Dual Monitor Protocol Comparing the Accuracy of the Oscar 2 & Spacelabs 90207 24-hr Ambulatory Blood Pressure Monitors

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Background
We developed a Dual Monitor Protocol with lab postural challenges to study the accuracy and reliability of ambulatory blood pressure monitors (ABPMs). First, we studied the Accutrack II ABPM (SunTech Medical) and determined in normotensives (n=29), hypertensives (n=12), and alcohol-dependent (n=11) that the monitor significantly underestimated shifts in diastolic pressure (DBP) and had the most problems with standing DBPs. When we used differences between mercury (Hg) column and ABPM systolic in the same arm measurements in the lab to correct for 24-hr DBPs, we found that several patients were misclassified. SunTech Medical discontinued manufacturing the auscultatory Accutrack II in 2010. Here we present our initial studies examining the accuracy and reliability of two oscillometric ABPMs, the Oscar 2 (SunTech Medical) and the Spacelabs 90207 (Spacelabs Healthcare).

Hypotheses
Ultimately, proprietary equations developed for oscillometric ABPMs were derived using auscultatory techniques. Constant pulse pressure assumptions or static equations cannot be applied to dynamic populations. Though mean arterial pressure (MAP) corresponds to the peak palpable pressure in the cuff, it is extremely difficult to project outward from MAP to estimate pressures, especially DBP 1. Thus, we predicted that oscillometric ABPMs also would have difficulties assessing DBP 2 and/or exhibit a “flashlight effect” with phase-shift inaccuracies at either the systolic-DBP or diastolic-end of the continuum.

Methods
Hypertensive subjects were randomized to Oscar 2 and Spacelabs 90207 ABPMs to record simultaneous, opposite arm BP for 24 hr in a hypertensive male (62 yr). Clocks were synchronized and cuffs were switched every 2-3 hr during waking hr. In the lab, observers assessed simultaneous same arm BP for both ABPMs using an Hg column and Telephon stethoscope with a second-generation ambient noise rejection and headout output. ABPMs recorded simultaneous opposite arm BP interspersed with Hg column measurements. To develop corrections factors for the 24-hr monitoring, all lab measurements were made in triplicate and differences were calculated between observers’ Hg column mean values and each ABPM’s mean value for supine, seated and standing postures. In attempt to examine extreme ends of the pressure continuum, we also used two Spacelabs ABPMs to assess simultaneous and sequential same and opposite arm pressures in a hypertensive male (52 yr) and a single Spacelabs ABPM to assess non-dominant arm pressures in a normotensive male (21 yr). Correction factors established in the lab were applied to 24-hr data.

Results

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Discussion
1. If patients do not match the subject sample used to develop specific nomogram-like prediction equations and/or have widely varying pulse pressure magnitudes, misclassification may be inappropriate for ABPMs diagnosed by 24-hr ABPMs. A flash effect or bias in oscillometric and/or auscultatory techniques observed especially with SBPs at either end of the continuum. DBPs and SBPs may be inconsistent and unpredictable depending on monitor used and patient’s pressure ranges, postures and activity levels.

2. Initial data implies that the Oscar II and Spacelabs ABPM equations were developed on subjects who were seated. This may be responsible for the significant ABPM measurement errors associated with all monitors using an Hg column in the lab. As with the auscultatory ABPM, standing DBPs may be problematic with hypertensives and subjects with normal pressures. Spacelabs proprietary equations developed from a single posture cannot be applied over an entire 24-hr monitoring period when patients move about and assume a variable % distribution of postures.

3. Though we have examined only a few subjects with oscillometric monitors, these limited data do provide compelling evidence that ABPM estimations may be poor and unpredictable depending upon the specific monitor and patient circumstances.

4. Prediction equations will not improve unless ABPMs can (a) detect unique postures and movements and (b) be designed and calibrated to make sensitivity adjustments based on known variations in K-sound and oscillometric-pulse magnitudes that occur with changes in posture and activity. Both the Oscar and Spacelabs ABPMs exhibit run-away inflations with simple movements like walking or stair climbing. It is likely that motion artifacts are interpreted by ABPMs as systolic peaks achieving postural pressures. These continuous inflations may be startling and at times painful for subjects.

5. The American Association for the Advancement of Medical Instrumentation (AAMI) and the European Society of Hypertension (ESH International) protocols must require ABPM validation for a variety of postures and activity levels. Additionally, manufacturers should be required to include exact descriptions of age ranges, genders, races and ethnicities examined in developing their proprietary equations. Until these basic steps become mandatory, ABPMs may provide inaccurate measurements that lead to misclassification, inappropriate and disorganized mismanagement of patients.

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