

Effectiveness of Self-Measurement of Blood Pressure in Patients With Hypertension: the Dioampa Study

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Objective. To evaluate the effectiveness of self-measurement of blood pressure (SMBP) in controlling hypertension.

Design. Randomized, controlled, pragmatic, open study. The unit of randomization was the basic health care unit (BCU), consisting of 1 physician and 1 nurse. All BCUs were randomized to the control group (usual clinical practice, n=94) or to the intervention group (n=86).

Setting. Primary care BCUs throughout Spain.

Participants. Patients with poorly controlled essential hypertension, defined as systolic blood pressure ≥ 140 or diastolic blood pressure ≥ 90 mm Hg.

Interventions. The patients were given an Omron[®] HEM-705CP automatic blood pressure monitor on two occasions, for use during 15 days at weeks 6 and 14. Blood pressure was recorded at each visit (baseline, 6, 8, 14, 16, and 24 weeks).

Main outcome measures. Main outcome variable: control of blood pressure, considered systolic/diastolic blood pressure $< 140/90$ mm Hg (130/85 in patients with diabetes).

Results. 180 BCUs serving 1325 patients (622 in the intervention group, 703 in the control group) participated. Baseline characteristics were similar in both groups. Immediately after the first period of SMBP (week 8) the proportion of patients whose blood pressure was well controlled was 7.6% higher in the intervention group than in the control group ($P=.01$). After the second period of SMBP (week 16) the difference between groups decreased to 4.1% ($P=.27$). At the end of the study the difference was 4.9% ($P=.19$).

Conclusions. Self-measurement of blood pressure was effective in controlling blood pressure in the short term, but its effects faded over time.

Key words: Hypertension. Self-measurement of blood pressure. Effectiveness. Self-monitoring of blood pressure.

EFFECTIVIDAD DE LA AUTOMEDICIÓN DE LA PRESIÓN ARTERIAL EN PACIENTES HIPERTENSOS: ESTUDIO DIOAMPA

Objetivo. Evaluar la efectividad de la automedición de la presión arterial (AMPA) sobre el control de la hipertensión arterial (HTA).

Diseño. Estudio aleatorizado por grupos, controlado, pragmático y abierto. La unidad de aleatorización fue la unidad básica asistencial (UBA) compuesta por un médico/a y un enfermero/a. Las UBA fueron aleatorizadas al grupo control (grupo C, n = 94) bajo práctica clínica habitual, o al de intervención (grupo I, n = 86).

Emplazamiento. UBA de atención primaria de toda España.

Participantes. Pacientes con HTA esencial mal controlada definida como una presión arterial sistólica (PAS) o diastólica (PAD) ≥ 140 o 90 mmHg.

Intervenciones. Se facilitaron medidores OMRON-HEM705CP en 2 ocasiones para su utilización durante 15 días (a las semanas 6 y 14). Se registró la presión arterial en cada visita de seguimiento (basal, 6, 8, 14, 16 y 24 semanas).

Mediciones principales. Variable principal: control de la presión arterial considerada como PAS/PAD $< 140/90$ mmHg (130/85 mmHg en pacientes diabéticos).

Resultados. Se incluyó a 1.325 pacientes de 185 UBA (622 en el grupo I y 703 en el grupo C), con características basales similares en ambos grupos. Inmediatamente después de la primera AMPA (semana 8), la proporción de pacientes bien controlados fue superior en el grupo I que en el C, con una diferencia del 7,6% ($p = 0,01$). Tras la segunda utilización (semana 16), esta diferencia se redujo al 4,1% ($p = 0,27$). Al final del estudio, la diferencia fue del 4,9% ($p = 0,19$).

Conclusiones. La AMPA es efectiva en el control de la presión arterial a corto plazo, pero su efecto se amortigua con el tiempo.

Palabras clave: Hipertensión. Automedida de la presión arterial. Efectividad. Automotivación de la presión arterial.

Spanish version available at
www.atencionprimaria.com/73.025

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This study was possible thanks to support provided by Novartis Farmacéutica, S.A., Barcelona, Spain.

Part of the results were presented as a poster at the XXIII Congress of the semFyC (Spanish Society of Family and Community Medicine) in Barcelona, 10-13 December 2003, and at the VI European Congress of the International Society for Pharmaco-economics and Outcomes Research (ISPOR6), Barcelona, 9-11 November 2003.

Manuscript received March 1, 2004.
 Manuscript accepted for publication September 15, 2004.

Introduction

The importance of hypertension (HT) as a cardiovascular risk factor has been demonstrated in a number of epidemiological studies.^{1,2} Nearly all current guidelines and consensus documents recommend accurate stratification of cardiovascular risk, a process which should entail not only screening for cardiovascular risk factors and the presence of target organ lesions or associated chronic disease, but also the accurate measurement of blood pressure (BP) in the doctor's office or in the clinic. Because of the variability of BP, and in order to overcome some of the limitations of blood pressure measurements in the clinic (small number of measurements, lack of information on BP outside the health care setting, white-coat effect, lower precision, and accuracy), current guidelines also recommend that BP be measured outside the clinical setting with (among other approaches) self-measurement of BP (SMBP).^{3,4} Self-measurement of BP is defined as BP readings obtained outside the clinical setting by persons who are not health professionals—in other words, by patients or persons close to them, usually at home under every-day living conditions. This avoids the white-coat effect,^{5,6} and repeated BP measurements on the same or different days make it possible to record variability in the patient's BP.⁷ Certain characteristics of SMBP such as its low cost, ease of use, ability to avoid biases in the readings, and usefulness in the diagnosis of isolated clinical HT, make this BP measurement technique especially advisable for use in primary care.⁸

The hypothesis this study set out to test was that SMBP would help raise patients' awareness about their condition and the need to comply with treatment,⁹ and would lead to treatments of HT that are easier to adjust¹⁰ in the light of BP figures obtained in the patient's home.¹¹

The Dioampa study was therefore designed to evaluate the effectiveness of SMBP in controlling BP in patients with HT, and its potential impact on treatment adjustment.

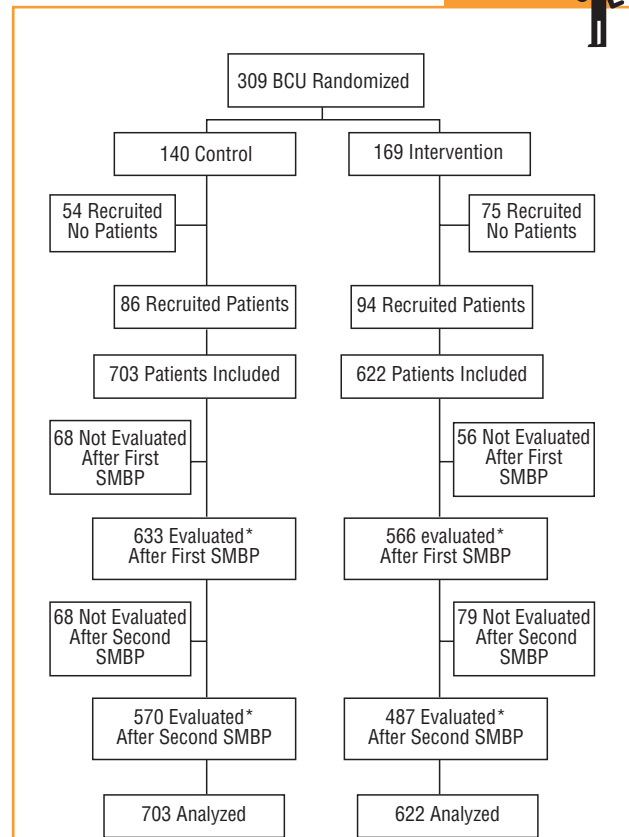
Methods

A pragmatic, open, cluster-randomized controlled study¹² was designed, and 309 basic health care units (BCU) in primary care centers located throughout Spain were to participate. Each BCU consisted of a physician and a nursing professional with experience working as a team for the follow-up of patients with HT. The BCU that agreed to participate in the study were assigned randomly to the intervention group (I) or the control group (C).

Study Population

Each BCU was responsible for recruiting 8 patients with HT older than 18 years of age whose BP was not well controlled (sys-

Material and methods



General Scheme of the Study

Open, pragmatic, and randomized study with a control. Intervention: devices to measure blood pressure provided for 2 weeks of use, weeks 6 and 14.

*Patients for whom the main outcome measure for good control of blood pressure was available.

tolic BP ≥ 140 mm Hg or diastolic BP ≥ 90 mm Hg). All patients gave their informed consent to participate in the study. In all patients we first ruled out secondary HT or other diseases or circumstances that might interfere with follow-up, contraindications for the drugs used to treat HT, pregnancy or breastfeeding. The inclusion of 309 BCU was expected to power the study at 80% to detect 5% differences in a two-tailed test with a 5% level of significance, assuming 16.3% of the patients were well controlled in group C, a within-cluster correlation coefficient of 0.01, and loss of 10 BCU.¹²

Definition of the Intervention

Patients in group I were asked to undertake SMBP for two 15-day periods (from weeks 6 to 8 and from weeks 14 to 16 after inclusion). They were instructed in how to use the Omron® HME-705CP monitor according to a standardized protocol (3 measurements in the morning before medication, and 3 in the evening before supper).¹³ The patients were urged to save the print-outs of all BP values and show them to the physician when

they returned their monitor. In group C, patients were treated in accordance with usual clinical practice.

Follow-up

In both groups BP was measured at each visit (inclusion, 6, 8, 14, 16, and 24 weeks later) with instruments and procedures used routinely at each BCU. Changes in pharmacological treatment were also recorded at each visit.

The patient's attitude toward antihypertensive treatment was evaluated at 6 and 14 weeks with the questionnaires developed by Morisky-Green and Haynes-Sackett.¹⁴ Patient satisfaction was evaluated at the end of follow-up (24 weeks) by summing the scores for the 9 items of a previously validated questionnaire¹⁵ for which scores ranged from 7 to 30 (greatest satisfaction). Satisfaction of health professionals was evaluated at the end of the study with a specially designed questionnaire.

Evaluation Criteria and Statistical Analysis

The main outcome measure was control of BP. Control was considered good when systolic BP was <140 mm Hg and diastolic BP was <90 mm Hg in patients without diabetes, and when systolic BP was <130 mm Hg and diastolic BP was <85 mm Hg (measured at the health center) in patients with diabetes. As secondary outcome measures we used control of systolic and diastolic BP separately.

The statistical analysis was based on intention to treat, considering as controls all cases that were not evaluated because of loss to follow-up. Control of BP was analyzed with a generalized linear model assuming binomial errors and a logit link function.¹⁶ All levels of significance reported here are for two-tailed tests. Normal approximation was used to calculate 95% confidence intervals (95% CI) for differences between the means and proportions.

The study protocol was approved by the Clinical Research Ethics Committee of the Jordi Gol i Gurina Foundation.

Results

A total of 1325 patients followed at 180 participating BCU were included in the study. There were no significant differences in the baseline characteristics of patients with HT assigned to either group (Table 1).

As Table 2 shows, after the first period of SMPB the proportion of patients whose HT was well controlled was significantly greater in group I. However, no positive effect was seen after the second period of SMBP.

Table 3 shows the percentages of patients whose systolic and diastolic BP were well controlled during the study. In general, the percentage of patients with well controlled HT was higher in group I, although the difference was significant only for systolic BP after the first period of SMBP (week 8).

Table 4 shows the changes in pharmacological treatment during the study. Changes during the 24-week period were somewhat more frequent in group I than in group C, although the differences were not statistically significant. The mean number of changes in treatment during the study was 0.50 in group I and 0.37 in group C, for a difference of 0.13 (95% CI, 0 to 0.26).

TABLE 1 Baseline Characteristics of Patients With Hypertension Assigned to Each Group*

	Control Group (N=703)	Intervention Group (N=622)
Age, years	62 (61 to 64)	60 (59 to 62)
Sex		
Men	260 (37.0)	253 (40.7)
Women	365 (51.9)	305 (49.0)
Not stated	78 (11.1)	64 (10.3)
BMI, kg/m ²	29.1 (28.5 to 29.6)	29.2 (28.7 to 29.6)
Years since HT was diagnosed	6.8 (5.9 to 7.6)	5.9 (5.1 to 6.8)
SBP, mm Hg	162 (160 to 164)	161 (159 to 163)
DBP, mm Hg	94 (93 to 95)	94 (93 to 95)
Comorbidity		
Hyperlipidemia	208 (29.6)	158 (25.4)
Diabetes mellitus	144 (20.5)	107 (17.2)
Osteoarthritis	126 (17.9)	86 (14.1)
Obesity	121 (17.2)	55 (8.8)

*Data are given as the number and percentage (in parentheses) or as the mean (95% CI). BMI indicates body mass index.

TABLE 2 Proportion of Patients With Well-Controlled Blood Pressure*

Group C	Group I (N=703)	P (N=622)	OR	95% CI
Week 8†	19.9%	27.5%	0.010	1.58 (1.11 to 2.25)
Week 16‡	33.3%	29.2%	0.270	1.24 (0.85 to 1.80)
Week 24	38.6%	33.7%	0.189	1.26 (0.89 to 1.79)

*C indicates control; I, intervention; OR, odds ratio for good control of BP in group I compared to group C; 95% CI, 95% confidence interval.

†After SMBP was used for the first time in Group I.

‡After SMBP was used for the second time in Group I.

TABLE 3 Percentage of Patients With Well-Controlled Systolic and Diastolic Blood Pressure Considered Separately*

	SBP			DBP		
	Group C (N=703)	Group I (N=622)	P	Group C (N=703)	Group I (N=622)	P
Week 8†	20.8%	28.6%	0.010	54.2%	55.1%	0.623
Week 16‡	30.7%	34.1%	0.316	59.3%	57.6%	0.782
Final measurement	34.4%	39.4%	0.153	64.7%	68.6%	0.299

*C indicates control; I, intervention; P, level of significance.

†After SMBP was used for the first time in Group I.

‡After SMBP was used for the second time in Group I.

The results of tests for compliance with treatment were not available for all patients (Table 5), but showed that the percentage of patients considered compliers was similar in

TABLE 4 Percentage of Patients Whose Pharmacological Treatment Was Changed During the Study (%)*

Changes Made	Group I (N=622)	Group C (N=703)	Difference (95% CI)
At any visit	34.9	29.9	5.0 (-15.5 to 25.5)
At 6 weeks	21.0	17.8	3.1 (-12.1 to 18.3)
At 8 weeks	14.3	10.3	4.0 (-5.8 to 13.8)
At 14 weeks	12.3	7.4	4.8 (-1.6 to 11.3)
At 16 weeks	9.9	5.3	4.6 (-2.4 to 11.6)
At 24 weeks	7.3	4.8	2.5 (-4.9 to 10.3)

*C indicates control; I, intervention; 95% CI, 95% confidence interval.

TABLE 5 Compliance by Patients According to Morisky-Green Haynes-Sackett Tests*

Test and Visit	Group I†	Group C†	Difference‡ (95% CI)
Morisky-Green			
Week 6	365/607 (60.1)	361/684 (52.8)	7.3 (-9.0 to 23.7)
Week 14	282/480 (58.7)	303/552 (54.9)	3.8 (-15.0 to 22.8)
Haynes-Sackett			
Week 6	462/533 (86.7)	531/607 (87.5)	-0.8 (-12.7 to 11.1)
Week 14	343/374 (91.7)	416/451 (92.2)	-0.5 (-9.3 to 8.2)

*Data are shown as the number of patients considered compliers for each test divided by the number of responses available for the test (percentages in parentheses). C indicates control; I, intervention; 95% CI, 95% confidence interval.

†Difference of proportions.

both groups according to the Haynes-Sackett test, and slightly higher in group I according to the Morisky-Green test.

Patient satisfaction, determined for 408 of the 703 (58%) patients in group C and for 367 of the 622 (59%) patients in group I, was greater in the latter group (20.6) than in group C (16.3), by a difference of 4.3 points (95% CI, -4.2 to 12.8).

Satisfaction of health care professionals is shown in table 6. In group I, both physicians and nursing professionals scored higher than in group C with regard to previous experience with SMPB and belief in the usefulness of this approach in optimizing the treatment and control of HT. The time physicians spent providing instructions to patients on how to use the SMBP monitor was less than 10 min in 62.5% of the cases, and the time nurses spent was 10 to 20 min in 73.3% of the cases.

Discussion

A number of organisms¹⁷⁻¹⁹ recommend the use of SMBP. Among other reasons, they suggest that this technique can help improve the control of HT and achieve

TABLE 6 Satisfaction Among Professionals*

Group	Physicians		Nurses	
	C (N=39)	I (N=38)	C (N=9)	I (N=30)
Previous experience with SMBP	53.8	60.5	48.3	30.0
Feels that SMBP raises the patient's awareness of his or her HT	82.0	94.7	86.2	96.7
Feels SMBP data are useful in optimizing HT treatment	92.3	97.4	93.1	100
Feels SMBP is useful in improving control of BP	92.3	92.1	89.7	100

*Data are given as the percentage of patient who answered "Yes." C = Control, I = Intervention.

greater patient involvement in compliance with recommended therapeutic measures.²⁰

Although the number of BCU we analyzed was much lower than the number initially foreseen when we calculated sample size, we found the intervention to have a positive effect after the first period of SMBP between week 6 and week 8. After this brief period the percentage of patients whose BP was reduced to target values was 27.5% in group I. Although the prevalence of obesity was slightly higher in the control group (Table 1), this difference was not statistically significant in light of the effect of the study design (cluster randomization), and in any case was insufficient to account for the finding, given that baseline values for systolic and diastolic BP were practically identical in the 2 groups. The apparent decrease in the effect after the second period with SMBP may be due to extinction of the effect in the medium term (after about 3-4 months) and to dilution owing the greater number of patients lost to follow-up, which were considered failures according to the intention-to-treat analysis.

When we analyzed changes in medication (treatment adjustment) we found them to be more frequent in the intervention group. However, this did not translate as better control of HT in the medium term. It is clear that SMBP is useful in the follow-up of patients with HT since it provides physicians with more BP values, which can then be used as a more solid basis to modify therapy than single BP measurements obtained in the clinic. Moreover, the usefulness of SMBP in selecting patients for participation in clinical trials has been demonstrated.²¹

Unlike other studies,^{22,23} our results based on data obtained with the questionnaires of Morisky-Green and Haynes-Sackett failed to show a greater commitment by patients to compliance with therapy.

The lack of clear findings with regard to patient satisfaction may be a result of insufficient sensitivity of the ques-

Discussion
Key points

What Is Known About the Subject

- Blood pressure varies widely during any given 24-hour period.
- Self-measurement of blood pressure (SMBP) is a blood pressure measuring technique that is especially suitable for primary care.
- The usefulness of SMBP in comparison to usual clinical practice for controlling blood pressure is unknown.

What This Study Contributes

- SMBP is effective in controlling blood pressure when used for the first time, but its effectiveness appears not to be maintained when it is used a second time.
- SMBP may make antihypertensive treatment easier to adjust.
- This study found no impact of SMPB on patient satisfaction.

tionnaire we used, which was designed to evaluate satisfaction with general aspects of the care.²⁴ The data provided by health professionals regarding their satisfaction with SMBP were too scarce to draw reliable conclusions. In other studies, improved user satisfaction and adherence to treatment through the use and spread of SMBP have been useful in enhancing the follow-up of patients with HT for longer periods.²⁵

The need for follow-up of patient with HT by both medical and nursing professionals has been well established. The latter are in a better position to carry out health education activities in general and to provide patients with information about SMBP. In the present study nursing staff spent more time teaching and training patients about the self-measurement technique than did physicians. However, in this report we did not analyze the differences between the 2 groups of health care professionals.

A limitation of this study is the smaller number of BCU and patients than in the initial estimate of sample size. This decreased the power of the study to detect differences between the 2 groups, especially in the second evaluation of BP after the second use of SMBP because of the loss of patients to follow-up (20% of the total number of patients).

In conclusion, the results of the present study show that SMBP is effective after an initial period of use, but its ef-

fectiveness appeared not to be maintained in a second period of use. This loss of effectiveness may compromise its practical usefulness for achieving good long-term control of blood pressure.

Acknowledgments

We thank Juani Zamora for her help with the statistical analyses, and the principal investigators of the Dioampa group for recruiting patients and gathering data.

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COMMENTARY

Self-Measurement of Blood Pressure, Compliance With Therapy and Blood Pressure Control

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Given the important place of hypertension in daily clinical practice, any advance or contribution that sheds light on new aspects of diagnosis, evaluation, treatment or follow-up is received by professionals with keen interest. In this connection, self-measurement of blood pressure (SMBP) has been introduced in recent years as a useful tool for managing patients with hypertension. Among its widely reported advantages are its diagnostic value (avoiding the alert reaction), its usefulness in evaluating variability in blood pressure, its contribution to the evaluation of the antihypertensive effects of different drugs, and its good correlation with involvement of target organs. These features clearly outweigh the limitations of this method,¹ which has been recommended in current international consensus documents on hypertension.

Key Points

- Self-measurement of blood pressure is a useful tool for the diagnosis and follow-up of hypertension.
- Involving patients in their health care process helps improve adherence to therapy and control of the illness.
- The findings of the Dioampa study do not support the usefulness of self-measurement of blood pressure in improving compliance with antihypertensive therapy or the control of blood pressure, although other studies do suggest a role for self-measurement by patients.

One of the biggest challenges now faced in actual clinical practice is obtaining patients' active participation in controlling their illnesses in general, and hypertension in particular. The patient's involvement in the health care process is needed to modify attitudes and behaviors related with fundamental aspects such as adherence to therapy. It should not be forgotten that noncompliance rates among patients with hypertension can be as high as 30%-40%,² so without progress in this area, improved control of the process will be difficult to achieve.

In this context the Dioampa study attempts to show that in addition to the advantages of SMBP noted above, it has the potential to raise patients' awareness and level of motivation, thus presumably improving compliance with therapy and control of their hypertension. The authors' working hypothesis seems reasonable: if we are able to involve our patients in the evaluation and follow-up of their illness, as with SMBP, this would probably have a positive effect on their awareness of their disease and their motivation to take part in its treatment. This attitude, in turn, would lead to improved compliance with treatment, and would eventually lead to better control of their hypertension, as suggested by the positive outcomes of previous studies.³⁻⁵ However, the results were not as positive as hoped, and contrasted with those of earlier studies. Although there was an initial increase in the percentage of patients whose blood pressure was well controlled, this positive effect was diluted over the short term with no gains in the rate of adherence to therapy or in the control of blood pressure.

Many studies have been published on the problem of non-compliance with therapy in patients with hypertension.² There is evidence that involving the patient in the health care process helps improve compliance, but it may be unrealistic to assume that a single intervention might provide the solution to a complex situation such as noncompliance with treatment. The etiology of this problem is multifactorial and represents a pattern of behavior that tends to recur with time. The best results among attempts to deal with this problem have been obtained with combined, long-term techniques; the effectiveness of a single technique used on a single occasion tends to be limited, and its benefits tend to fade with time.^{6,7}

With regard to the other main objective analyzed in this study—the degree of control of blood pressure achieved—

lack of adherence to therapy is undoubtedly one of the most important factors in the poor results seen on a national and international level. However, there are other factors that should also be considered in any evaluation of the problem, such as underdiagnosis or treatment that is insufficient to meet real needs.^{8,9} These factors also depend on attitudes and behaviors, but in this case it is the attitude and behavior of health professionals, not their patients, which are involved.

The article by Dalfó i Baqué et al may thus serve to place SMBP in perspective. It cannot be considered a miracle method that provides an instant cure—all for all the problems faced by our patients with hypertension. Nevertheless, we should not neglect SMBP because of its limitations, as its drawbacks are amply compensated by its well-documented usefulness.

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