

# Self-Measurement and Self-Titration in Hypertension

## A Pilot Telemedicine Study

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**Background:** Because of poor patient compliance and clinical inertia, hypertension control rates remain poor. Home blood-pressure measurements (HBPM) improve compliance of patients and achievement of blood pressure (BP) targets. However, few studies have evaluated self-BP management by patients.

**Methods:** In a multicenter, prospective, single-group, open-label pilot study of 111 patients whose hypertension was uncontrolled despite monotherapy, we studied satisfaction with, and feasibility of, HBPM and self-titration of antihypertensive treatment using telemedicine for compliance, efficacy, and safety. After education (protocol, action plan, and use of the HBPM device), patients performed a sequence of HBPM every 2 weeks for 8 weeks. Following a stepwise approach, treatment was increased by the patient at weeks 4 and 6 if average HBPM values exceeded predefined limits. For each titration, the patient informed the Core Center by telemedicine, but BP values were transferred automatically.

**Results:** Overall, 80% of patients were satisfied (58% or very satisfied (23%) with the program (95% confidence interval, 73% to 87%). Regarding compliance, 78% of patients fully complied with self-measurement, and just over 71% titrated their treatment adequately. Physicians were satisfied (52%) or very satisfied (22%) with the program. Between the first and final visits (at week 8), office systolic/diastolic BP (mean  $\pm$  SD) decreased significantly from  $151 \pm 9/91 \pm 6$  to  $143 \pm 13/84 \pm 11$  mmHg. During the trial, HBPM (mean  $\pm$  SD) decreased significantly from  $149 \pm 13/86 \pm 12$  to  $138 \pm 16/81 \pm 10$  mmHg. No significant safety issues were reported.

**Conclusions:** This innovative approach to the management of hypertension, combining self-measurement and self-titration, is feasible, well-accepted by both patients and physicians, and safe. *Am J Hypertens* 2007;20:1314–1320 © 2007 American Journal of Hypertension, Ltd.

**Key Words:** Hypertension, self blood-pressure measurement, self-titration, telemedicine.

Recent hypertension guidelines for the management of hypertension have once again underscored the need for strict blood pressure (BP) control to decrease the risk of morbidity and mortality in hypertensive patients.<sup>1–3</sup> However, control rates in treated hypertensive patients remain poor (20% to 50%),<sup>4</sup> which could be explained in part by poor patient compliance<sup>5</sup> and by the clinical inertia of physicians.<sup>6</sup>

Home blood-pressure monitoring (HBPM) is a well-established technique. The latest guidelines for BP man-

agement endorse its use to provide more information for clinical decision-making.<sup>2,7</sup> Home blood-pressure monitoring could also improve patient adherence to treatment regimens<sup>8</sup> and the achievement of target BP levels.<sup>9</sup> The use of telemedicine might yield incremental benefits and decreases in BP.<sup>10,11</sup> Further improvement of BP control would certainly require additional and alternative models of care, including HBPM and self-BP management, with patients adjusting their antihypertensive regimen according to a predefined action plan.<sup>12,13</sup> However, unlike other

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\*Self-Evaluation and Titration in High Blood Pressure.

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successful experiences in asthma, diabetes mellitus, or diseases requiring long-term oral anticoagulation, there are very few initiatives evaluating self-BP management by patients.<sup>14,15</sup>

We designed a pilot study to assess the satisfaction of patients as well as the feasibility of self-titration based on self-evaluation of BP in a small group of hypertensive patients with a novel education program assisted by telemedicine. Because such an approach has not been formally tested, we felt that it would be more relevant to focus our main objective on satisfaction. Indeed, the generalization of this approach would be impossible in the event of poor satisfaction. Given the high prevalence of hypertension, even a small percentage of satisfied patients would mean that this novel approach could be proposed to a significant number of patients. By choosing captopril, a short-acting antihypertensive agent requiring several intakes per day, initially prescribed at a low dose and once daily, we sought to avoid achieving BP control too quickly, so as to encourage the necessity of titration. For safety reasons, we used a validated electronic HBPM device<sup>16</sup> which allowed the tele-transmission of BP data and of the titration decisions made by the patient to a Core Center via a standard telephone line.

## Methods

### Patient Population

The study was performed by 42 office-based physicians belonging to a French nationwide network of general practitioners (GPs) involved in clinical research (MG Recherches). Hypertensive patients aged  $\geq 18$  years treated by monotherapy, with either uncontrolled hypertension (systolic blood pressure [SBP]  $\geq 140$ , or diastolic blood pressure [DBP]  $\geq 90$  mm Hg) or treatment-related side effects, were eligible for the study. Exclusion criteria included severe hypertension (SBP  $\geq 180$ , or DBP  $\geq 110$  mm Hg); a known or suspected allergy to diuretics, angiotensin-converting enzyme-inhibitors, or angiotensin receptor blockers; hyponatremia or hypovolemia; secondary hypertension; uncontrolled hypertension after the administration of two antihypertensive drugs; diabetes mellitus; renal impairment (serum creatinine,  $\geq 150$   $\mu\text{mol/L}$ ); the concomitant use of other antihypertensive drugs; obesity (with which the HBPM device is not validated); or any other significant associated disease (cardiovascular, neurologic, endocrinologic, metabolic, or oncologic).

Of 112 patients enrolled in the study, one patient who was diabetic was excluded before the first drug intake and did not participate. The analyzed population included 111 patients: four patients completed the study despite two major (diabetes mellitus,  $n = 2$ ) or two minor (untreated hypertension,  $n = 1$ ; use of another antihypertensive drug,  $n = 1$ ) protocol deviations. Eleven patients did not complete the entire 8-week program because of a technical problem ( $n = 5$ ), a suspected side effect ( $n = 3$ ), or the

**Table 1.** Baseline characteristics

|                                      |                |
|--------------------------------------|----------------|
| Total number of subjects             | 111            |
| Age (y)                              | 59 $\pm$ 11    |
| Sex (male/female, %)                 | 57.6/42.4      |
| BMI (kg/m <sup>2</sup> )             | 27.6 $\pm$ 4.5 |
| Hypertension duration (y)            | 5.9 $\pm$ 5.4  |
| Systolic OBP (mm Hg)                 | 151 $\pm$ 9    |
| Diastolic OBP (mm Hg)                | 91 $\pm$ 6     |
| Systolic HBPM (mm Hg) ( $n = 103$ )  | 149 $\pm$ 19   |
| Diastolic HBPM (mm Hg) ( $n = 103$ ) | 86 $\pm$ 12    |

All values are expressed as mean  $\pm$  standard deviation.

BMI = body mass index; OBP = office blood pressure; HBPM = home blood-pressure measurement.

patient's withdrawal of consent ( $n = 3$ ). Baseline characteristics are summarized in Table 1.

### Study Design

The Self-Evaluation and Titration in High Blood Pressure (SETHI) Trial was a multicenter, prospective, open-label, single-group pilot study. Eligible patients were assessed by the investigator to ascertain that they could understand the use of the evaluation scales and communicate with the Core Center.

In addition to collecting detailed information on medical history and risk factors, the enrollment visit included a full physical examination and seated BP measurements with the same device used for HBPM. Patients were also required to fill out a simple questionnaire to evaluate their awareness of their hypertensive disease. The investigator then delivered some general background information about hypertension before explaining the action plan, the use of the HBPM device and HBPM protocol, the use of the telecommunication system for transmitting BP data and titration decisions, and the need to report any adverse event during the course of the study. Patients received detailed instructions for dose titration based on HBPM performed at weeks 2, 4, and 6, as well as a study handbook and a videotape which summarized all the necessary information.

### HBPM Protocol

At the end of weeks 2, 4, 6, and 8, patients performed HBPM twice a day for 3 consecutive days: three seated measurements at 1-min intervals between 6 and 11 AM and between 6 and 11 PM before their next drug intake. The device was set to be used only in these predetermined weeks and at these predetermined times during the day, thus ensuring the patient did not deviate from protocol.

### Recording of BP Data, Titration Decisions, and Events

Patients indicated decisions concerning their self-titration (increase, maintain, or decrease) by pressing a button a certain number of times on the device. This information

was automatically tele-transmitted, along with BP measurements, via a standard telephone line to a Core Center, which subsequently communicated the results to each investigator. All data were available for consultation in real time to the investigator, via the Internet, for health safety reasons.

Patients also recorded HBPM values in their study handbooks, along with the level and timing of dosing, changes in concomitant medications, adverse events, and any other study-related comments. They also filled out a simple questionnaire.

### Action Plan for Titration

At the initial visit, the current antihypertensive monotherapy was replaced by the study treatment for 8 weeks. Patients initially received captopril 25 mg every morning for 2 weeks (level 1). At the end of week 2, captopril was force-titrated to 50 mg daily (level 2, 25 mg twice daily), unless home SBP was  $\leq 110$  mm Hg. At the end of weeks 4 and 6, self-titration to the next level was based on the average HBPM values: if SBP was  $\geq 135$  or DBP was  $\geq 85$  mm Hg, the patient received captopril at 50 mg twice daily (level 3) at the end of week 4, and captopril 50 mg twice daily + hydrochlorothiazide 25 mg every day (level 4, captopril 50 mg/hydrochlorothiazide 25 mg, fixed combination in the morning, and captopril 50 mg in the evening). At each titration step, the investigator was informed by the Core Center within 12 h if SBP was  $\leq 110$  mm Hg or  $\geq 180$  mm Hg, to decide if the patient had to be withdrawn from the study.

### Evaluation

To avoid any direct interference from the physician with the patient action plan, no visit was scheduled during the study. The second and final visit occurred at the end of week 8, when a full clinical examination was performed, including seated BP measurements with the same device used for HBPM. The investigator carefully reviewed with the patient all data collected in the study handbook to assess compliance with the protocol procedures and timelines, changes in concomitant medications, and the incidence of adverse events. Finally, patients and investigators filled out a final satisfaction questionnaire comprising a number of items on a 4-point scale, adapted from a previously described questionnaire,<sup>17</sup> which we tested in a small number of hypertensive patients before the study. Satisfaction scores were derived from three main dimensions: information delivered (seven items; range, 7 to 28), difficulty of the protocol (two items; range, 2 to 8), and anxiety (four items; range, 4 to 16). The protocol and informed consent were approved by a National Ethics Committee, and all patients gave written, informed consent before any study-related procedure was undertaken.

### Outcome Measurements

The primary efficacy outcome measure was the overall satisfaction of patients, based on a single question, answered on a standardized 4-point scale, administered by the investigator at the final visit (On the whole, what is your level of satisfaction with this program: very dissatisfied, dissatisfied, satisfied, or very satisfied?).

Secondary efficacy outcome measures included:

- Patient acceptability and satisfaction were assessed with 4-point-scale questionnaires self-administered every 2 weeks (patient handbook), and with a more detailed questionnaire at the final visit.
- Patient compliance with both self-measurement and self-titration, according to the action plan, was assessed at the two elective titration phases (end of weeks 4 and 6). Compliance with HBPM was based on the number and timing of BP measurements: very good (at least 12 measurements performed at both periods), acceptable (at least 12 measurements performed at only one of the two periods), or poor (none of the above, or delay between the two periods  $\geq 21$  days). Compliance with self-titration was rated as follows: very good (valid titration at the end of both periods documented either electronically or in the patient's study handbook), acceptable (valid titration at the end of only one period, or valid titration at the end of both periods but not documented), or poor (invalid titration at the end of both periods).
- Physician satisfaction with the overall program for each individual patient was based on a final questionnaire.
- The efficacy (BP lowering) and safety of the captopril-based regimen after 8 weeks were evaluated.

### Statistical Methods

The primary endpoint and a number of secondary endpoints were based on patient and physician perceptions related to the overall program, in terms of satisfaction, feasibility, acceptability, and reliability. These multidimensional concepts are influenced by numerous factors, so we developed questionnaires with multiple dimensions and items. Each item was rated according to the Likert scaling method, using a four-point scale ranging from 1 to 4.

The primary efficacy analyses were performed on the analyzed population, ie, all patients enrolled and receiving the study drug, with at least one postdosing value for the primary outcome measure, including the 11 patients withdrawn from study. Questionnaires with multiple items were analyzed by item and according to a global score obtained after summing up the individual scores.

For the primary criterion related to overall patient satisfaction, the number and proportion of patients within each of the four categories were described, and the proportion of "satisfied" or "very satisfied" patients was calculated with its corresponding 95% confidence interval (95% CI). The sample size was calculated so that the lower

**Table 2.** Patient satisfaction throughout study

|                   | Week 2   |     | Week 4   |     | Week 6   |     | Week 8 or withdrawal |     |                         |
|-------------------|----------|-----|----------|-----|----------|-----|----------------------|-----|-------------------------|
|                   | <i>n</i> | %   | <i>n</i> | %   | <i>n</i> | %   | <i>n</i>             | %   | 95% confidence interval |
| Very satisfied    | 14       | 13% | 11       | 10% | 13       | 12% | 25                   | 23% | 15% to 30%              |
| Satisfied         | 48       | 43% | 48       | 43% | 43       | 39% | 64                   | 58% | 48% to 67%              |
| Dissatisfied      | 8        | 7%  | 5        | 5%  | 4        | 4%  | 10                   | 9%  | 4% to 14%               |
| Very dissatisfied | 2        | 2%  | 6        | 5%  | 6        | 5%  | 6                    | 5%  | 1% to 10%               |
| Missing data      | 39       | 35% | 41       | 37% | 45       | 41% | 6                    | 5%  | 1% to 10%               |
| Total             | 111      |     | 111      |     | 111      |     | 111                  |     |                         |

Data at weeks 2, 4, and 6 were collected via self-administered questionnaires at home in the study handbook. Data at week 8 were collected via a questionnaire administered by the investigator at the final visit.

bound of the 95% CI of the proportion of satisfied and very satisfied patients would be >15% (considered the acceptable proportion limit for such a program), assuming that the observed proportion would be  $\geq 25\%$ .

For the secondary evaluation criteria, the mean, median, and standard deviation were used for quantitative and ordered categorical variables, and the size or percentages for other categorical variables. For efficacy criteria, a sensitivity analysis was performed after imputing missing data, using the "last observation carried forward" principle. For office BP at week 8, no imputation was done, because baseline was the only prior available measurement. For HBPM at week 8, the last available measure was used (week 2, 4, or 6; baseline was never carried forward).

Paired tests (*t* tests or nonparametric tests) were used for statistical evaluation when appropriate;  $P < .05$  was considered significant. No adjustments were made for multiple comparisons. All analyses were performed using SAS 6.08 software (SAS Institute, Inc., Cary, NC).

## Results

The overall patient satisfaction assessed at the final visit (week 8 or withdrawal), based on a single item, could be

analyzed in 105 patients (six patients did not fill out the questionnaire): 25 patients were very satisfied (23%), 64 were satisfied (58%) 10 were dissatisfied (9%), and six were very dissatisfied (5%). On the whole, around 80% (95% CI, 73% to 87%) of patients were either satisfied or very satisfied with the program (Table 2). The low rate of response to the intermediate questionnaires probably occurred because data at weeks 2, 4, and 6 were collected via self-administered questionnaires at home in the study handbook, without the necessity or obligation to work with the medical investigators. In contrast, data at week 8 were collected via a questionnaire administered by the investigator at the final visit (week 8 or withdrawal). Based on the final patient questionnaire, patients felt well-informed about the protocol (average score,  $19.8 \pm 3.8$ ; range, 7 to 28;  $n = 96$ ), did not find the protocol difficult (average score,  $2.59 \pm 1.2$ ; range, 2 to 8;  $n = 98$ ), and felt low anxiety levels (average score,  $5.9 \pm 2.3$ ; range, 4 to 16;  $n = 83$ ).

Table 3 indicates the compliance with self-measurement and self-titration. The missing data are attributable to a noncompliance with protocol as specified before chart on the part of patients, and to certain temporary technical problems (failure of data tele-transmission) which did not lead to a cessation of protocol. About three quarters of

**Table 3.** Compliance with self-measurement and self-titration (end of weeks 4 and 6)

|                   | <i>n</i> | %   | Comments  |
|-------------------|----------|-----|---|
| Self-measurement  |          |     |   |
| Very good         | 87       | 78% | $\geq 12$ measurements performed at end of both periods   |
| Acceptable        | 6        | 5%  | $\geq 12$ measurements performed at end of one period   |
| Poor              | 1        | 1%  | None of the above, or delay between two periods $\geq 21$ days  |
| Not interpretable | 17       | 15% | Discontinuation of trial, or technical problem  |
| Total             | 111      |     |   |
| Self-titration    |          |     |   |
| Very good         | 57       | 51% | Valid titration at end of both periods, documented either electronically or in patient's study handbook |
| Acceptable        | 22       | 20% | Valid titration at end of only one period, or valid titration at end of both periods but not documented |
| Poor              | 14       | 13% | Invalid titration at end of both periods  |
| Not interpretable | 18       | 16% | Discontinuation of trial, or technical problem  |
| Total             | 111      |     |   |

**Table 4.** Efficacy results: Blood pressure differences (week 8 versus baseline)

|                              | <i>n</i> | Mean ± SD | Paired <i>t</i> Test |
|------------------------------|----------|-----------|----------------------|
| Office measurements          |          |           |                      |
| SBP                          | 61       | −10 ± 16  | <i>P</i> < .0001     |
| DBP                          | 61       | −8 ± 11   | <i>P</i> < .0001     |
| HBPM (observed data)         |          |           |                      |
| SBP                          | 75       | −10 ± 16  | <i>P</i> < .0001     |
| DBP                          | 75       | −4 ± 7    | <i>P</i> < .0001     |
| HBPM (sensitivity analysis)* |          |           |                      |
| SBP                          | 101      | −6 ± 17   | <i>P</i> = .0008     |
| DBP                          | 101      | −2 ± 8    | <i>P</i> = .017      |

SBP = systolic blood pressure; DBP = diastolic blood pressure; HBPM = home blood-pressure measurement.

\* Missing data were imputed using “last observation carried forward” methodology.

patients performed at least 12 measurements before the two elective titration phases, and just over 70% of patients titrated the treatment adequately (compliance rated very good or acceptable).

Physicians were globally satisfied with the program (two missing questionnaires). They were very satisfied with 22% of their patients, satisfied with 52%, dissatisfied with 15%, and very dissatisfied with 11%. The proportion of satisfied or very satisfied physicians (74%) was consistent with, although slightly less than, the proportion of satisfied or very satisfied patients (80%). Overall, physicians believed that their patients were satisfied or very satisfied with taking a more active role in the management of their disease in 79% of cases, and the program greatly improved the dialogue concerning disease management with patients in 59% of cases. However, physicians had to deal with a number of problems in 41% of patients: mostly technical (56%) or medical (19%), or based on the complexity of the protocol (21%).

Efficacy results are presented in Table 4. Between the first and final visits, office SBP/DBP (50 missing data) decreased from 151 ± 9/91 ± 6 to 143 ± 13/84 ± 11 mm Hg. The average decrease was 10 ± 16/8 ± 11 mm Hg (*P* < .0001/< .0001). Between weeks 2 and 8, HBPM decreased from 149 ± 13/86 ± 12 mm Hg to 138 ± 16/81 ± 10 mm Hg (36 missing data). The average decrease was 10 ± 16/4 ± 7 mm Hg (*P* < .0001/< .0001).

Safety analyses were performed in 110 patients (one patient did not receive any study drug). Overall, 43 patients reported 63 adverse events and three serious adverse events (relapse of non-Hodgkin’s malignant lymphoma = 1, angor = 1, and hypokalemia = 1). The relationship of the study drug to the serious events was either nonexistent (*n* = 2) or unlikely (*n* = 1). The intensity of other adverse events was mild to moderate in 81.9% of cases, and more than half of those events were either unrelated or unlikely related to the study drug, to the BP decrease, or to the overall program (54.5%).

## Discussion

This pilot study shows that a novel approach to the management of hypertension, combining self-measurement,

self-evaluation of BP results, and self-titration, is feasible and well-accepted by both patients and physicians. Our initial goal, ie, a satisfaction rate ≥15%, was clearly exceeded: overall, 80% of patients and 74% of physicians were either satisfied or very satisfied with this program. Good compliance with self-measurement and self-titration was 83% and 71%, respectively, with a marked decrease in BP, even if the use of the “last value carried forward” method to deal with missing data did not lead to accurate estimates of effect. In addition, there were no significant safety issues related to the program throughout the 8 weeks of follow-up. Therefore, similar to the established situation in the management of asthma, diabetes, or diseases requiring long-term oral anticoagulation, a self-management program based on self-measurement of BP and self-titration after patient education is well-accepted, effective, and safe in essential hypertension.

The main limitation of this pilot study was that it was a clinical trial, performed by GPs with a keen interest in clinical research who enrolled carefully selected patients. This type of program is probably not applicable to all physicians and patients: both must be motivated and convinced that it will translate into a more effective management of uncontrolled hypertension. Patients must also be able to understand and perform a technical procedure before making a decision regarding the appropriate titration to the next step. A qualitative study found that participants who demonstrated knowledge and understanding of hypertension tended to welcome their own involvement in the management of their disease, and expressed a willingness to make decisions for themselves.<sup>18</sup>

Only two small-scale studies evaluating self-titration were reported in the field of hypertension, and their findings are consistent with our own. In a group of 52 non-compliant hypertensive patients, the first study showed lower DBP values, better pill counts, and better attendance in patients trained to measure their own BP and to select their own drugs, compared with a control group.<sup>14</sup> In the second study, 31 hypertensive patients were randomized to either a patient-directed management strategy using HBPM to adjust drug therapy if required, or office-based management through physician visits for 8 weeks. Al-

though compliance rates and quality-of-life scores were no different between groups, a significant difference in mean BP decrease was observed, favoring patient-directed management.<sup>15</sup>

Self-measurement of BP is increasing, mostly through the direct access of patients to cheaper, more reliable, and easy-to-use devices. Patients find HBPM to be the most acceptable method.<sup>19</sup> The advantages of HBPM are significant: it allows the detection of white-coat and masked hypertension, and it defines cardiovascular prognosis more accurately than office BP measurement.<sup>20,21</sup> In addition, it has an important role in the education of patients and ultimately in the improvement of patient adherence to treatment.<sup>8</sup> The logical next step, in selected patients who are able and willing to become more involved in the management of their hypertension, is to give them the opportunity to take part in the adaptation of their antihypertensive treatment. This recommendation appears to be in conflict with the latest hypertension guidelines of the European Society of Hypertension and European Society of Cardiology,<sup>2</sup> which state that self-measurement of BP at home should be discouraged whenever it induces self-modification of the treatment regimen. However, self-titration can be achieved within a strict framework set by the physician and endorsed by the patient, based on a keen and open physician-to-patient relationship, with the use of tele-monitoring as an essential component to increase both compliance<sup>10,11</sup> and safety. Self-titration as part of an action plan with a stepwise approach requires the education of patients regarding their BP goals; ignorance of the BP target is one of the main predictors of poor BP control.<sup>22</sup> The involvement of patients in their own titration should also reduce the lack of titration related to clinical inertia.<sup>6</sup>

However, further research is required to demonstrate that the more widespread use of self-measurement and self-titration in hypertensive patients will translate into a significant improvement in BP control in the community and, more importantly, in the reduction of cardiovascular events.

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