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RESPONSE AND COMPLIANCE OF HYPERTENSIVES TO TREATMENT BY DEVICE-GUIDED BREATHING EXERCISES: INTERIM RESULTS
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Previous studies have demonstrated a sustained reduction of high blood pressure (BP) with device guided breathing exercises. We are evaluating compliance & performance of patients using “treat & measure” devices at home and the possible occurrence of placebo effect. Methods: Patients, were uncontrolled hypertensives, age 30 to 65 either unmedicated or medicated with antihypertensive drugs. The design includes 4 visits (#1 to #4) at the office defining a 2-weeks baseline (#1 to #2) followed by an 8-weeks treatment phase (#2 to #4) with follow up at #3. Self treatment takes place at home 15 minutes every evening using the RESP RATE device (InterCure Ltd., Israel), which guides the user interactively to slow breathing while storing automatically compliance & performance data. BP & heart rate (HR) are measured at both office & home using a digital BP monitor with automatic data logging (A&D, Japan). Self measurements at home are applied every morning between visits #1 to #4. Outcomes are average BP & HR changes from Baseline (applied over visits #1[0002] for “office” and daily for “home”) to “End” (visit #4 for “office” and last 3 treatment weeks for “home”). Compliance & performance are evaluated using data logged by the devices. Placebo effect during baseline is tested by linear regression of daily averaged BP & HR changes during Baseline. The time course of home BP changes from baseline - by nonlinear regression using a logistic function. Results: Interim analysis of the first 17 treated patients with available outcomes shows that patient were compliant in both BP measurements and treatment and were able to achieve slow breathing, as required. Significant systolic & diastolic BP reduction was observed in response to treatment for both “office” (from 141±16/88±8 to 125±11/81±9 mmHg with \( p<0.01 \)) and “home” (from 133±8/82±9 to 125±8/77±8 mmHg with \( p<0.0001 \)) with no significant HR changes (69 to 67 at “office” and 68 to 70 at “home”). No placebo effect was observed during baseline. The home BP reduction was developed in 2 to 5 treatment weeks and then reached a plateau.

Conclusion: Self-treatment of hypertension by device-guided breathing exercises with self-BP monitoring at home is technically feasible and enables objective quantification of the patients compliance and performance as well as time course of the BP response.

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Key Words: non-pharmaceutical treatment, blood pressure monitoring, therapeutic exercises

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HIGH SPECIFICITY AND LOW SENSITIVITY OF AMBULATORY BLOOD PRESSURE MEAN FOR THE EARLY DIAGNOSIS OF HYPERTENSION IN PREGNANCY
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To test the ability of 24-hour blood pressure (BP) recording to identify hypertension in pregnancy earlier than traditional clinic BP measurements, 68 automated 24-hour BP recordings from women with uncomplicated pregnancies and 60 from pregnant women who later developed gestational hypertension or preeclampsia were collected at five gestational stages (5-13, 14-20, 21-25, 26-30 and >30 weeks) and compared to previously obtained period-specific reference limits of normality (95% confidence limit of 24-hour BP means) derived from 413 24-hour BP profiles recorded in 166 women with uncomplicated pregnancies. Sensitivity and specificity of the diagnosis based on 24-hour BP mean at each examined gestation period are reported in the Table, separately for diastolic (DBP) and systolic (SBP) blood pressure.

<table>
<thead>
<tr>
<th>Time (weeks)</th>
<th>5 - 13</th>
<th>14 - 20</th>
<th>21 - 25</th>
<th>26 - 30</th>
<th>&gt; 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>DBP sensitivity</td>
<td>37.5</td>
<td>53.8</td>
<td>72.7</td>
<td>63.6</td>
<td>82.3</td>
</tr>
<tr>
<td>DBP specificity</td>
<td>100</td>
<td>97.5</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>SBP sensitivity</td>
<td>37.5</td>
<td>61.5</td>
<td>45.4</td>
<td>45.4</td>
<td>58.8</td>
</tr>
<tr>
<td>SBP specificity</td>
<td>81.8</td>
<td>68.7</td>
<td>91.7</td>
<td>83.8</td>
<td>76.5</td>
</tr>
</tbody>
</table>

Comparison of individual diastolic BP means to the specific reference limits demonstrated a very high specificity. Sensitivity was low, reaching 80% for diastolic BP only in the last examined period; it must be noted, however, that no woman who later developed gestational hypertension or preeclampsia could be correctly classified by clinic BP measures at the time 24-hour BP recording was performed. These results support the expanding use of ambulatory BP monitoring in pregnancy.

Key Words: blood pressure, pregnancy, ambulatory monitoring

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BLOOD PRESSURE CHANGES DURING PREGNANCY CHARACTERIZE WOMEN WHO WILL DEVELOP GESTATIONAL HYPERTENSION OR PREECLAMPSIA
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To analyze blood pressure (BP) characteristics in normal and complicated pregnancies, 24-hour ambulatory BP was longitudinally evaluated in 362 recordings obtained by validated automated devices in 75 women with uncomplicated pregnancies (normal population) at three or more of 5 gestational periods (period 1 to 5, respectively at 5-14, 14-20, 21-25, 26-30 and >30 weeks of gestation) and in 122 BP recordings performed in the same periods in 30 age-matched women who developed gestational hypertension or preeclampsia in the third trimester.

Systolic (SBP) and diastolic (DBP) 24-h means±SD at the various gestational ages in the two groups of pregnant women are shown in the Figure (dots indicate complicated pregnancies).

At group level, women with complicated pregnancies demonstrated significantly higher systolic and diastolic BP means starting from the 14th week of gestation. Despite these differences, it was impossible to define, on the basis of ambulatory BP means, clinically useful criteria for the early identification of women with complicated pregnancies, because of the wide overlap of the distribution of individual BP means in the two groups.

Women with complicated pregnancies, however, invariably showed a progressive BP rise in the first half of pregnancy. This pattern was the opposite of that shown by the women of the normal population. Thus, the absence of the normal BP fall in the second trimester may represent a useful marker of the hypertensive complications of pregnancy.

Key Words: ambulatory monitoring, pregnancy, blood pressure