



Original article

Home blood pressure vs. clinic blood pressure measurement-based follow up in type II diabetics: Effect on 24-h ambulatory BP and albuminuria. Randomised trial[☆]



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ABSTRACT

Background and objective: To compare the efficacy of two strategies of blood pressure (BP) measurement-based follow-up in hypertension and albuminuria control.

Patients and methods: Multicentre, prospective, randomized, open trial with a parallel-group design. Nineteen primary care centres and a hospital clinic participated. Adult type 2 diabetics with systolic BP ≥ 140 mmHg without relevant renal disease were randomized to one of two follow-up strategies: (1) standard follow up, with a clinic BP target $<140/90$ mmHg and (2) self-monitoring home BP (SMHBP)-based follow up, with a BP target $<135/85$ mmHg. Biochemical standard blood variables, albuminuria, and 24-h ambulatory BP monitoring were performed at entry, 12 and 24 months. The main outcome measurement was 24-h ambulatory systolic BP variation. Albuminuria change was analyzed as a secondary outcome.

Results: 116 patients were analyzed (mean age: 66.8 years). Mean systolic ambulatory 24-h BP change in two years was 3.9 mmHg (95% CI 1.8–6.1). We did not find significant differences between both groups ($p=0.706$). Similarly, no differences were found when we compared other ambulatory BP values. Initial albuminuria was similar in both groups and did not significantly changed throughout the follow-up period.

Conclusion: In type 2 diabetics without relevant nephropathy a SMHBP- based follow up was equivalent to a standard clinic-based BP follow up in BP and albuminuria control.

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Automedición en el domicilio frente a lectura de la presión arterial en la consulta en el seguimiento de diabéticos tipo II: efecto sobre la presión arterial ambulatoria y la albuminuria. Estudio aleatorizado

RESUMEN

Fundamento y objetivo: Comparar la eficacia en el control de la hipertensión arterial (HTA) y la albuminuria de 2 estrategias de seguimiento basadas en diferentes métodos de evaluación de la presión arterial (PA).

Pacientes y métodos: Estudio de intervención aleatorizado, abierto, con grupo control, de 2 años de duración, realizado en 19 centros de atención primaria y una consulta de medicina interna.

Palabras clave:

Automedición de la presión arterial

Presión arterial en domicilio

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Se incluyó a diabéticos adultos tipo 2 con PA sistólica (PAS) ≥ 140 mmHg sin nefropatía relevante. Los pacientes fueron aleatorizados a: 1) grupo de seguimiento convencional, con un objetivo de PA en la consulta $< 140/90$ mmHg; y 2) grupo de seguimiento basado en cifras de automedición domiciliar de la PA (AMPA), con un objetivo de PA en el domicilio $< 135/85$ mmHg. En las visitas basal, anual y final se realizaron un perfil bioquímico, medición de albuminuria y monitorización ambulatoria de la PA de 24 h. La principal variable de eficacia fue la variación de la PAS ambulatoria de 24 h. Como variable secundaria se analizó la albuminuria.

Resultados: Fueron evaluados 116 pacientes (edad media: 66,8 años). El descenso medio de la PAS ambulatoria de 24 h en 2 años fue de 3,9 mmHg (IC del 95%: 1,8–6,1), sin observarse diferencias significativas entre los 2 grupos ($p=0,706$), así como tampoco entre el resto de valores de PA ambulatoria. La albuminuria inicial fue similar en ambos grupos y no se modificó significativamente durante el seguimiento.

Conclusión: En pacientes diabéticos sin nefropatía relevante, un seguimiento basado en AMPA mostró una eficacia similar en el control de la HTA y la albuminuria que el seguimiento convencional.

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Introduction

Poor high blood pressure (HBP) control represents a serious worldwide problem.¹ In our country it is estimated that half of hypertensive patients treated in primary care have a suboptimal control of blood pressure (BP), especially diabetic patients.^{2–4}

The diagnosis and control of HBP is traditionally based on the BP values recorded in the clinic. However, self-measured blood pressure (SMBP) by the patient at home offers important advantages over the traditional method. Among them, its potential to improve therapeutic adherence and inertia,^{5–7} its higher correlation with organ damage secondary to HBP⁸ and its closer relationship with long-term cardiovascular morbidity and mortality.⁹

Multiple randomized studies have shown that the use of SMBP in the follow-up of hypertensive patients leads, generally, to a better control of BP values, compared to conventional follow-up, based on the BP values obtained in the clinic.^{10–12}

In diabetic patients, the values recorded by SMBP are more closely related to the progression of albuminuria, macro and microvascular complications, and mortality than the values obtained in the clinic.¹³

A small number of intervention studies using SMBP in diabetics have been published, none in Spain.^{14–18} In them, there was a trend towards better control of BP values in patients randomized to SMBP, compared to the conventional follow-up group, although with heterogeneous results.

The present study, conducted in type 2 diabetic patients, evaluates the efficacy of a treatment strategy based on the values obtained by SMBP in the control of BP and albuminuria in comparison with the usual follow-up, based on the values obtained in the nurse's office.

Patients and methods

A multicentre, randomized, open-label, controlled, intervention study of 2 years duration was carried out in 19 primary care centres and one internal medicine clinic located in a tertiary hospital.

Randomization was performed stratifying by centre, age (< 65 years and ≥ 65 years) and sex, in a centralized manner, using a table of random numbers. The investigator was informed by an external collaborator (non-health staff) using sealed envelopes that were opened each time a physician recruited a new patient.

The recruitment took place between May 2011 and December 2013.

Study population

It included, consecutively, adult Caucasian patients diagnosed with type 2 diabetes, with systolic BP values between 140 and

170 mmHg (both included) in the screening visit. Exclusion criteria: pregnancy, breast-feeding, life expectancy less than 5 years, history of cardiovascular disease in the previous 12 months, serum creatinine > 1.5 mg/d, albuminuria ≥ 300 mg/g of creatinine in a random urine sample, inability to go to the health centre for scheduled visits and inability to give written consent.

Description of the intervention

The patients were randomized to 2 groups: (1) control group, or conventional follow-up, and (2) intervention group, or follow-up based on SMBP.

In the control group, BP was exclusively evaluated by nurses. An oscillometric sphygmograph was used that automatically performed 3 BP readings, each separated by one minute, displaying the average value on the screen. The therapeutic targets were a systolic BP of less than 140 and a diastolic BP of less than 90 mmHg.¹⁹

In the intervention group, BP was evaluated exclusively by SMBP, following the protocol recommended by the European Society of Arterial Hypertension.²⁰ BP measurements were made by the patient at home in the 7 days prior to each visit, in 2 sessions (morning and afternoon), with 2 readings in each session. The “BP figure for each visit” was defined as the result of the average of all the readings, excluding those of the first day. The therapeutic targets were a systolic BP of less than 135 mmHg and a diastolic BP of less than 85 mmHg.²⁰

Study and follow-up protocol

The selected patients were given appointments for these visits: baseline, 1 month, 3 months, 6 months, 12 months, 18 months and 24 months. The doctor could schedule “extra” visits in case of poor BP control.

At the baseline visit, informed consent was collected as well as the following information: sex, age, education level, cardiovascular risk factors, cardiovascular disease history, use of drugs, clinic BP values, weight and height. The education level was classified into 2 categories: low level: illiteracy or primary studies; medium-high level: higher education. The following procedures were carried out: randomization, blood extraction (blood count, glycosylated haemoglobin [HbA1c], total cholesterol, high density lipoprotein cholesterol [HDL], triglycerides and creatinine). In addition, the patient was given an appointment for ambulatory BP monitoring (ABPM) for 24 h and will deliver 3 samples of morning urine, collected in 3 non-consecutive days, for the determination of albuminuria. The doctor remained blinded as to the results of the ABPM, both in this visit as well as in the annual check-up, so that the results would not influence his therapeutic decisions.

All patients were given an appointment in a nurse's office, after the baseline visit, in which they received training about how to

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