**Lack of placebo effect on ambulatory blood pressure**

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**Abstract**

Several studies have reported that, at variance with clinic blood pressure, ambulatory blood pressure is not reduced by treatment with placebo. However, this evidence has usually been obtained in small groups of subjects and no data are available from a larger sample of patients. To address this issue we have analyzed data from 116 outpatients involved in placebo-controlled studies on antihypertensive treatment. The patients were studied before and at the end of a 6- to 8-week period of placebo. In all patients, blood pressure was measured by sphygmomanometry and over the 24 h by automatic ambulatory monitoring. Administration of placebo was accompanied by a significant reduction in systolic and diastolic clinic blood pressure (−5.3 ± 1.1 and −4.4 ± 0.6 mm Hg, respectively; *P* < .01), but not in 24-h, daytime and nighttime blood pressure. Hourly systolic and diastolic blood pressure profiles were virtually superimposable in the two different periods, except for the first 4 h, in which systolic blood pressure was slightly but significantly lower during than before placebo (149.5 ± 1.2 *v* 146.4 ± 1.2 mm Hg; *P* <.05). These results provide a large database indicating that 24-h average blood pressure is not reduced by placebo, thus it is not necessary to include a placebo control group in antihypertensive drug studies in which ambulatory blood pressure monitoring is employed. A small placebo effect occurs, however, in the first hours of ambulatory monitoring. This may lead to a slight overestimation of the peak blood pressure effect of a drug and an underestimation of its trough-to-peak ratio if placebo correction of the data is not made or if the first part of ambulatory blood pressure monitoring is not excluded from data analysis.

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Ambulatory blood pressure monitoring, placebo effect, antihypertensive drug trials

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