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Within-subject variability of differences between conventional and automated blood pressure measurements in pregnancy

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Abstract

Objective: To determine whether measured differences between standard mercury sphygmomanometry and the SpaceLabs 90207 ambulatory blood pressure monitor in pregnant women remain constant during 24 h measurements. Study design: Repeated comparisons between standard mercury sphygmomanometry and Spacelabs 90207 were performed at nine predetermined time points during 24 h ambulatory blood pressure measurements in a group of ten pregnant women with various pregnancy complications, including hypertension. Individual and group differences between standard mercury sphygmomanometry and SpaceLabs 90207 were calculated for each time point. Friedman's ANOVA was used to test stability of differences across time. Results: Mean group differences (standard deviation) between mercury sphygmomanometry and the SpaceLabs 90207 were −2 (6) mmHg and 3 (7) mmHg for systolic and diastolic pressure respectively. For systolic pressure the differences between time points were not statistically significant. Although a statistical significant trend was found for diastolic pressure differences (P<0.05), none of the contrasts between any pair of time points reached statistical significance. For both systolic and diastolic pressure the minimal and maximal difference lay at least 10 mmHg apart in seven patients. Conclusions: Despite standardisation and training, a substantial within-subject variability of the pressure difference between observers and SpaceLabs was found in this heterogeneous group of women. However, a systematic time-related effect on this pressure difference could not be demonstrated. The pressure difference between both methods cannot be estimated with great precision. This is a serious impediment for the clinical interpretation of automated or ambulatory blood pressure data.

Keywords: Validation; Ambulatory blood pressure monitor; Pregnancy

1. Introduction

Although the importance of blood pressure measurement in pregnancy is widely accepted [1], the shortcomings of mercury sphygmomanometry as the standard method have only recently been recognised by obstetricians [2,3]. Hence, years after its introduction in general hypertension practice, ambulatory blood pressure measurement (ABPM) has been suggested to supplement or even substitute standard mercury sphygmomanometry in antenatal care [3,4]. Several ambulatory blood pressure devices have been validated against standard mercury sphygmomanometry in pregnant women according to the protocol of the British Hypertension Society (BHS) and the recommendations of the Association for the Advancement of Medical Instrumentation (AAMI) [5–7]. These devices appear to be acceptably accurate in pregnancy although large differences from standard mercury sphygmomanometry may occur in the individual pregnant woman [8–12]. Absolute blood pressure levels are regarded as highly relevant for obstetrical decision making. However, conventional cut-off points are derived from studies relating the office antenatal mercury blood pressure to pregnancy outcome [13,14]. Except for one recently published study which tried to assess the role of mid-second trimester ABPM as a predictive test for the
development of hypertension in pregnancy [15], there are no studies of appropriate size which relate ambulatory blood pressure behaviour to morbidity. Therefore, comparison of the ambulatory device against mercury sphygmomanometry – the accepted clinical gold standard of blood pressure measurement – remains inevitable in each individual pregnant woman to interpret the ambulatory recordings in clinical practice. Such a comparison is most conveniently made at the beginning of the 24 h measurement when the device is installed. However, it is questionable whether this single initial comparison is an appropriate estimate of the pressure difference between the ambulatory device and mercury sphygmomanometry. All published validation studies were cross-sectional and in each patient the comparison was made at only one single time point. To our knowledge, validation studies have not been performed longitudinally, with repeated comparisons during the 24 h period the machine was designed for.

Our aim was to determine whether the difference between standard mercury sphygmomanometry and the SpaceLabs 90207 ambulatory blood pressure monitor in pregnant women is stable during a 24 h period.

2. Materials and methods

The oscillometric SpaceLabs 90207 ambulatory blood pressure monitor has been validated in pregnant and non-pregnant individuals [8–10,12,16,17]. The machine deflates in 8 mmHg bleed steps. Ten hospitalised pregnant women were selected for the study, each patient serving as her own control.

The cuff of the SpaceLabs 90207 was applied at the right arm of the woman and connected to both the ambulatory monitor and a calibrated mercury sphygmomanometer by a Y-tube. Validation measurements were carried out under highly standardised conditions as described in the BHS protocol using the sequential same arm method [5,6]. Mercury sphygmomanometry was performed by two trained observers, using a binaural stethoscope. The observers were blinded for each other’s and the SpaceLabs measurements. Simultaneously, they recorded Korotkoff phase 1 systolic blood pressure and Korotkoff phase 5 diastolic blood pressure. Although some authors have recommended Korotkoff phase 4 as the diastolic endpoint in pregnant women [13], evidence accumulates that Korotkoff phase 5 should be used [18–23]. Furthermore, most ambulatory blood pressure devices render a diastolic value closer to Korotkoff phase 5 [9,11,12]. For these reasons our observers only recorded Korotkoff phase 5 as the diastolic endpoint. Three SpaceLabs readings were taken which were all preceded and followed by an observers reading: observers – SpaceLabs – observers – SpaceLabs – observers – SpaceLabs – observers. Thus, seven readings were taken with a one minute interval between each reading. This validation procedure was performed every two hours during a 24 h recording with the SpaceLabs monitor at 9, 11, 13, 15, 17, 19, 21 and 23 h on the first day and at 9 h on the second day just before the 24 h measurement was ended. This schedule allowed for a total of nine validation procedures per patient.

For statistical analysis, individual differences between the observers and the SpaceLabs 90207 were calculated according to the 1990 BHS protocol [5], for each of the nine time points in each individual woman. For each woman the mean pressure difference during the 24 h period was calculated, and within-subject variability expressed by the minimum and the maximum value. To compare our results with previous cross-sectional studies of SpaceLabs 90207 in pregnancy [8,9,12], we first calculated one single systolic and diastolic mean difference and its standard deviation between observers and SpaceLabs from all obtained measurements in all women. Then, the group’s mean differences and their standard deviations were computed for each time point separately. Friedman’s two-way analysis of variance was used for statistical analysis. If the calculated value of the Friedman statistic ($F_r$) was significant ($P<0.05$), contrasts between all separate time points were tested by Dunn’s multiple comparisons test [24].

3. Results

Characteristics of the ten patients are given in Table 1. The women were hospitalised because of various pregnancy complications, including pregnancy-induced hypertension ($n$=4), preterm rupture of the membranes ($n$=2), preterm labour ($n$=1), vaginal blood loss ($n$=1), hyperemesis ($n$=1) and pyelonephritis ($n$=1). The mean (SD) maternal age was 31.7 (3) years and the mean (SD) gestational age was 30.2 (6) weeks. Since we found larger pressure differences between mercury sphygmomanometry and the SpaceLabs 90207 in hypertensive compared to normotensive pregnant women in a previous study [12], we deliberately included four women with pregnancy-induced hypertension, defined as a diastolic blood pressure >90 mmHg [13]. None of these four hypertensive women was on antihypertensive medication. The six normotensive women did not receive medication which could influence blood pressure.

The group’s mean differences (SD) between the observers and the SpaceLabs 90207 for all measurements were $-2$ (6) mmHg for systolic pressure and $3$ (7) mmHg for diastolic pressure, which is in accordance with our previous findings [12].

Fig. 1 shows the observed pressure differences between the observers and SpaceLabs for each of the nine time points in each of the four hypertensive women (patients 1 to 4). Fig. 2 shows these differences in the six normotensive women (patients 5 to 10). Within-subject variability of
Table 1
Characteristics and pressure differences for individual patients

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Par</th>
<th>GA</th>
<th>AC</th>
<th>BMI</th>
<th>CBB</th>
<th>SPdiff</th>
<th>DPdiff</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30</td>
<td>0</td>
<td>34</td>
<td>27</td>
<td>22.2</td>
<td>130/95</td>
<td>3 (-1,7)</td>
<td>8 (2.16)</td>
</tr>
<tr>
<td>2</td>
<td>31</td>
<td>1</td>
<td>34</td>
<td>28</td>
<td>32.6</td>
<td>150/100</td>
<td>-1 (-4,2)</td>
<td>4 (0.12)</td>
</tr>
<tr>
<td>3</td>
<td>29</td>
<td>0</td>
<td>34</td>
<td>32</td>
<td>36.1</td>
<td>140/90</td>
<td>8 (3.13)</td>
<td>14 (9.19)</td>
</tr>
<tr>
<td>4</td>
<td>38</td>
<td>2</td>
<td>31</td>
<td>30</td>
<td>31.6</td>
<td>140/90</td>
<td>0 (-7.7)</td>
<td>-2 (-14.7)</td>
</tr>
<tr>
<td>5</td>
<td>35</td>
<td>1</td>
<td>20</td>
<td>27</td>
<td>25.0</td>
<td>110/65</td>
<td>-5 (-12,-2)</td>
<td>-2 (-8.1)</td>
</tr>
<tr>
<td>6</td>
<td>30</td>
<td>0</td>
<td>32</td>
<td>28</td>
<td>28.0</td>
<td>120/70</td>
<td>-13 (-21,-3)</td>
<td>-1 (-6.8)</td>
</tr>
<tr>
<td>7</td>
<td>29</td>
<td>0</td>
<td>20</td>
<td>30</td>
<td>25.8</td>
<td>110/60</td>
<td>-1 (-5.7)</td>
<td>0 (-4.4)</td>
</tr>
<tr>
<td>8</td>
<td>34</td>
<td>1</td>
<td>33</td>
<td>32</td>
<td>32.6</td>
<td>120/55</td>
<td>-2 (-7.2)</td>
<td>10 (4.14)</td>
</tr>
<tr>
<td>9</td>
<td>31</td>
<td>2</td>
<td>36</td>
<td>29</td>
<td>27.7</td>
<td>125/60</td>
<td>-4 (-8,-1)</td>
<td>-1 (-6.3)</td>
</tr>
<tr>
<td>10</td>
<td>30</td>
<td>1</td>
<td>28</td>
<td>21</td>
<td>18.3</td>
<td>120/65</td>
<td>-1 (-13.6)</td>
<td>-1 (-7.4)</td>
</tr>
</tbody>
</table>

* maternal age (year), | parity, | gestational age (weeks), | arm circumference (cm), | body mass index (kg/m²), | clinical blood pressure (systolic/diastolic in mmHg), | pressure difference for systolic pressure between observers and SpaceLabs in mmHg, expressed as mean value (minimum and maximum value) during the 24 h period, | pressure difference for diastolic pressure between observers and SpaceLabs in mmHg, expressed as mean value (minimum and maximum value) during the 24 h period.

Fig. 1. Pressure differences (mmHg) between standard mercury sphygmomanometry and the Spacelabs 90207 for both systolic (upper graph) and diastolic pressure (lower graph) in four hypertensive pregnant patients (patients 1 to 4). For each patient the nine differences as observed during a 24 h ambulatory blood pressure measurement are shown in chronological order. Each bar represents the pressure difference at one time point.
the pressure difference between observers and SpaceLabs was considerable. For both systolic and diastolic pressure the minimum and the maximum value differed by 10 mmHg or more in six patients for systolic pressure and in seven patients for diastolic pressure (Table 1). The direction of the pressure difference between observers and SpaceLabs, either positive or negative, was the same in all patients with one or more differences >10 mmHg, except for two (patients 4 and 10).

Fig. 3 shows the mean group’s pressure differences (standard deviation) between observers and SpaceLabs for each time point. On average, this difference did not seem to increase in the course of the 24 h measurement.

For the systolic differences between the observers and SpaceLabs no statistically significant trend during the 24 h period was demonstrated. Although a statistically significant trend was found for diastolic blood pressure (P < 0.05), none of the contrasts between any pair of the nine time points reached statistical significance. Separate analysis for the hypertensive and the normotensive group did not yield different results.

4. Comment

To our knowledge, this is the first validation study of an ambulatory blood pressure monitor with repeated comparisons during a 24 h ambulatory blood pressure measurement.

In confirmation with our previous studies [11,12], the pressure differences between standard mercury sphygmomanometry and the ambulatory monitor varied considerably in both magnitude and direction (positive or negative) between subjects, as is shown in Figs. 1 and 2. Our present findings suggest that changes in magnitude and direction of these pressure differences also occur...
Fig. 3. Group ($n=10$) pressure differences, represented as means and SD, between standard mercury sphygmomanometry and the Spacelabs 90207 for systolic (upper graph) and diastolic (lower graph) pressure, at nine time points during the 24 h of the ambulatory blood pressure measurements. The black bars represent the period of sleep, during which no mercury blood pressure measurements were made.

Our findings should be interpreted with caution. First, the number of patients was small and the range of pressure differences between the ambulatory and standard techniques wide. However, we do not expect that expanding the group will yield different results. Even in this small group the mean group pressure differences between both methods seem fairly stable during the day (Fig. 3) and these differences are similar to those found in larger cross-sectional studies in pregnant women [8–12]. The obstetrician’s main concern is the safety of each individual pregnant woman. We do not believe that increasing the number of women will alter our conclusion on this point, since within-subject variability is already considerable in these ten women (Figs. 1 and 2). Second, our patients were hospitalised and bedrest had been prescribed. Therefore our findings may not be valid for ambulatory patients. Although no validation studies have been performed under

*within subjects* in the course of 24 h measurements. These *within-subject* changes are probably due to random error, since a systematic time-related effect could not be demonstrated. Reassuringly, the direction of clinically relevant differences (arbitrarily taken as differences $>10$ mmHg) appears to remain stable in most patients (Figs. 1 and 2). On the other hand, the magnitude of the pressure difference between standard mercury sphygmomanometry and the ambulatory monitor cannot be estimated with great precision in the individual.

In three hypertensive patients (patients 1, 2 and 3, see Fig. 1) diastolic pressure differences $>10$ mmHg between the conventional and the automated method occurred. As we have demonstrated before [11,12], automated blood pressure measuring devices tend to underestimate conventionally measured diastolic pressure in hypertensive pregnant women.
ambulatory conditions, there is some evidence that ambulatory blood pressure monitors perform worse under ambulatory than under resting conditions [25]. Third, the sequential same arm method, designed for devices with rapid deflation rates, may result in considerable bias in favour of the automated device [26]. Fourth, mercury sphygmomanometry is a questionable gold standard of comparison. Lack of concentration, background noises, impaired perception, technical differences between observers and other sources of observer bias with this method should not be underestimated. One could also argue that the two observers were increasingly prejudiced by their previous recordings with every next measurement in the same patient. This would make comparison of initial with subsequent measurements even more hazardous.

In conclusion, we have demonstrated that the pressure difference between conventional and automated blood pressure measurement techniques cannot be estimated with precision in the individual pregnant woman. This is a serious impediment for the clinical interpretation of automated or ambulatory blood pressure data. We feel that the true merits of ambulatory blood pressure monitoring for the surveillance of pregnant women can only come forth from prospective studies of appropriate size, relating this technique to pregnancy outcome and comparing it with office mercury sphygmomanometry in this respect.

5. Condensation

Repeated comparisons under standardised conditions between conventional and automated indirect blood pressure measurements in ten pregnant women demonstrated a substantial within-subject variability of the difference between both methods.

Acknowledgements

We thank Janet Frederiks and Pascale Robles de Medina for their assistance with the blood pressure measurements.

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