Effect of Unrestricted Activity on Accuracy of Ambulatory Blood Pressure Measurement

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A validation study of the Takeda TM-2420 ambulatory blood pressure recorder was performed on 10 subjects using the Oxford ambulatory intra-arterial recording apparatus during unrestricted activity. Electronic linkage of the two recorders ensured simultaneous blood pressure readings, taken from opposite arms. Although there was close approximation of intra-arterial and automated sphygmomanometric recordings over the range of blood pressure encountered in this study, there was a wide scatter of points and a tendency for the machine to underestimate systolic pressure by more than 15 mm Hg in the hypertensive range (systolic blood pressure more than 160 mm Hg) was detected. These findings suggest that automated recording of blood pressure during unrestricted activity may have a proportion of artificial readings. Although simultaneous intra-arterial blood pressure recording may not be appropriate for widespread use in device validation, this study illustrated some potential disadvantages of the current validation recommendations, namely, the absence of assessment of device accuracy during unrestricted and ambulatory activity. (Hypertension 1991;18:593-597)

There is an increasing trend to include recording of ambulatory blood pressure in the clinical assessment of patients with mild-to-moderate hypertension. It has become recognized that ambulatory blood pressure recorders must be subjected to critical evaluation to determine accuracy and reliability. The validation protocols that are currently recommended1-2 rely on static bench testing of the instrument, but such assessment does not necessarily predict how a model will perform in the role for which it is intended, namely, on an ambulant and unrestricted patient. Even well-validated recorders will not measure blood pressure accurately if normal motion interferes with the process of measurement. Although a few validation studies have been reported during formal or graded forms of exercise testing,3,4 the protocols recommended by both the American Society for Advancement of Medical Instrumentation guidelines1 and the British Hypertension Society2 describe validation in laboratory conditions with the subject still and seated. In addition, studies involving comparison of indirect sphygmomanometric blood pressure with ambulatory recorders during exercise testing may suffer from the loss of accuracy that has been reported to occur in conventional sphygmomanometry during exercise tests.5

The aim of the present study was to assess the accuracy of a noninvasive ambulatory blood pressure recorder (Takeda TM-2420 Version 1, A & D Instruments, Tokyo) against ambulatory intra-arterial blood pressure during unrestricted activity. Electronic linkage of the Takeda TM-2420 inflation air line to the event channel of the Oxford intra-arterial recorder allowed accurate simultaneous blood pressure recording. Patient-activated recording and automatic machine-activated recording were compared to identify whether either technique was associated with an alerting response, defined as a rise in intra-arterial systolic blood pressure exceeding 5 mm Hg at the onset of cuff inflation.

Methods

Subjects

Ten subjects undergoing intra-arterial blood pressure measurement using the Oxford apparatus (previous manufacturer, Oxford Instruments, Oxford, UK)6 were studied. Subject details are given in Table 1. All subjects were in sinus rhythm, and none had an interarm blood pressure difference at rest of more than 5/5 mm Hg, measured by two independent observers using a standard mercury sphygmomanometer with the subject still and seated. Blood pressures

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at rest ranged from 96/60 mm Hg to 215/110 mm Hg. Inclusion of patients with heart failure and syncpe increased the range of blood pressure to which the Takeda system was exposed.

Calibration of the intra-arterial recording apparatus was performed using a standard mercury manometer at chest height with calibration pressures at 50, 100, 150, 200, and 250 mm Hg at the beginning and end of each study. The playback from the intra-arterial recording was monitored on an oscilloscope monitor continuously before further analysis so that episodes of artefact such as line damping could be identified. The study was confined to daytime activity since the majority of artifact episodes associated with intra-arterial recording occur during sleep as a result of line damping. Temperature-associated drift, linearity, and other sources of drift in the zero signal have been assessed previously in our laboratory: zero stability, less than 5% change over 24-hour period; linearity, response linear over range 30-270 mm Hg; gain stability, less than 5% change over 24-hour period; temperature drift, dimensionless; zero drift, most observed minus 10 mm Hg/24 hr; linearity, response linear over range 30-270 mm Hg; gain stability, less than 5% change over 24-hour period; temperature drift, zero drift ±2 mm Hg.

The intra-arterial cannula was inserted into the brachial artery of the nondominant arm and linked to the recording apparatus/perfusor device worn at the patient's chest. The cuff of the Takeda TM-2420 was positioned securely over the brachial artery of the contralateral (dominant) arm. After intra-arterial cannulation, the subjects remained resting in the semisupine position so that a single Takeda recording was activated, and the result was compared with the simultaneous intra-arterial value to obtain a baseline assessment of accuracy at rest.

Study Design

Normal unrestricted activity was encouraged, although patients were asked to keep both arms still and at heart level while cuff inflation took place. The study commenced 1 hour after insertion of the intra-arterial cannula. The Takeda TM-2420 was programmed to record blood pressure at 30-minute intervals, in line with our standard laboratory practice. Patients were asked to initiate self-activated Takeda recordings at 15-minute intervals during a defined 2-hour recording period. Recording of blood pressure during sleep was not performed in this study. The Takeda system was removed at retiring, and the intra-arterial cannula was removed the following morning.

The event channel of the Oxford recording apparatus was automatically activated by a switch connection linked to the cuff inflation tube of the Takeda TM-2420 system. A 1-second electrical signal was produced in response to the rapid rise in air pressure within the inflation tube. The intra-arterial record was played out on light-sensitive paper, and the episodes of Takeda measurement could be identified by the event signal. The intra-arterial traces were analyzed using a microcomputer digitizing tablet calibrated for both pressure and time over the period of automatic sphygmomanometric measurement. The simultaneous systolic and diastolic intra-arterial pressures were defined as the mean of five beats 5 seconds after the onset of the event signal for systolic intra-arterial pressure and 30 seconds after the event signal for diastolic intra-arterial pressure. Cuff deflation was timed to occur over a time period of approximately 30 seconds, with a period of 5 seconds required to complete cuff inflation to a suprasystolic level. The presence of an alerting response, which we defined as an intra-arterial systolic pressure rise exceeding 5 mm Hg during Takeda measurement, was sought in the intra-arterial trace during both patient-activated and machine-activated recordings. Readings were rejected from the analysis if machine error was registered or if cuff deflation failed to register a satisfactory recording.

Statistical Methods

There were occasional gross discrepancies between the pairs of blood pressure readings between the two methods, and therefore nonparametric statistical methods were used. The Kruskal-Wallis test was used to compare the blood pressure differences (defined as Takeda TM-2420 value minus intra-arterial value) for different subjects. To examine the data for evidence of systematic error over the range of blood pressure values and to assess the range of variability found during uncontrolled ambulatory monitoring, the blood pressure differences for each subject were plotted against the blood pressure averaged over all readings for each subject obtained using both recording modalities. This form of plot allowed a distinction between the results of different subjects. Systematic error was assessed by considering the proportions of differences in arbitrary accuracy bands ranging from ±5 mm Hg and ±15 mm Hg with respect to blood pressure.

Results

Static Testing

The plots of single paired readings of a simultaneous Takeda TM-2420 reading against intra-arterial pressure are displayed in Figure 1.
Ambulatory Recording

The number of successful readings obtained with each of the 10 subjects was somewhat variable mainly because of activation of machine error codes within the Takeda apparatus (also, detachment of the cuff air line occurred in some subjects, as encountered by Jamieson et al7), and ranged from 4 to 17 readings, but 90 paired recordings of blood pressure by the two methods were obtained. An alerting response (as defined above) was not identified during either automatic measurement or patient self-activated measurement.

The difference between the Takeda TM-2420 and intra-arterial values showed significant variation in median level among the 10 subjects ($p<0.001$ for systolic, $p<0.05$ for diastolic pressure). The nature of this subject-to-subject variation is shown in Figure 2, a plot of Takeda and intra-arterial blood pressure differences against the average of all readings using both recording modalities for each subject. For systolic blood pressure, the readings for the two subjects whose mean systolic blood pressure exceeded 160 mm Hg suggested a tendency for the Takeda TM-2420 to underestimate intra-arterial pressure. For diastolic blood pressure, however, there was no clear pattern to account for the variation between subjects.

If the potential influence of subject-to-subject variation is overlooked, Table 2 shows the frequencies of blood pressure differences in the various accuracy bands we have classified above ($\pm 5$ mm Hg and $\pm 15$ mm Hg) against levels of blood pressure. The percentages of differences exceeding 15 mm Hg were 15.5% for systolic pressure and 6.6% for diastolic pressure. Overall, the median value for Takeda TM-2420 systolic pressure minus intra-arterial systolic pressure was $-2$ mm Hg with 95% confidence intervals...

<table>
<thead>
<tr>
<th>Mean BP (mm Hg)</th>
<th>Difference (Takeda minus intra-arterial BP) (mm Hg)</th>
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<td></td>
<td>$&lt;-15$</td>
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<tr>
<td>Systolic</td>
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The plots show blood pressure difference for the two methods during static recording, expressed as (Takeda TM-2420 reading—simultaneous intra-arterial reading) against mean systolic (panel A) and mean diastolic (panel B) pressure. Average of all blood pressure readings for each subject using both recording modalities was used. Accuracy bands of $\pm 5$ mm Hg and $\pm 15$ mm Hg are shown.
FIGURE 2. Plots show blood pressure difference for the two methods during ambulatory recording, expressed as (Takeda TM-2420 reading—simultaneous intra-arterial reading) against mean systolic (panel A) and mean diastolic (panel B) pressure. Average of all blood pressure readings for each subject using both recording modalities was used. Although most readings fall within the accuracy bands of ±5 mm Hg and ±15 mm Hg, there was a tendency for the Takeda TM-2420 to underestimate systolic pressure above 160 mm Hg.

Discussion

Machine Accuracy

The main purpose of the present study was to examine whether ambulatory activity itself interfered with machine efficacy and to explore the role of the intra-arterial technique to assess accuracy in the ambulant patient. In a small number of subjects, it appeared that the Takeda TM-2420 demonstrated a satisfactory level of agreement between ambulatory sphygmomanometric blood pressure and intra-arterial pressure over a wide range of blood pressure in both static and ambulatory conditions. The relatively high standard deviations, however, showed a large degree of scatter, which has been reported in a previous validation study of this recorder.7 However, when the Takeda recordings were grouped against corresponding values of accuracy bands of ±5 mm Hg and ±15 mm Hg of intra-arterial pressure, it was possible to detect a tendency in two subjects for the Takeda TM-2420 to systematically underrecord systolic pressure at higher values of blood pressure. This finding may reflect a known tendency for early versions of the Takeda TM-2420 to register a pressure of 185 mm Hg when Korotkoff sounds are already present at the initial inflation pressure of 190 mm Hg without recognizing its own error. The present study did not address the issue of machine accuracy or alarm reaction during sleep since the Takeda TM-2420 apparatus was removed on retiring.

Alarm Reaction

The findings of the present study also suggested that automatic sphygmomanometric recording with this device was not associated with an “alarm” reaction during unrestricted activity. In this respect, there was no difference between recording by machine-activated or patient-activated techniques. Similar findings have been reported with the Vita-Stat 901 recorder8 in nonambulant subjects studied in laboratory conditions.

Intra-arterial Validation

Other groups have attempted ambulatory sphygmomanometric recorder validation procedures by comparison with intra-arterial pressure but, in the studies of freely ambulant patients, have not linked the two recording methods automatically. A study of the nonautomated Remler M20009 required the use of a patient-activated event marker to identify the timing of the recorder measurements. A study of the Spacelabs 5300 recorder10 relied on the timing of cuff inflation (15-minute intervals with known start time) to obtain the signal from the intra-arterial recording.

The methodology described in this study cannot be widely applied in validation protocols since few centers routinely record intra-arterial blood pressure and be-
cause subject numbers are necessarily limited. However, the extension of validation work into the ambulant setting we have described highlighted potential problems with ambulatory recorders and suggested that some aspects of ambulatory validation should be included in the current bench test protocols. Other authors have also encountered difficulties during clinical use of ambulatory recorders such as the Takeda TM-2420 described in the present study, which supports the recent suggestion by White\textsuperscript{11} that some aspect of ambulatory, and possibly sleep-period, validation should be included in the future assessment of automatic ambulatory blood pressure recorders.

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