

# Office versus ambulatory recordings of blood pressure (OvA): a European multicenter study

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The long-term prognostic value of ambulatory blood pressure recordings in essential hypertension is poorly documented. A European Multicenter study has been set up to evaluate office versus ambulatory (OvA) recordings during a follow-up period of 5 years in a minimum of 2000 patients. The end-point of the study is the question of whether ambulatory blood pressure measurements are better correlated with patient morbidity and mortality than office recordings. In a specific substudy, short-term evolution (6 months) of left ventricular hypertrophy will be followed in untreated hypertensives with randomly allocated treatment. A number of readaptations of the primary protocol are discussed.

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## Introduction

The value of ambulatory blood pressure recording in determining the prognosis of hypertensive patients is not clear at present. Several studies have shown a better correlation between blood pressure and organ damage when blood pressure was measured under ambulatory conditions compared to blood pressure measured at the consultation [1-5] but there is only one study on the correlation between long-term prognosis and ambulatory blood pressure [6].

The techniques used in that study are no longer up to date and the treatment used in those patients is quite different from the present-day treatment of hypertension. Therefore, a prospective long-term study was set up to correlate blood pressure with long-term prognosis, and to compare office and ambulatory blood pressure data [7,8]. This paper discusses the results of a feasibility study and suggestions for readaptation of the primary protocol.

## Comments on the questions being posed

The protocol was presented at different meetings, and the questions being posed were clearly accepted as being the

key questions to be answered about ambulatory blood pressure recordings by a multicenter prospective study. There was some suggestion of a different study protocol for each aim. Any study of a possible correlation between blood pressure measurement and the long-term prognosis of hypertension requires a long-term protocol with as many patients as possible. A comparison between office and ambulatory blood pressure to determine which is more useful for treatment decisions is better served by a protocol where patients are randomly allocated either to office or to ambulatory blood pressure measurement.

## Division of the patients into two groups according to the difference between office and ambulatory blood pressure

In the original protocol, the patients were to be divided into two groups according to whether they showed a large or a small difference between office and ambulatory measurements. Initial experience in many centers has shown that this protocol excludes a large number of patients who are, in fact, suitable for the study. Therefore it was suggested that all patients within certain blood pressure limits be considered for the study, irrespective

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of the difference between office and ambulatory blood pressure.

### Study of the evolution of left ventricular hypertrophy

Many investigators and clinicians felt that in the evaluation of organ damage the degree and evolution of left ventricular hypertrophy is a major item. However, left ventricular hypertrophy is known to be strongly influenced by treatment. Therefore a specific study arm was suggested to follow untreated patients over a short period of time with a randomly allocated treatment schedule. Within the protocol,  $\beta$ -blockers, calcium antagonists and angiotensin converting enzyme inhibitors will be compared and where the need for treatment is not clear-cut, a placebo will be included. Left ventricular hypertrophy will be assessed by ECG and echocardiography and compared with office and ambulatory blood pressure measurements. For the first 6 months every effort will be made to maintain the patients with monotherapy so that the evolution of left ventricular hypertrophy can be assessed during randomly allocated treatment, the evolution to be correlated with office and ambulatory blood pressure.

In patients who are already being treated the treatment will be kept as constant as possible in the early part of the study. There will be no attempt to specify treatment in those patients as the major question is long-term prognosis in correlation with office or ambulatory blood pressure measurements. After 1-3 months, the office-ambulatory difference and possible organ damage will be re-evaluated for reproducibility of the data. After 6 months of treatment the group of untreated patients will join the group of the treated patients in one large study protocol.

### Title of the study

In the original protocol HOME BP was given as the title of the study, i.e. Home versus Office Monitoring of blood pressure: a European multicenter study on high Blood Pressure. Several clinicians felt that this title could be misleading in many countries because HOME BP is considered the technique whereby patients record their own pressure. Therefore the title was changed to OVA, Office versus Ambulatory recordings of pressure.

### Instruments

Only fully validated instruments will be used, according to the United States Association for the Advancement of

Medical Instrumentation or equivalent national standards. Dr E. O'Brien's experience in this area will be used to evaluate all newer instruments that are used regularly. At the time of writing only the SpaceLabs and the Oxford Medilog had been fully validated by these rules but it is expected that several other instruments will be evaluated.

### Follow-up of patients on the basis of ambulatory recordings only

In one center the ethical committee considered it unsafe to follow-up patients only on the basis of ambulatory recordings. The reasoning was that there are no data available to prove that this is the better way of measuring blood pressure. This is, of course, the basic question in the present study. The study protocol will therefore be adapted so that all patients can be followed up on the basis of office blood pressure measurements, but all will undergo ambulatory recording as well, so that the question of which blood pressure is best correlated with the long-term prognosis can be answered. This protocol will also eliminate the need for a 'neutral' person, a requirement that presented practical problems in some centers. Further, the objection of the ethical committee will be met.

### Conclusion

The different comments and experiences outlined here, which came from several centers carrying out a pilot and feasibility trial, were considered positive and worthwhile by the protocol committee. The protocol is now being adapted to take care of all these comments and will shortly be finalized and distributed to the different participating centers throughout Europe. Since this study is considered to be of the highest importance all delegates to the meeting were asked to take an active part in the study and to recruit as many patients as possible. Preliminary figures suggest that a minimum of 2000 patients will be followed over a period of 5 years. It is hoped that this study protocol will be feasible in all the different European centers so that the basic questions that are most relevant for day-to-day hypertension treatment can be answered.

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