Automated Office Blood Pressure—Incorporating SPRINT Into Clinical Practice

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The Systolic Blood Pressure Intervention Trial (SPRINT) used the automated office blood pressure (AOBP) technique for determining the BP status of patients, including BP criteria for enrollment and the BP target for treatment. Following the publication of the results of SPRINT, there has been considerable discussion about how to incorporate the findings in SPRINT to the management of hypertension in clinical practice. Most of the research into AOBP has been conducted in Canada using the automated BpTRU sphygmanometer (BpTRU Medical Devices, Coquitlam, BC, Canada), which is similar to the Omron 907XL device (Omron Healthcare, Lake Forest, IL) used to record AOBP in SPRINT. The Canadian hypertension guidelines first recommended AOBP for BP measurement in 2011, with AOBP now being the preferred method for recording BP in the office. In contrast, AOBP is rarely used in routine clinical practice in the United States. This article will review the current use of electronic, oscillometric sphygmomanometers for office BP measurement, including the evidence supporting the use of AOBP devices in routine clinical practice.

DIFFERENT OPTIONS FOR AOBP MEASUREMENT

There are 3 basic requirements for AOBP readings. BP must be recorded with a fully automated, electronic sphygmomanometer which takes multiple readings with the patient resting alone and undisturbed in a quiet place. Initially, AOBP recordings were taken with patients being alone in an examining room. However, subsequent research showed that valid AOBP readings could be taken in an office waiting room or in a community pharmacy, provided that the patient is sitting alone, resting quietly and is not disturbed.

The BpTRU records an initial ‘test’ reading and then automatically records 5 readings, usually 1 or 2 minutes apart, timed from the start of 1 reading to the start of the next one. The Omron 907XL can be set to take 2 or 3 readings, usually at 1- or 2-minute intervals, after zero, 3 or 5 minutes of antecedent rest. In SPRINT, 3 readings were taken at 1-minute intervals after a 5-minute period of rest, with the device timing the interval between the readings from the end of one reading to the start of the next one.

Both the Omron 907XL and the BpTRU have been validated for accuracy independent of the manufacturer in accordance with standard criteria. A number of studies have been performed in a variety of settings comparing AOBP recorded using the BpTRU with the awake ambulatory BP. The mean BP values using these 2 methods were virtually identical. Although the Omron 907XL has not as yet been compared to the awake ambulatory BP, its readings have been compared to those taken using the BpTRU.

In 50 patients referred for 24-hour ambulatory BP monitoring (ABPM), mean AOBP recorded with the BpTRU set to take 5 readings at 1-minute intervals (139/74 mm Hg) was similar to the mean AOBP taken with the Omron 907XL set to take 3 readings at 1-minute intervals (141/73 mm Hg). There was also a strong correlation for systolic/diastolic BP between the 2 sets of readings (r = 0.78/0.81). Neither set of readings was preceded by a period of rest. In a parallel study, 50 patients had 5 BpTRU readings taken at 2-minute intervals after a 5-minute period of rest vs. 3 Omron 907XL readings taken at 2-minute intervals after a 5-minute period of rest (the method used in SPRINT). The mean BP recorded was 132/78 mm Hg compared to 132/73 mm Hg for the Omron 907XL with the individual systolic/diastolic BP readings exhibiting a strong correlation for the 2 methods of measurement (r = 0.87/0.88). In other studies comparing Omron 907XL BP readings with standardized manual BP readings recorded with a mercury sphygmomanometer, the Omron device has tended to record the diastolic BP several mm Hg lower. For example, in a validation study conducted by White and Anwar, in 100 subjects, the Omron 907 recorded BP 1.6/4.6 mm Hg lower than a standardized manual BP taken with a mercury sphygmomanometer. Similarly, in validating this device, El Assaad et al. found the diastolic BP to be 5 mm Hg lower than the mercury sphygmomanometer, whereas the systolic BP readings only differed by 1 mm Hg. One exception is a study by Davis et al.
who found that the Omron 907XL recorded diastolic BP 4 mm Hg higher than the mercury sphygomanometer in women who were hypertensive during pregnancy.

This aspect of the Omron 907XL has obvious implications for using this device in routine clinical practice. In an older population such as the participants in SPRINT, the systolic BP is of paramount importance with a slightly lower diastolic BP being of less concern. However, if the Omron 907XL is to be used for the diagnosis of hypertension in younger subjects, then having an accurate diastolic BP becomes more important. The BpTRU does not have this limitation and neither does another AOBP device validated for accuracy,16 the WatchBP Office (Microlife AG, Widnau, Switzerland), marketed in the United States and Canada as the PRO BP2400 (Welch-Allyn, Skaneateles Falls, NY). This latter device is capable of taking an AOBP reading based upon 3 readings recorded at 1-minute intervals with a 1-minute delay before the first reading is taken. The BpTRU or WatchBP Office could be substituted for the Omron 907XL, if there is concern about the accuracy of the latter device for diastolic BP. Thus, the debate over using AOBP in clinical practice should not be device specific and is not limited to the Omron 907XL.

PRACTICAL ASPECTS OF AOBP IN CLINICAL PRACTICE

AOBP has a number of advantages over conventional manual office BP measurement. AOBP is not subject to the white coat effect and provides more accurate and standardized readings. Mean manual BP recorded in routine clinical practice averages 16/7 mm Hg higher than the mean AOBP, with the latter being similar to the awake ambulatory and home BP.17 Overall, the improved accuracy of AOBP over manual BP is due to limited involvement of the human factor in the measurement process and the use of multiple BP readings.18

In SPRINT, the mean AOBP at entry was 139.7/78.2 mm Hg with 90.6% of subjects receiving antihypertensive drug therapy. In 10 comparative studies19 in different settings and in both treated and untreated patients, the mean AOBP using the BpTRU (136.5/78.7 mm Hg) was similar to the mean awake ambulatory BP (137.3/79.0 mm Hg). Thus, the evidence supporting AOBP as being similar to the awake ambulatory BP, a gold standard for BP measurement, should also apply to the baseline AOBP in the SPRINT study population.

Unfortunately, there are no comparative data using the AOBP protocol in SPRINT, aside from the study noted above9 with the BpTRU as the comparator. However, there has recently been a preliminary report on an ABPM substudy performed in 876 participants in SPRINT.20 At 27 months, the daytime systolic BP in the Intensive and Standard Treatment groups was 126.5 and 138.5 mm Hg, respectively, whereas the corresponding AOBP readings were 119.6 and 135.5 mm Hg. The lower value for AOBP, especially in the Intensive Treatment group, has raised concerns about how the measurements in SPRINT can be applied to clinical practice. However, there are data using the BpTRU which may explain the lower AOBP findings. In a study21 involving 300 patients referred for 24-hour ABPM, mean AOBP using the BpTRU set to take readings at 1-minute intervals in the 161 individuals who were normotensive was 123/76 mm Hg compared to a mean awake ambulatory BP of 132/78 mm Hg. In contrast, mean AOBP in the remaining 139 hypertensive subjects was 141/82 mm Hg compared to a mean awake ambulatory BP of 142/81 mm Hg. In a population survey in Ontario, Canada,22 mean AOBP using the BpTRU device in a random sample of 238 subjects was 115/71 mm Hg compared to 118/74 mm Hg for readings recorded with a mercury sphygomanometer.

These studies in normotensive subjects, including a population sample derived from a randomized clinical trial, referrals for 24-hour ABPM, and a random population sample in the community, exhibited somewhat different relationships between AOBP and the awake ambulatory BP. It should be noted that AOBP eliminates the white coat component associated with conventional office BP measurement. Subjects who are very normotensive, such as in the Intensive Treatment group in SPRINT and patients referred for 24-hour ABPM, may have variable degrees of white coat effect and, under different circumstances, may respond in different ways to the conditions of AOBP. Regardless, the AOBP and ABPM values recorded in the Intensive Treatment group in SPRINT were associated with a significant benefit in terms of fewer cardiovascular events, compared to the Standard Treatment group. Moreover, antihypertensive therapy was adjusted according to AOBP and not ABPM.

USING SEMIAUTOMATED ELECTRONIC PHYGMOMANOMETERS INSTEAD OF AOBP

The first attempt to apply the AOBP technique occurred several years before fully automated electronic devices were available. In this study,23 BP was recorded in duplicate after 5 minutes of rest in 27 hypertensive patients who activated an Omron IC home sphygomanometer while seated alone in an examining room. The mean Omron IC reading was 157/83 mm Hg compared to a mean awake ambulatory BP of 145/78 mm Hg.

In a study involving 30 treated hypertensives, Stergiou et al.24 compared 3 home BP readings with 3 readings recorded by the patient in the physician’s office, both using an Omron 705CP, manually activated, electronic sphygmomanometer. The self-recorded mean office BP was 9.3/4.9 mm Hg higher than the mean home BP.

In the previously mentioned study involving 139 hypertensive patients,21 mean office BP was recorded 5 times at 1-minute intervals using a validated home BP device with the subjects activating the device while resting alone in an examining room. The mean BP was 146/86 mm Hg compared to 142/81 mm Hg for the awake ambulatory BP.

Finally, Al-Karkhi et al.25 had 162 subjects perform self-measurement of BP with an Omron IC-10 recorder while sitting alone in an office examining room, with readings taken after 5 minutes of rest in triplicate, 1-minute apart, after an initial activation of the device by the patient. Mean self-measured office BP was 138.0/85.9 mm Hg compared to the mean self-measured BP recorded in triplicate at home using the same device (131.0/81.7 mm Hg).

These studies demonstrate that self-measurement of BP in the office using a device designed for use in the home produces readings which are not comparable to AOBP readings, which are similar to the awake ambulatory and home BP. Furthermore, there is no standardized method
for self-measurement of BP in the office setting and sphygmomanometers designed for home use are unlikely to be sufficiently durable to provide sustained, accurate office BP readings.

AOBP IN THE POST-SPRINT ERA

There is no perfect method for measuring BP to diagnose hypertension. Under different circumstances, different techniques will produce different readings. One factor which can affect BP readings is the extent of human involvement.\textsuperscript{18} The 24-hour ambulatory BP, which involves the least involvement of patients or medical staff, is now considered to be the gold standard for evaluating an individual’s BP status, since there is more evidence favoring ABPM as the best predictor of future cardiovascular events than any other BP measurement technique. There is now general agreement that patients being evaluated for possible hypertension should undergo 24-hour ABPM, whenever feasible.

As with ABPM, the AOBP involves less human involvement in recording BP than do the other methods of recording BP in the office. The mercury sphygmomanometer is in the process of being eliminated because of environmental concerns, whereas aneroid devices continue to be used, despite concerns about their accuracy due to infrequent recalibration. Given that manual office BP is about 10/6 mm Hg higher than a ‘guidelines quality’ manual BP recorded in research studies,\textsuperscript{19} the continued use of conventional office BP measurement could require that the cut-point for defining hypertension be increased to 150/95 mm Hg. However, electronic sphygmomanometers designed for use in the home have not been evaluated in clinical practice and are not designed for professional use. In contrast, there are at least 3 validated devices specifically designed for AOBP measurement, the BpTRU, the Omron 907XL, and the WatchBP Office (PRO BP2400). Moreover, the cut-point for defining hypertension using AOBP (135/85 mm Hg), based upon both comparative BP studies\textsuperscript{a} and cardiovascular outcome data,\textsuperscript{a,10} is the same as the cut-point for home and awake ambulatory BP. When it comes to office BP, the convincing results of SPRINT virtually mandate that AOBP be considered the method of choice for office BP measurement.

The overwhelming evidence favors replacing current office BP measurement, the BpTRU, the Omron 907XL, and the WatchBP Office (PRO BP2400). Moreover, the cut-point for defining hypertension using AOBP (135/85 mm Hg), based upon both comparative BP studies\textsuperscript{a} and cardiovascular outcome data,\textsuperscript{a,10} is the same as the cut-point for home and awake ambulatory BP. When it comes to office BP, the convincing results of SPRINT virtually mandate that AOBP be considered the method of choice for office BP measurement.

The Canadian experience\textsuperscript{6} demonstrates that it is possible to respond to new scientific evidence by adopting not only AOBP, but also home BP and 24-hour ABPM for the diagnosis and management of hypertension. The limited availability of new technology for sphygmomanometry in affluent countries should not be a reason for not promoting for patients this new and more accurate technology of blood pressure measurement.

REFERENCES


DISCLOSURE

The author declared no conflict of interest.
Commentary