

# Home blood pressure telemonitoring improves hypertension control in general practice. The TeleBPCare study

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**Background** Self blood pressure monitoring at home may improve blood pressure control and patients' compliance with treatment, but its implementation in daily practice faces difficulties. Teletransmission facilities may offer a more efficient approach to long-term home blood pressure monitoring.

**Methods** Twelve general practitioners screened 391 consecutive uncontrolled mild–moderate hypertensive patients (80% treated), 329 of whom ( $58 \pm 11$  years, 54% men) were randomized to either usual care on the basis of office blood pressure (group A,  $n = 113$ ) or to integrated care on the basis of teletransmitted home blood pressure (group B,  $n = 216$ ). Twenty-four-hour ambulatory blood pressure monitoring was performed at baseline and after 6 months, during which treatment was optimized according to either office (group A) or home (group B) blood pressure values. We compared differences between groups in the rate of daytime ambulatory blood pressure normalization ( $<130/80$  mmHg), need of treatment changes during follow-up, quality of life scores, and healthcare costs.

**Results** Baseline office blood pressures were  $149 \pm 12/89 \pm 9$  and  $148 \pm 13/89 \pm 7$  mmHg in groups A ( $n = 111$ ) and B ( $n = 187$ ) respectively, the corresponding daytime values being  $140 \pm 11/84 \pm 8$  and  $139 \pm 11/84 \pm 8$  mmHg. The percentage of daytime blood pressure normalization was higher in group B (62%) than in group A (50%) ( $P < 0.05$ ). There were less frequent treatment changes in

group B than in group A (9 vs. 14%,  $P < 0.05$ ). Quality of life tended to be higher and costs lower in group B.

**Conclusion** Patients' management based on home blood pressure teletransmission led to a better control of ambulatory blood pressure than with usual care, with a more regular treatment regimen. *J Hypertens* 27:198–203  
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**Keywords:** ambulatory blood pressure monitoring, antihypertensive treatment, arterial hypertension, blood pressure control, home blood pressure monitoring, home blood pressure teletransmission, office blood pressure, patients' compliance, quality of life, self blood pressure monitoring at home

**Abbreviations:** ABP, Ambulatory Blood Pressure; DBP, Diastolic Blood Pressure; HBPM, Home Blood Pressure Monitoring; SBP, Systolic Blood Pressure

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## Introduction

Self home blood pressure monitoring (HBPM) has a number of potential advantages in the management of hypertension [1]. These advantages include avoidance of the 'white-coat effect', availability of multiple BP readings over a wide time window, evaluation of the effects of treatment on BP at different times of the day, and improvement in patients' adherence to therapy [1,2]. However, this approach also has potential drawbacks that can make its current implementation difficult in the clinical practice. These include the use of nonvalidated devices, need of patient's training, the risk of patients becoming neurotically obsessed by the procedure, not infrequently with self-modifications of the prescribed antihypertensive treatment [3], and the possibility of an inaccurate report of home BP values by patients [4]

as well as the difficulty for the physician to reach appropriate diagnostic conclusions from evaluation of often badly hand-written patients' BP reports. Indeed, it has been reported that in 54% of the cases, general practitioners (GPs) fail to draw any meaningful conclusion out of patients' BP log books [5].

Progress in technology over the last few years has led to the availability of a number of systems for digital storage of HBPM data and for their teletransmission to remote sites [6]. Some observations have suggested that a combination of HBPM with teletransmission facilities may remove some of the inconveniences related to HBPM alone, allowing better clinical results to be achieved [7,8]. The aim of our study was to address this issue more specifically and to assess the impact of HBPM and data

teletransmission (TeleBPCare) on the achievement of ambulatory blood pressure (ABP) control by hypertensive patients followed in general practice.

## Methods

### Study design

This was a multicenter, open-label, randomized, controlled, parallel group study that included 12 primary care physicians operating in the Milan area (Italy) and was aimed at demonstrating the ability of HBPM data teletransmission as compared with usual care based on office BP measurements only, to obtain a higher rate of ABP normalization, defined as a daytime average systolic blood pressure (SBP) less than 130 mmHg and diastolic blood pressure (DBP) less than 80 mmHg. We did not plan to include an HBPM group without telemonitoring to keep the study design as simple as possible (given its implementation in a general practice setting) and because comparisons between patients' management based on 'regular' HBPM or office BP measurements have already been made in previous studies (see below).

### Patients and sample size

On the basis of the expectation of a 15% difference in the number of patients reaching average daytime ABP normalization in favour of the group randomized to HBPM and telemonitoring as compared with the control group, a minimum number of 288 patients were required to guarantee a power of 80% and a minimum level of significance of 0.05. Three hundred and ninety-one hypertensive patients, consecutively seen in the GPs' offices, were screened for inclusion in the study. Inclusion criteria were an age between 18 and 75 years, a diagnosis of uncontrolled essential hypertension, as defined by the occurrence of an office SBP of at least 140 mmHg or DBP of at least 90 mmHg and by an ambulatory mean daytime SBP of at least 130 mmHg or DBP of at least 80 mmHg (regardless of whether patients were or were not treated). Exclusion criteria were a diagnosis of secondary hypertension; major systemic diseases; atrial fibrillation or frequent cardiac arrhythmias or severe atrioventricular block, that is, conditions that could make HBPM and ABP measurements unreliable; obesity (BMI >30 kg/m<sup>2</sup>) or an arm circumference of more than 32 cm or both, to avoid inaccuracies in automated BP readings due to arm-cuff mismatch; and any condition that might prevent patients' participation in the study, for example, technical problems due to incompatible phone lines at home.

### Study groups

Three hundred and twenty-nine out of the screened 391 patients (age, 58 ± 11 years; 54% men) fulfilled the study inclusion/exclusion criteria and were randomized at an approximate 1:2 ratio into two groups. Group A (control group, 113 patients) was assigned to an office BP-based management, treatment being aimed at reducing office BP to less than 140/90 mmHg [9]. Office BP values were

measured by the physician at the time of the visits through the same automated device used for home BP measurement in the other group (see below). Group B (TeleBPCare group, 216 patients) was assigned to a management based on HBPM combined with teletransmission of home self-measured BP values in between the scheduled clinic visits. In this group, treatment was titrated to reduce home BP to less than 135/85 mmHg [10]. In both groups, the rate of BP control was determined by the number of patients who achieved a daytime average ABP value of less than 130/80 mmHg at the end of the follow-up period. In order to achieve the treatment BP goals, physicians were allowed to prescribe any anti-hypertensive drug or drug combination they regarded as clinically appropriate [9].

### Study procedures

All patients were subjected to at least five office visits: at screening (visit one), at randomization (visit two, after 1 week), and during follow-up (visits three to five, after 4, 12, and 24 weeks, respectively). At inclusion, the patient's history was taken, combined with a physical examination and two BP measurements at a 5 min interval using the validated oscillometric device that had to be used for HBPM (Tensiophone device; Tensiomed, Budapest, Hungary). The software of this device was validated according to the International Protocol recommended by the European Society of Hypertension Working Group on BP monitoring [11]. The device is equipped with a built-in modem permanently plugged to the house phone line and subjected to remote programming of the frequency of measurements as well as of the time of a telerecalling beep, which can be sent to the patient to stimulate adherence to measurement schedule whenever appropriate. Self-monitored BP values were regularly transmitted to a referral centre where data were checked and stored in a digital database. Values exceeding upper and lower predefined arbitrary safety thresholds (180/110 and 100/60 mmHg, respectively) triggered an alarm, on the basis of which a dedicated trained nurse called the patient at home to check his/her clinical status and the possibility of artefactual measurements. Whenever needed, the physician in charge was immediately alerted, and an additional office visit was scheduled. At each of the subsequent visits, BP was measured according to the same procedure, and information was obtained on adverse events and the occurrence of changes in the treatment regimen made by the patient. In patients randomized to TeleBPCare, information was also obtained on the patients' compliance with HBPM using the data available at the call centre. This information was sent to the GPs together with the processed HBPM data by regular mail, fax, or e-mail immediately before any scheduled office visit.

In each patient, additional measurements included hematochemistry values; an ECG; two 24-h ABP monitorings (randomization and study end) by means of a

**Table 1 Demographic and clinic characteristics of patients at baseline**

	Control group (N = 111)	TELE HBPM (N = 187)	P
Age, mean $\pm$ SD (years)	58.1 $\pm$ 10.8	57.2 $\pm$ 10.7	0.490
Men, n (%)	60 (54.1)	102 (54.5)	0.934
BMI, mean $\pm$ SD (kg/m <sup>2</sup> )	26.9 $\pm$ 3.6	26.9 $\pm$ 4.1	0.949
Treated hypertensive patients, n (%)	85 (76.6)	148 (79.1)	0.604
Clinic SBP, mean $\pm$ SD (mmHg)	148.7 $\pm$ 11.7	148.4 $\pm$ 12.6	0.820
Clinic DBP, mean $\pm$ SD (mmHg)	88.8 $\pm$ 8.6	88.7 $\pm$ 7.4	0.918
Daytime SBP, mean $\pm$ SD (mmHg)	140.3 $\pm$ 10.5	139.4 $\pm$ 11.0	0.508
Daytime DBP, mean $\pm$ SD (mmHg)	84.3 $\pm$ 8.2	83.9 $\pm$ 8.0	0.640

DBP, diastolic blood pressure; SBP, systolic blood pressure; TELE HBPM, teletransmission of home blood pressure monitoring values.

validated oscillometric device (Tensioday, Tensiomed) [11] using the same hardware components and software as the Tensiophone device used for home and office BP measurements; and a quality of life score, assessed by the administration of a modified short form-12 questionnaire [12] at randomization and at the end of follow-up. Information on additional doctors' visits as well as on treatment changes between visits was also obtained from the electronic clinical chart.

#### Endpoints and statistical analysis

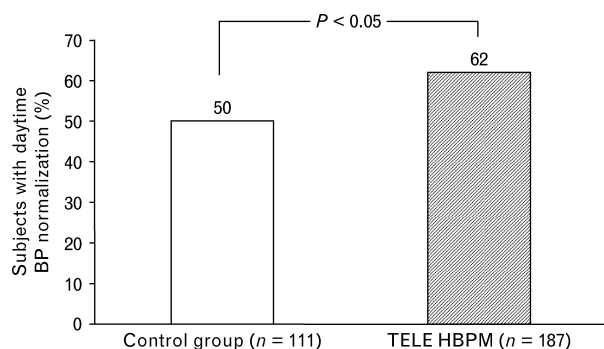
The study primary endpoint was the percentage of patients who reached normalization of daytime ambulatory SBP and DBP (i.e. <130/80 mmHg) at the end of the follow-up period. Secondary endpoints were the rate of normalization of office and home SBP/DBP (the latter, by protocol, only in group B), the frequency of treatment changes originated either by the physician or by the patient, and the impact of the assigned management system on the quality of life and healthcare costs. Healthcare costs were computed by considering the number of unscheduled additional visits, the number and type of examinations prescribed, and the number and type of drugs prescribed during follow-up. Also, the costs of renting of the TeleBPCare service for the duration of the study were considered.

Out of these 329 patients, 288 patients, in whom all data were available at the end of the study, were included in the intention-to-treat analysis. Data analysis was carried out by the SPSS for Windows software, version 11.5 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were described through the calculation of average  $\pm$  SD values for each dataset. Discrete variables were described by their absolute and relative frequency of occurrence. Between-group differences were assessed by analysis of variance for continuous variables and by the chi-squared test of Mantel-Haenszel for discrete variables. The between-group comparison of the percentage of patients with normalized ABP was made by chi-squared test. Throughout the study, the level of statistical significance was set at a *P* value of less than 0.05. Patients were included in the study after obtaining informed consent. The study was approved by the Ethics Committee of one of the institutions involved.

#### Results

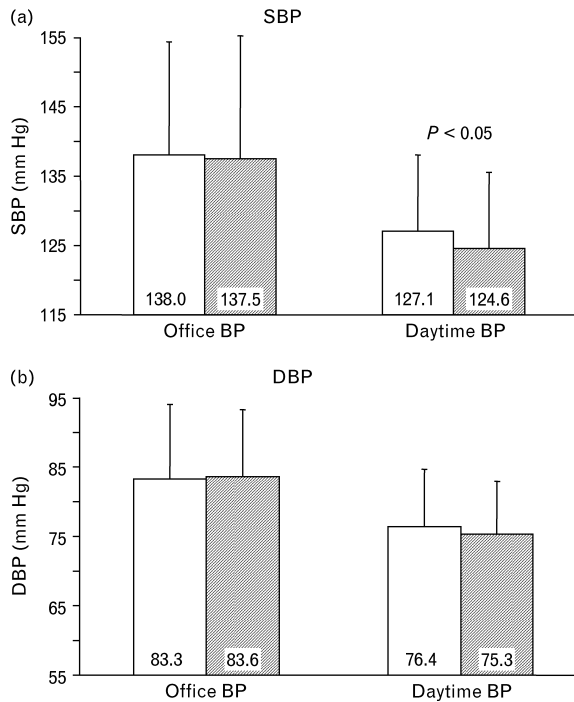
Table 1 shows that the baseline demographic and clinical characteristics of the 288 patients of the intention-to-treat population were similar in the two groups. Treatment induced a clear reduction in daytime ABP in both groups, but the percentage of patients in whom daytime ABP was normalized by treatment was significantly greater in the group assigned to TeleBPCare than in the control group (Fig. 1). As shown in Fig. 2, daytime ABP recorded at the end of the follow-up was also lower in the TeleBPCare than in the control group, the difference being statistically significant for SBP, whereas the achieved office BP did not exhibit a significant between-group difference. This was also the case for the rate of office BP normalization (52% TeleBPCare vs. 53% control group). Conversely, in patients of the TeleBPCare group, rate of home BP normalization was very high (74% of patients), with a persistent BP reduction during follow-up (Fig. 3).

As shown in Table 2, in the group randomized to HBPM teletransmission, there was a nonsignificant trend towards a reduction in the number of additional diagnostic examinations prescribed by GPs. This was also the case for calculated healthcare costs, which also considered renting

**Fig. 1**

Percentage of patients with daytime normalization (SBP <130 mmHg and DBP <80 mmHg). Data refer to the intention-to-treat population and to patients randomized to conventional management (control group, open bar, *n* = 111) or teletransmission of home BP values (TELE HBPM, striped bar, *n* = 187). BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; TELE HBPM, teletransmission of home blood pressure monitoring values.

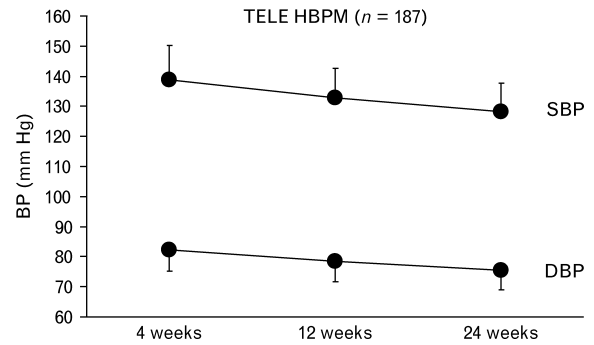
Fig. 2



Average ( $\pm$ SD) office and daytime systolic blood pressure (a) and diastolic blood pressure (b) values at the end of the study in the patients randomized to conventional management (control group, open bars,  $n = 111$ ) or to teletransmission of home BP values (TELE HBPM, striped bars,  $n = 187$ ). BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; TELE HBPM, teletransmission of home blood pressure monitoring values.

costs of the TeleBPCare service for the duration of the study. Patients randomized to TeleBPCare were more adherent to the prescribed treatment schedule than the control group, as shown by the significantly lower rate of treatment self-modification (Table 2). No significant between-group differences were found in the rate of change in treatment regimens prescribed by the physicians and in the quality of life assessment (Table 2).

Fig. 3



Average ( $\pm$ SD) home systolic and diastolic blood pressure values during the study in the patients randomized to teletransmission of home BP values ( $n = 187$ ). BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; TELE HBPM, teletransmission of home blood pressure monitoring values.

## Discussion

In the patients of our study, self-measurement of BP at home combined with teletransmission of the data so obtained was associated with a significant increase in the number of patient achieving ABP control at the end of the study period as compared with the group randomized to traditional management. This provides evidence that when self-measurements of BP are regularly and objectively transmitted to the physicians in charge of patients' care, management of hypertensive patients is definitively more successful. This is of obvious clinical relevance because the low rate of BP control in the hypertensive population represents a major health problem [13] and a factor responsible for hypertension being considered as one of the major causes of death and disease worldwide [14,15].

Several other points of our study deserve to be mentioned. First of all, in our study, BP control was determined by ABP monitoring which provides BP values devoid of inconveniences such as the white-coat effect

**Table 2** Additional diagnostic examinations, patient management costs, treatment modifications by physicians or patients, and quality of life scores (Quality Of Life Assessment in Hypertensive Patients questionnaire) during the randomized study phase

	Control group (N=111)	TELE HBPM (N=187)	P
Diagnostic examinations, n (%)	67 (20.1)	95 (16.9)	0.232
Diagnostic examinations per patient (mean $\pm$ SD)	1.8 $\pm$ 3.3	1.3 $\pm$ 2.6	0.189
Cost of examinations (€, mean $\pm$ SD)	7.31 $\pm$ 21.30	5.83 $\pm$ 12.76	0.451
Overall cost of patient management (€, mean $\pm$ SD)	125.26 $\pm$ 60.61	123.41 $\pm$ 36.49	0.742
Treatment modification			
By patients, n (%)	45 (13.5)	49 (8.7)	0.040
By physicians, n (%)	51 (15.3)	75 (13.4)	0.419
Quality of life			
Baseline	38.2 $\pm$ 4.5	37.7 $\pm$ 4.8	0.502
End of study	38.3 $\pm$ 5.4	38.4 $\pm$ 4.6	
End of study - baseline difference	0.1 $\pm$ 3.9	0.7 $\pm$ 4.3	0.273
End of study - baseline difference (%)	0.5 $\pm$ 10.4	2.6 $\pm$ 12.7	0.090

TELE HBPM, teletransmission of home blood pressure monitoring values.

and the physicians' bias affecting office BP measurements [16,17]. This adds to the reliability of our results, the clinical implication of which is further reinforced by the fact that data were obtained in a general practice setting. Second, in our study, the advantage of combining self-measurement of BP at home with data teletransmission is supported by two additional findings. That is, in patients randomized to HBPM and teletransmission, the percentage of treatment modifications by the patients was significantly ( $-35.6\%$ ,  $P < 0.05$ ) less than in the control group, with a concomitant nonsignificant trend towards a reduced number of requested diagnostic examinations and a better quality of life. Third, although the study design prevented a comparison with the control group, home BP values were substantially reduced in the group subjected to HBPM and teletransmission with a high rate of BP control on the basis of upper normality values indicated by available hypertension guidelines (74% of patients with home BP  $< 135/85$  mmHg) [9]. This is also of clinical relevance because home BP has recently been repeatedly found to have an important prognostic value [18–22].

Our study has a few limitations. One, the design adopted does not allow us to discriminate the role played by HBPM *per se* and by HBPM combined with teletransmission facilities in obtaining a greater rate of BP control. This would have needed comparison of BP control in groups with HBPM combined or not with teletransmission. We deliberately did not add such a comparison in our study. This was done to keep our study design as simple as possible, given its implementation in a general practice setting, where investigation protocols may raise more difficulties than in a research laboratory. Moreover, it should be emphasized that in a number of previous studies, on comparing office BP measurements with HBPM alone, the rate of BP control was not or only marginally increased, which speaks in favour of a possible added value of the teletransmission approach [23–26]. However, we acknowledge that a comparison between HBPM with or without its association with telemonitoring has not yet been systematically performed, and that this issue should be specifically addressed by future studies. Two, the advantage shown by combined HBPM and teletransmission was less evident on BP control and on BP values measured by the physicians in their office. This may unmask the limits of conventional BP measurements (persistent white-coat effect, physician's bias, impact of short duration of the visit, etc.) particularly in general practice and suggest that demonstration of the benefit of new technologies applied to hypertension management, such as telemedicine facilities, may have to be addressed by means of more objective BP measurements such as ABP monitoring. Finally, in our study, the between-group difference in some secondary parameters, such as reduction in the number of additional diagnostic examinations, calculated healthcare costs, and quality of

life scores, was not statistically significant, although showing a trend towards an improvement in the telemonitoring group. This might depend on the fact that the sample size was estimated focusing on the primary endpoint only. The interest of demonstrating possible favourable changes induced by telemonitoring also in these parameters should thus stimulate additional studies with a larger sample size.

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