study of 3 devices—Omron M1 Plus, Microlife BP 3AS1–2 and A&D UA-705—was carried out in the Centre for Epidemiological Studies and Clinical Trials, Ruijin Hospital, Shanghai at a cost €13,000. The field testing in Africa was carried out at a cost of €30,992. The study coordinators worked on a voluntary basis for various expenses including travel to Africa and between Italy and Ireland. The remaining €707 was donated by a voluntary contribution.

Disclosures

All authors declare that they have no conflicts of interest.

References

1. Lawes CMM, Vander Hoorn S, Rodgers A for the International Society of Hypertension. Global burden of blood-pressure-related disease, 2001. *Lancet*. 2008;371:1513–1518.
2. Mendis S, Abegunde D, Oladapo O, Celletti F, Nordet P. Barriers to management of cardiovascular risk in a low resource setting using hypertension as an entry point. *J Hypertens*. 2004;22:59–64.
3. Lawes CMM, Vander Hoorn S, Law MR, Elliott P, MacMahon S, Rodgers A. Blood pressure and the global burden of disease 2000. Part II: Estimates of attributable burden. *J Hypertens*. 2006;24:423–430.
4. Kearney PM, Whelton M, Reynolds K, Whelton PK, He J. Worldwide prevalence of hypertension: a systematic review. *J Hypertens*. 2004;22:11–19.
5. Lopez DA, Mathers CD, Ezzati M, Jamison DT, Murray JL. Global and regional burden of disease and risk factors 2001: systematic analysis of population health data. *Lancet*. 2006;367:1747–1757.
6. Gaziano TA, Bitton A, Shuchi A, Weinstein MC for the International Society of Hypertension. The global cost of nonoptimal blood pressure. *J Hypertens*. 2009;27:1472–1477.
7. B. Collins R, Peto R, MacMahon S, Hebert P, Fiebach NH, Eberlein KA. Blood pressure, stroke, and coronary heart disease. Part 2: Short-term reductions in blood pressure: overview of randomized drug trials in their epidemiological context. *Lancet*. 1990;335:827–838.
8. World Health Organization. WHO CVD-Risk Management Package for low- and medium resource settings. Geneva: WHO; 2002.
9. Walker RW, McLarty DG, Kitange HM, Whiting D, Masuki G, Mtasiwa DM, Machibya H, Unwin N, Alberti KG. Stroke mortality in urban and rural Tanzania. Adult Morbidity and Mortality Project. *Lancet*. 2000;355:1684–1167.
10. Whitworth JA; World Health Organization, International Society of Hypertension Writing Group 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. *J Hypertens*. 2003;21:1983–1992.
11. Parati G, Mendis S, Abegunde D, Asmar R, Mieke S, Murray A, Shengelia B, Steenvoorden G, Van Montfrans G, O'Brien E. Recommendations for blood pressure measuring devices for office/clinic use in low resource setting. *Blood Press Monit*. 2005;10:3–10.
12. Affordable technology: blood pressure measuring devices for low-resource settings. Geneva, World Health Organization, 2005.
13. O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, Mengden T, Imai Y, Waeber B, Palatini P with the statistical assistance of Atkins N and Gerin W 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.
14. Howson CP, Reddy KS, Ryan TJ, Bale JR. Editors, Committee on Research, Development, and Institutional Strengthening for Control of Cardiovascular Diseases in Developing Countries, Institute of Medicine. Control of Cardiovascular Diseases in Developing Countries: Research, Development, and Institutional Strengthening. http://www.nap.edu/catalog/6218.html. National Academy Press, Washington, D.C. 1998; 1–104.
15. Atkins N, O'Brien E. The dabl®Educational Trust device equivalence procedure. *Blood Press Monit*. 2007;12:245–249.
16. O'Brien E, Asmar R, Beilin L, Imai Y, Mallion J-M, Mancia G, Mengden T, Myers M, Padfield P, Palatini P, Parati G, Pickering T, Redon J, Staessen J, Stergiou G, Verdecchia P on behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. *J Hypertens*. 2003; 21:821–848.
17. Bland JM, Altman DG. Measuring agreement in method comparison studies. *Stat Methods Med Res*. 1999;8:135–160.
18. Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG. Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension. *Vasc Health Risk Manag*. 2007;3:389–400.
19. O'Brien E. A website for blood pressure measuring devices: dableducational.com. *Blood Press Monit*. 2003;8:177–180.
20. dabl®Educational Trust [Online]. 2009 [cited 2009 Oct 29];[8 screens] Available from: URL: http://www.dableducational.org/sphygmomanometers.html.
21. O'Donnell MJ, Xavier D, Liu L, Zhang H, Chin SL, Rao-Melacini P, Rangarajan S, Islam S, Pais P, McQueen MJ, Mondo C, Damasceno A, Lopez-Jaramillo P, Hankey GJ, Dans AL, Yusoff K, Truelsen T, Diener H-C, Sacco RL, Ryglewicz D, Czlonkowska A, Weimar C, Wang X, Yusuf S, on behalf of the INTERSTROKE investigators. Risk factors for ischaemic and intracerebral haemorrhagic stroke in 22 countries (the INTERSTROKE study): a case-control study. *Lancet*. 2010;376:112–123.
22. Tu JV. Reducing the global burden of stroke: INTERSTROKE. *Lancet*. 2010;376:74–75.
23. O'Brien E. Replacing the mercury sphygmomanometer. *BMJ*. 2000;320:815–816.
24. O'Brien E. Whither conventional blood pressure measurement? *Am J Hypertens*. 2006;19:659.
25. ANSI/AAMI/ISO 81060–2:2009 (Revision of SP10:2002 and Amendment 1:2003 and Amendment 2:2006) Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. Association for the Advancement of Medical Instrumentation 1110 N. Glebe Road, Suite 220 Arlington, VA 22201-4795 www.aami.org.
26. Mendis S, Lindholm LH, Mancia G, Whitworth J, Alderman M, Lim S, Heagerty T. World Health Organization (WHO) and International Society of Hypertension (ISH) risk prediction charts: assessment of cardiovascular risk for prevention and control of cardiovascular disease in low and middle-income countries. *J Hypertens*. 2007;25:1578–1582.

ONLINE SUPPLEMENT

A new solar powered blood pressure measuring device for low resource settings

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Appendix

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Disclaimer: The views expressed in this paper are solely the responsibility of the authors and do not necessarily reflect the decisions or stated policy of the World Health Organization or its Member States.

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Subject characteristics:

Of the 700 subjects, 409 (58%) were female; average body mass index (BMI) was 24.6 ± 5 kg/m^2 and average arm circumference was 28.2 ± 4.4 cm, each with significant between-centre differences . Average waist circumference was 85.6 ± 12.5 cm and average heart rate was and 74.6 ± 11.6 beats/min. The physical characteristics of the three study populations are summarised in Table S1.

Environmental variables:

Recommended operating temperatures for the Omron HEM-SOLAR are 10 °C to 40 °C with 30% to 85% relative humidity. Mean ambient temperature was 25.6 ± 3.5 °C, 27.2 ± 7.1 °C and 29.8 ± 2.5 °C in Kampala, Gulu and Chirundu, respectively. The corresponding ambient relative humidity was around 72.4 ± 10.2% in Uganda and 37.3 ± 3.6% in Zambia, being in most cases, within the ranges recommended by the manufacturer for proper performance of the tested device.

Sub group analysis:

In a subgroup of 354 subjects continuing to attend the study centres at weekly intervals for follow-up of various medical conditions had BP measurements recorded twice with the mercury sphygmomanometer and twice with the Omron HEM-SOLAR after two weeks according to the randomized sequential measurement order described and heart rate was also recorded. In the these subjects the between-method difference in BP levels was similar to that observed at baseline.

Distribution and Whisker Plots:

Figure S1 shows the distribution plots for systolic and diastolic BP values and Figure S2 compares systolic and diastolic BP values obtained with auscultatory measurements and with the Omron HEM-Solar device using box and whisker plots to show the distribution around the median value. In keeping with the results of regression analysis and with the Bland-Altman plots, an acceptable degree of between-method correspondence is documented showing a similar auscultatory and automated data distribution, particularly for systolic BP.

Table S1. Physical characteristics of the study populations

Study centres	Body Mass Index (kg/m^2)		Arm Circumference (cm)		Waist Circumference (cm)	
	Mean	SD	Mean	SD	Mean	SD
All centres	24.6	5.0	28.1	4.4	85.6	12.5
Kampala, Uganda	25.1	5.2	28.3	4.2	86.0	13.1
Lacor, Gulu, Uganda	23.9	4.6	28.5	5.7	85.7	12.3
Chirundu, Zambia	23.1	4.5	27.0	2.9	84.1	10.1
t-Test with Bonferroni, p	<0.01*; =0.054°		<0.01*°; <0.05°		NS	

ANOVA demonstrated a significant between-centre difference in these parameters with a post-hoc comparison demonstrating significant between centre differences in BMI ($p < 0.001$) and in arm circumference ($p < 0.01$). p values: * Chirundu vs Kampala; ° Chirundu vs Gulu

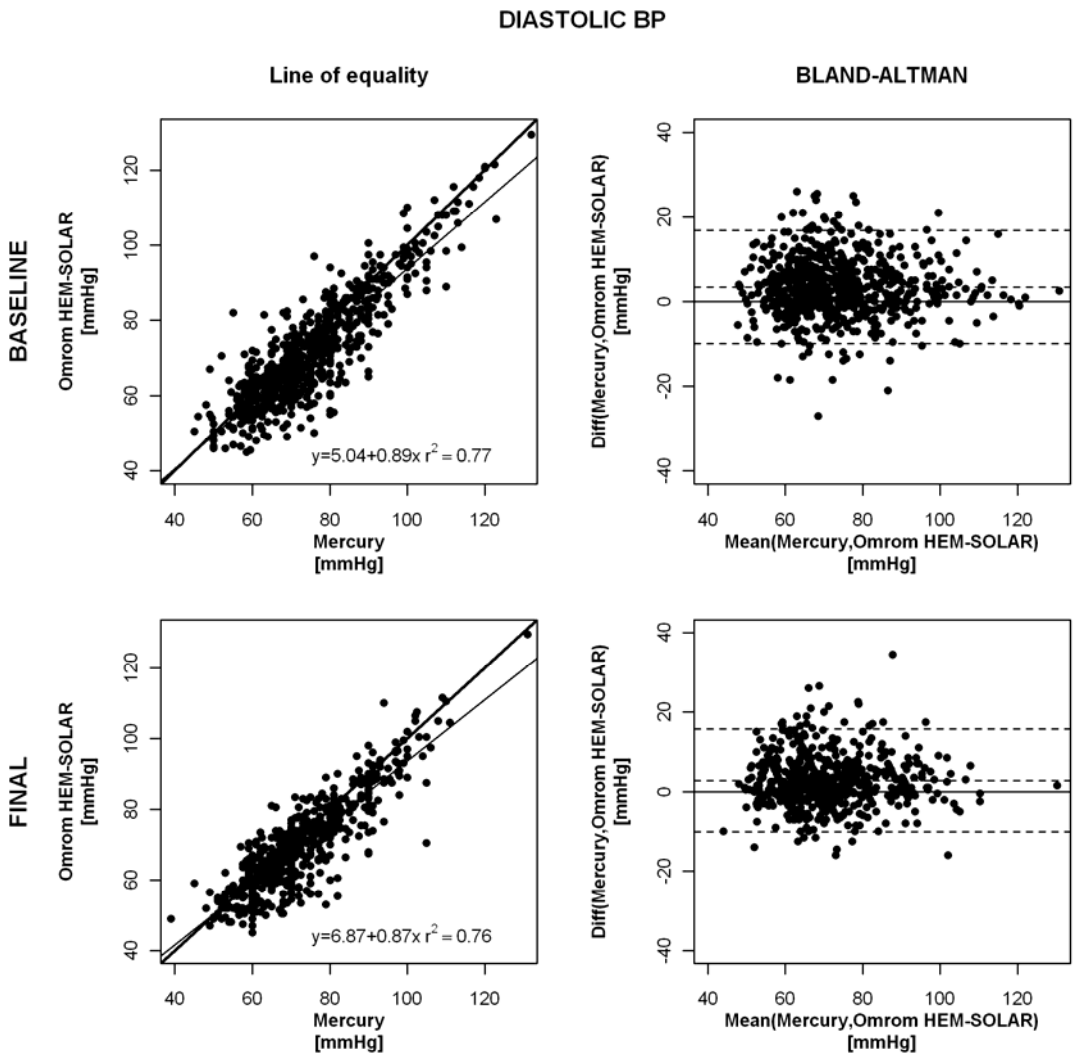

Figure S1. Comparison between the Omron HEM-SOLAR and mercury devices for diastolic (BP) blood pressure

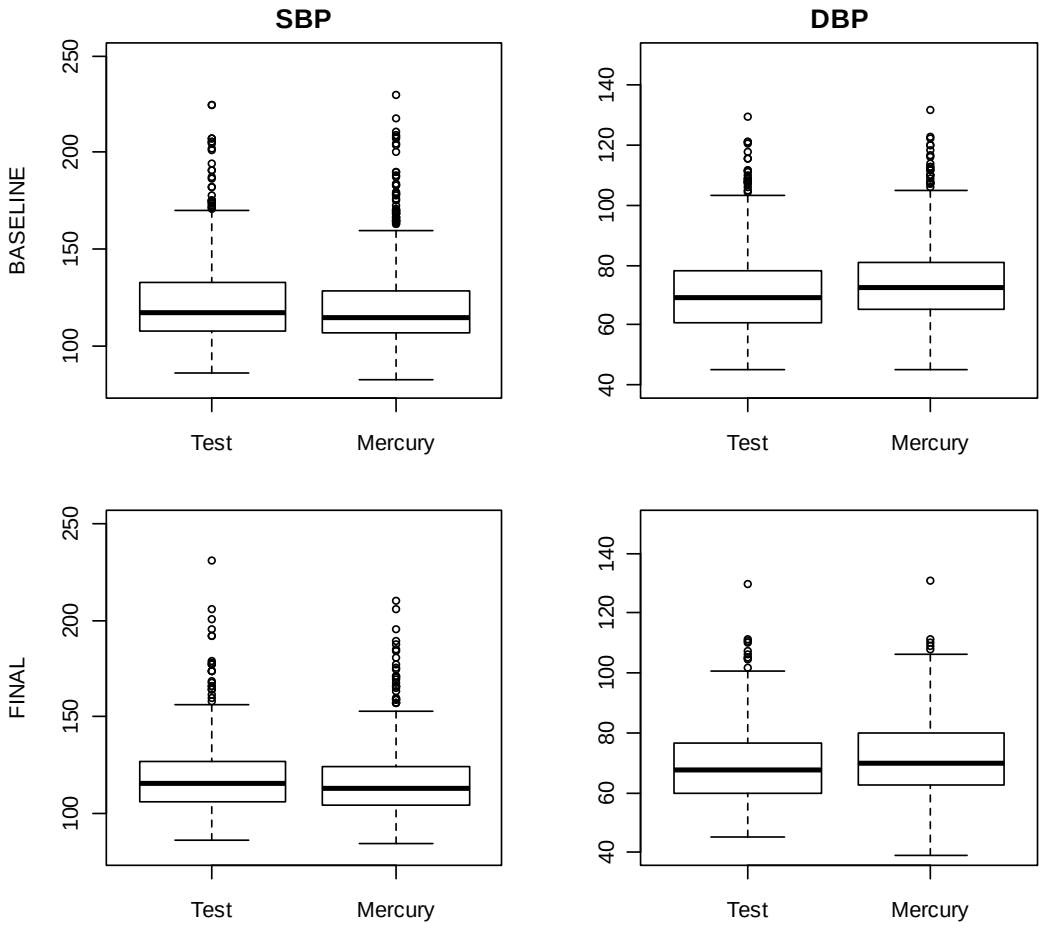

Figure S2. Box and whiskers plots representing the data obtained with auscultatory (mercury) and automated (test) readings, respectively. The thick horizontal line in each box is the median value of the distribution. The upper and lower box limits represent the lower and upper quartile value respectively (interquartile range, IQR). The vertical lines extending from each end of the box are called whiskers. The ends of the whiskers represent the lowest and highest values still included within 1.5 of the IQR, for the lower and the upper quartile respectively. Individual symbols beyond the ends of the whiskers represent outliers, i.e. values beyond 1.5 times the IQR.