Evaluation of Noninvasive Blood Pressure Monitoring Devices Spacelabs 90202 and 90207 Versus Resting and Ambulatory 24-Hour Intra-arterial Blood Pressure

Antonella Groppelli, Stefano Omboni, Gianfranco Parati, and Giuseppe Mancia

This study evaluated the accuracy of blood pressure values provided by the Spacelabs 90202 and 90207 devices in comparison with intra-arterial recording in 19 subjects at rest and in nine subjects in ambulatory conditions (Oxford method). At rest Spacelabs monitors reflected intra-arterial systolic blood pressure values very closely but overestimated to a considerable extent intra-arterial diastolic blood pressure (Spacelabs-intra-arterial differences, -0.8±9.2, NS, and 9.1 ±8.8 mm Hg, p<0.01, for systolic and diastolic blood pressures, respectively). In ambulatory conditions Spacelabs-intra-arterial average differences in 24-hour values were +0.4±5.1 mm Hg for systolic blood pressure (NS) and +14.0±2.9 mm Hg for diastolic blood pressure (p<0.01) when group data were considered. The performance of both Spacelabs devices was worse when assessed in individual subjects or for each hourly interval. In spite of these differences between noninvasive and intra-arterial absolute blood pressure values, however, Spacelabs 90202 and 90207 monitors were able to faithfully reflect directional hour-to-hour changes in intra-arterial blood pressure (x²=18.2 and x²=23.1 for systolic and diastolic blood pressures, respectively, p<0.01). No differences were found between the performance of the two Spacelabs devices. Thus, although the absolute accuracy of blood pressure values provided by these monitors in ambulatory subjects is still limited, they seem to be suitable for studies aimed at assessing 24-hour blood pressure profiles quantitatively as well as qualitatively.

KEY WORDS • blood pressure monitors • blood pressure measurement • 24-hour blood pressure profiles • ambulatory blood pressure monitoring

The Spacelabs 90202 and 90207 are widely used devices for measuring ambulatory blood pressure. To date, however, validation of these devices has been obtained by comparison with sphygmomanometric blood pressure at rest. Furthermore, comparison with intra-arterial blood pressure has been limited to rest and physical exercise in laboratory conditions with no information on the device performance during a 24-hour monitoring period.

Methods

Subjects

Our study included 21 inpatients with mild or moderate essential hypertension (19 men, two women) whose mean age±SEM was 41.1±3.1 years (range, 17–60 years). The patients had discontinued antihypertensive treatment for at least 10 days. Criteria for enrollment in the study were: 1) arm circumference less than 33 cm, 2) between-arm difference in mean blood pressure 5 mm Hg or less when simultaneously assessed by two trained operators using two cuffs connected to a single mercury column via a Y tubing, and 3) 24-hour blood pressure recording that was required because of a history of pronounced variations in blood pressure. All patients gave informed consent to the study, which was approved by the ethical committee of our institution.

Blood Pressure Measurements at Rest

In 19 subjects, who were resting in the supine position, blood pressure was measured simultaneously by an intra-arterial line and by the noninvasive Spacelabs 90202 or 90207 devices (Spacelabs Inc., Redmond, Wash.). The intra-arterial measurements were obtained by a thin catheter (11 cm length, 1.3 mm i.d.) percutaneously introduced by the Seldinger technique into the brachial artery of the nondominant arm with previous local anesthesia with 2% lidocaine. A rigid polyethylene tube connected the catheter to a model P23ID transducer (Statham Division, Gould Inc., Oxnard, Calif.) positioned at the patients' bedside approximately at the level of the heart. The intra-arterial signal was displayed on a stripchart polygraph (model 7D, Grass Instruments Co., Quincy, Mass.) operated at a speed of 50 or 100 mm/min.

The noninvasive devices employed in the present study use identical oscillometric criteria, and the only difference is that compared with the 90202 model, the
Blood Pressure Measurements in Ambulatory Conditions

In nine subjects 24-hour blood pressure monitoring was performed simultaneously by the intra-arterial Oxford method and by the Spacelabs 90207 (five subjects) or 90207 (four subjects) devices. To perform the 24-hour intra-arterial monitoring, the catheter used for measuring intra-arterial blood pressure in the resting condition (see above) was connected, via a rigid-walled polyethylene tube, to an Oxford transducing-perfusing unit contained in a Plexiglas box fastened to the subjects' thorax at heart level. The blood pressure signal was sent to an amplifier and then stored on a magnetic tape cassette fastened to the subjects' waist. As in previous studies, the system had a frequency response of -3 db at 8–10 Hz. Furthermore, when calibrated against a mercury column before and after the 24-hour recording, the system showed no substantial drift in the zero signal; it also showed a linear response to a calibration signal between 50 and 250 mm Hg both before and after the recording period. Other details of the Oxford method have been reported previously.

To perform the 24-hour noninvasive monitoring, the Spacelabs device was set to provide measurements at 10-minute intervals from 6 AM to midnight and at 20-minute intervals from midnight to 6 AM. In each subject the proper positioning of the cuff was ensured by the similarity (difference of less than 5 mm Hg) between three Spacelabs blood pressure measurements and three auscultatory readings simultaneously obtained either before or after the 24-hour recording.

Both the intra-arterial and the noninvasive recordings were started at 7 PM. During the recording period, the subjects were free to move within the hospital area and to engage in the social activities of the hospital patients (watching TV, visiting with relatives, playing cards, walking within the hospital area). They were only asked to comply with hospital meal and bed times and to remain with their arm still during the automatic blood pressure measurements.

Data Analysis

The resting systolic and diastolic blood pressure measurements provided by the Spacelabs devices were stored in a RAM memory pack and sent to a PC computer (Olivetti M380-XP1, Olivetti & C, Ivrea, Italy). Because Spacelabs monitors do not provide an analog output for cuff pressure and oscillometric signals, it was impossible to precisely identify which intra-arterial pulse wave the automatic systolic and diastolic blood pressure readings referred to. The Spacelabs systolic and diastolic values were then compared with the average intra-arterial systolic and diastolic blood pressures obtained during the first and last 20 seconds of the deflation period. The beginning and the end of cuff deflation were marked on the strip chart recording where the intra-arterial signal was displayed. The cuff deflation rate was set at 4 mm Hg/sec; thus, total deflation time from a pressure of 200 mm Hg was 40–50 seconds. Although there may be some overlapping, the two 20-second periods on which systolic and diastolic blood pressure were computed on the intra-arterial signal were easily recognizable. In each subject the comparison was made by linear regression analysis and by calculation of the average between-method discrepancy ±1 or 2 SD, the latter representing the 96% confidence limits. Individual discrepancies were averaged to obtain mean data ±SEM for the group as a whole.

The 24-hour intra-arterial signal stored on the magnetic tape cassette was visualized at high speed on an oscilloscope to check its quality and remove artifacts and periods of pulse pressure dampening. The edited signal was sent to a computer (Digital PDP 11/23, Digital Equipment Corporation, Maynard, Mass.), sampled at 165 Hz, digitized on 12 bits, and stored on a magnetic disk. Systolic, diastolic, and mean arterial pressures were computed over consecutive 3-second segments. Heart rate was also calculated over the same segments as the reciprocal of the interval between contiguous systolic peaks. The systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate values provided by the Spacelabs devices over the 24-hour monitoring period were also screened for artificial readings both by the editing criteria automatically provided by the Spacelabs software and by additional criteria previously reported. For all subjects the number of artifacts was 2.1±0.8% (mean±SEM) of the total number of values collected over the 24-hour period, with no difference between the two Spacelabs devices. In each subject systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate values were averaged to obtain mean values for each hour and for the whole 24-hour period, and the results were compared with the corresponding intra-arterial hourly and 24-hour average values. Only hourly and 24-hour average data were compared because, at variance with other noninvasive blood pressure monitoring devices, the Spacelabs devices do not allow identification of the precise time of their systolic or diastolic blood pressure measurements on the intra-arterial tracing.

Data from individual subjects were averaged to obtain mean values±SEM for the group as a whole, as was done for the measurements at rest. The differences between the hourly blood pressure values obtained intra-arterially and noninvasively were assessed by two-way analysis of variance for repeated measurements and by two-tailed paired t test with the Bonferroni correction. The statistical analysis was extended to the qualitative and quantitative correspondence between the hour-to-hour blood pressure changes detected by the intra-arterial and noninvasive method. This was assessed by the coefficient of contingency and by the χ2 test of independence with calculation of Pearson χ2. This test is based on the assumption that two sets of data are independent. A statistically significant χ2 rejects this assumption and thus proves dependency. A value of p<0.05 was taken as the level of statistical significance throughout the study.
Results

Blood Pressure Measurements at Rest

Figure 1 (left panels) shows that in resting conditions, the correlation coefficients between the systolic and diastolic blood pressure values measured by the Spacelabs devices and those measured by the intra-arterial line were both statistically significant and high. However, as shown in the right panels of Figure 1, this was associated with noticeable Spacelabs-intra-arterial blood pressure discrepancies in several individual subjects. The average discrepancy for systolic blood pressure in the group as a whole was close to zero, indicating that the individual positive and negative discrepancies balanced each other. However, the average discrepancy for diastolic blood pressure was 9.1 mm Hg, indicating that the intra-arterial values were systematically overestimated by the noninvasive method.

Blood Pressure Measurements in Ambulatory Conditions

The hourly values obtained by monitoring 24-hour blood pressure through the Spacelabs devices and intra-arterially are shown as individual discrepancies in Figure 2 and as absolute average values for the group as a whole in Figure 3. Although somewhat different in different individuals and hours, systolic blood pressure discrepancies were fairly small, and the average 24-hour systolic blood pressure values for the group as a whole were almost identical. Individual and average mean arterial pressure values were similar to systolic blood pressure. In contrast, the diastolic blood pressure values obtained by the Spacelabs devices were almost invariably higher than those obtained intra-arterially, and the average 24-hour difference was 14.2±2.9 mm Hg (p<0.01). The individual discrepancies in the heart rate values provided by the two methods were usually small, and the 24-hour averages were superimposable.

Discussion

Performance of the Spacelabs Devices at Rest and During Ambulatory Monitoring

Our observations confirm previous reports\(^1,2\) that at rest, the values provided by the Spacelabs 90202 and 90207, i.e., two devices using the same oscillometric...
criteria to identify systolic and diastolic blood pressure, reflect very closely resting intra-arterial systolic blood pressure. At variance from previous reports, however, our observations also show that these devices overestimate to a considerable extent resting intra-arterial diastolic blood pressure. Furthermore, our data clearly demonstrate that the performance of the Spacelabs devices in dynamic conditions is worse than at rest.

For systolic blood pressure, this was shown by the fact that in several subjects, the values provided by the Spacelabs devices during 24-hour blood pressure monitoring were considerably different from the intra-arterial values with a trend toward overestimation during the night and underestimation during several hours of the daytime. For diastolic blood pressure, it was shown by the fact that the Spacelabs overestimation, already seen at rest, was greater during the ambulatory 24-hour monitoring period: the average Spacelabs–intra-arterial difference was 9.1 and 14.2 mm Hg for resting and ambulatory values, respectively. Finally, for both systolic and diastolic blood pressures the discrepancies between the Spacelabs devices and the intra-arterial line observed during the 24-hour monitoring period showed interindividual differences that were more marked than those seen at rest. The reasons for the Spacelabs overestimation of diastolic blood pressure are unknown, although it is likely that the adoption of oscillometric rather than microphonic criteria is at least in part involved. It is also possible that this overestimation depends on the fact that intra-arterial and noninvasive measures of diastolic blood pressure are not identical, although the difference we found is much larger than that reported for comparisons between invasive and noninvasive measurements.

It is also unknown why these devices have a poorer performance in ambulatory conditions than at rest. One possibility is that ambulatory intra-arterial blood pressure measurements were not accurate under all circumstances, i.e., that the reference technique failed to invariably represent a standard. However, because during the 24-hour period the intra-arterial recording showed no substantial drift of the zero signal and no deviation from linearity, this is unlikely. Another possibility is that the few hourly values provided by the Spacelabs devices (six during the day and three during the night) did not reflect the hourly intra-arterial blood pressure means, which are based on more than 4,000 values. However, sampling blood pressure two times per hour does not prevent a precise estimate of the 24-hour mean value, which means that a reduced sampling rate is also an unlikely explanation. A third and more likely explanation is that a number of behavioral and environmental factors occurring during the 24-hour period reduce the accuracy of the Spacelabs devices. This explanation is supported by the observation that several noninvasive blood pressure monitoring devices, in particular the Spacelabs devices, are more accurate at rest than during physical activity, i.e., a condition not rare during the 24-hour period. This may combine with the effects of noise, muscle contraction, displace-
Figure 3. Line graphs show absolute hourly average systolic (SBP) and diastolic (DBP) blood pressures, mean arterial pressure (MAP), and heart rate (HR) values (±SEM) obtained by Spacelabs devices and intra-arterially in nine subjects. Twenty-four-hour average values are shown by the symbols at the extreme right of each panel. Asterisks refer to statistical significance of differences in 24-hour average values. Symbols are as in preceding figures.

...ment of the cuff, and changes in arm versus heart level, which may have increased inaccuracy even though measurements were obtained with the arm still.

Also, the different postures taken by the patients over the 24-hour period might have been responsible for some between-method discrepancy. However, the cuff of the Spacelabs devices and the intra-arterial transducer were at the same level in the supine position, the sitting position, and the upright position, making it unlikely that changes among these postures affected the discrepancy in noninvasive and intra-arterial values. A possible exception might have been the right- or left-side posture assumed during sleep, because in these instances, the Spacelabs cuff and the Oxford transducer would be at a different level. However, the lateral position could hardly be maintained for a prolonged time by our patients because the side locations of the Oxford and Spacelabs equipments made these postures less comfortable than the supine one.

Differences Between Spacelabs 90202 and 90207

The conclusion on the lack of any significant difference between the two Spacelabs devices was derived from observations made in four versus five subjects only. In spite of this limited number, however, the comparison between the performance of the two Spacelabs devices was based on 24-hour average data from each individual recording, which means a total of 96 (Spacelabs 90207) versus 120 (Spacelabs 90202) points.

Furthermore, no difference between the two Spacelabs devices was found when the huge body of information provided by resting values in 19 subjects was considered. This justifies our conclusion that the performance of these two devices is similar.

Spacelabs 90202 and 90207 Versus Other Devices

Twenty-four-hour intra-arterial recording has been used to test the accuracy of the Pressurometer III, the Sandoz SPS 1558, and the Spacelabs 5300 model in dynamic conditions. In all instances strikingly large and erratic daytime and nighttime discrepancies have been reported. In light of these results, the performance of the Spacelabs 90202 and 90207 should be regarded favorably. First of all, the Spacelabs 90202 and 90207 appear to more accurately monitor systolic blood pressure not only at rest but also in ambulatory conditions, at least when 24-hour average data are considered. Furthermore, the device estimate of mean arterial pressure, i.e., of the variable more properly defining the blood pressure load, resembles that of systolic blood pressure. Finally, these devices rather accurately reproduce hour-to-hour changes in intra-arterial systolic, mean, and diastolic blood pressure. These features make the Spacelabs 90202 and 90207 acceptable for qualitatively and quantitatively evaluating 24-hour blood pressure profiles and thus for identifying their alterations by diseases and treatment. The acceptability of these devices is further emphasized by their ability to...
suggested by the guidelines of expert committees.\textsuperscript{17,18} Even when complex and demanding, these guidelines may offer an unduly optimistic view on devices that perform less well when used in moving subjects.\textsuperscript{15,19–21}

\textbf{Implications for Validation Criteria}

We have previously shown that discrepancies between the systolic and diastolic blood pressure values provided by the Sandoz SPS 1558 and by an intra-arterial line were considerably greater in ambulatory conditions than at rest.\textsuperscript{13,16} This is in line with our present findings that even the more accurate new Spacelabs devices performed worse in ambulatory than in resting conditions. Thus, testing noninvasive ambulatory blood pressure monitoring devices only at rest may not offer precise information on their performance during a 24-hour ambulatory monitoring period, i.e., the condition in which they have to work. The testing procedures should thus not be limited to the examination of the device performance in immobile subjects, as

\textbf{References}

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