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Effectiveness of an Intervention to Provide Information to Patients With Hypertension as Short Text Messages of Reminders Sent to Their Mobile Phone (HTA-Alert)

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Objective. To analyze the effect of an intervention to provide information with mobile phone text messages to patients with hypertension on compliance with therapy for hypertension.
Design. Comparative, controlled, multicenter, randomized cluster study.
Setting. 26 primary care health centers in Spain.
Participants. 26 researchers were randomized to a control group or an intervention group (52 patients each, for a total of 104 patients). All patients were receiving monotherapy for uncontrolled hypertension.
Intervention. Patients in the control group received their physician's usual interventions. Patients in the intervention group received messages and reminders sent to their mobile phones 2 days per week during 4 months.
Main outcome measures. Tablets were counted and blood pressure was measured at the start of the study and 1, 3, and 6 months later. The percentage of compliers, mean percentage of compliance and degree of control of hypertension were compared. The reduction in absolute and relative risk was calculated, as was the number of individuals needed to treat to avoid noncompliance.
Results. The results were evaluated for a total of 67 individuals (34 in the intervention group and 33 in the control group). The rate of compliance was 85.1% (CI, 74.9%-95.3%) overall, 85.7% (CI, 70.5%-100.9%) in the control group and 84.4% in the intervention group (CI, 70.7%-95.3%) (*P*=NS). Mean percentage compliance was 90.2%±16.3% overall, 88.1%±20.8% in the control group and 91.9%±11.6% in the intervention group (*P*=NS). The percentage of patients whose hypertension was controlled at the end of the study was 51.5% (CI, 34.4%-68.6%) in the control group and 64.7% (CI, 48.6%-80.8%) in the intervention group (*P*=NS).
Conclusions. The telephone messaging intervention with alerts and reminders sent to mobile phones did not improve compliance with therapy in patients with hypertension.

Key words: Compliance. Treatment. Hypertension. Educational intervention. Telemedicine.

EFICACIA DE UNA INTERVENCIÓN INFORMATIVA A HIPERTENSOS MEDIANTE MENSAJES DE ALERTA EN EL TELÉFONO MÓVIL (HTA-ALERT)

Objetivo. Analizar la eficacia, en el cumplimiento terapéutico de la hipertensión arterial, de una intervención informativa mediante mensajes de alerta al teléfono móvil de hipertensos.
Diseño. Estudio comparativo, controlado, aleatorizado por grupos y multicéntrico.
Emplazamiento. Veintiséis consultas de atención primaria de España.
Participantes. Veintiséis investigadores aleatorizados a 2 grupos, que incluyeron a 104 hipertensos no controlados en monoterapia. Los investigadores se aleatorizaron al grupo control (GC) y al grupo de intervención (GI), compuestos ambos por 52 pacientes.
Intervención. Los pacientes GC recibieron la intervención habitual de su médico, y los pacientes GI recibieron mensajes de alerta al teléfono móvil 2 días a la semana durante 4 meses.
Mediciones principales. Se realizaron el recuento de comprimidos y la determinación de la presión arterial al inicio y a los 1, 3 y 6 meses. Se compararon los porcentajes de cumplidores, el porcentaje medio de cumplimiento y el grado de control de la hipertensión arterial. Se calculó la reducción del riesgo absoluto y relativo, así como el número de individuos en los que es necesario intervenir para evitar un incumplimiento.
Resultados. Fueron evaluables 67 individuos (34 individuos en GI y 33 en GC). Tuvieron un buen cumplimiento terapéutico el 85,1% (intervalo de confianza [IC], 74,9-95,3) en el GC, el 85,7% (IC, 70,5-100,9), y el 84,4% en el GI (IC, 70,7-95,3) (p = NS). El porcentaje medio ± desviación estándar de cumplimiento fue de 90,2 ± 16,3 globalmente (GC, 88,1 ± 20,8; GI, 91,9 ± 11,6; p = NS). El porcentaje de controlados al final fue del 51,5% (IC, 34,4-68,6) en el GC y del 64,7% (IC, 48,6-80,8) en el GI (p = NS).
Conclusiones. La intervención mediante mensajes de alerta al teléfono móvil de hipertensos no ha mejorado el cumplimiento terapéutico.

Palabras clave: Cumplimiento terapéutico. Hipertensión. Intervención educativa. Telemedicina.

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A commentary follow this article (pág. 406)

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Introduction

The high prevalence of hypertension (HT) in Spain and the low percentage of patients in whom the disorder is well controlled[1] are indications of the magnitude of this primary care problem. To improve the degree of control of HT, interventions aimed at different health care professionals are a key approach to providing them with the conviction and capacity to put into clinical practice current expert group recommendations and consensus guidelines for HT.[1]

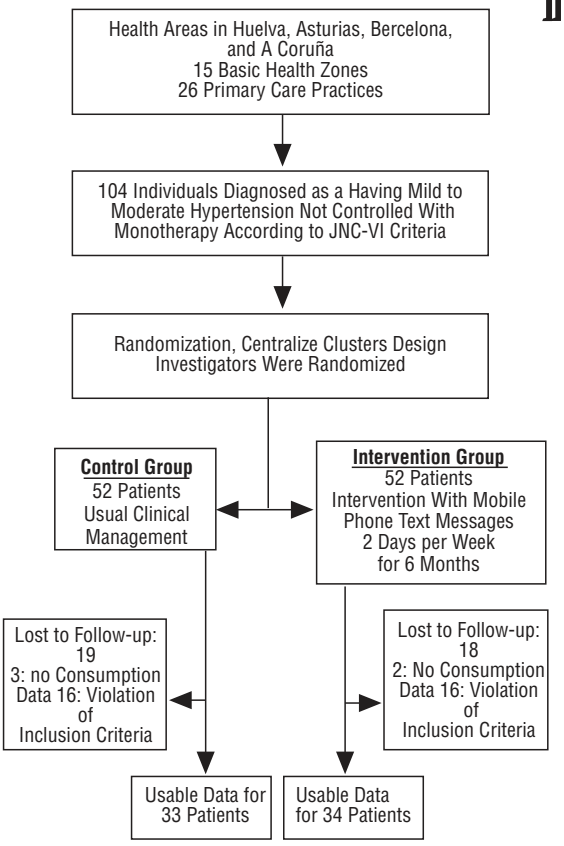
Compliance can be defined as the extent to which the patient accepts the physician's rules or advice in relation to recommended lifestyle, habits or prescribed pharmacological treatment. Compliance should result from a well-reasoned decision-making process, and it should be free of any connotations of submission that the term implies for the patient.[1]

The magnitude of noncompliance in Spain ranges from 7.1% to 66.2%, figures similar to those reported for other countries.[2] The medical literature contains few studies in which the main objective was to investigate compliance with HT therapy. Even more relevant is the lack of studies that investigate interventional strategies to improve compliance in Spain[1-3] and other countries.[4-7] This makes clear the need for studies of different compliance-enhancing strategies that are easy to apply in practice.

The results of a survey of 2363 patients treated at 37 HT units in Spain[8] showed that 43.5% were willing to receive health advice via their mobile phone. Moreover, text messaging with Short Message System (SMS) technology has been used as a support measure in young patients with asthma.[9]

The main objective of the present study was to determine whether an intervention based on mobile telephone text messaging to send alerts and reminders improved compliance with antihypertensive therapy.

Material and methods



General Scheme of the Study

Controlled, open, randomized study of the effectiveness of an intervention with mobile phone text messaging to improve compliance with pharmacological treatment in patients with hypertension.

Methods

Design

This was a prospective, multicenter, controlled, randomized, open study. The participants were individuals diagnosed as having mild to moderate HT according to JNC-VI diagnostic criteria. The patients were chosen by 26 researchers at 15 urban and rural primary care centers in the provinces of Huelva, Asturias, Barcelona, and A Coruña in Spain. Each researcher was responsible for recruiting 4 individuals.

Participants

The sample needed was calculated[10] for studies that use proportions as the main outcome measure and that require two-sided contrast analysis. The differences considered clinically significant[10,11] were 25% for compliance between groups, 65% for estimated prevalence of compliance in the control group, and 90% for the proportion of compliance in the intervention group. This yielded a sample size of 52 individuals per group. The study period lasted for 12 months starting in January 2002. The total number of subjects included was 104. A cluster method of randomization was used. Researchers were randomized to one of the 2 groups with a random number table, so that all patients recruited by the same investigator were assigned to the same group. The 2 groups compared in this study were: *a)* control group (CG): 52 patients with HT who received their usual care from their general practitioner, and *b)* intervention group (IG): 52 patients with HT whose disease was managed with the intervention described below in addition to their usual care. The inclusion criteria were: *a)* ambulatory patients of both sexes older than

18 years; *b)* patients whose HT was not well uncontrolled with monotherapy (SBP greater than or equal to 140 mm Hg or SBP greater than or equal to 90 mm Hg in patients without diabetes; SBP≥130 mm Hg or SBP≥85 mm Hg in patients with diabetes); *c)* patients with HT eligible for starting treatment with a combination of a single-dose angiotensin II antagonist and a diuretic; *d)* patients with a mobile telephone for their personal use or whose life partner had a mobile phone; *e)* patients who knew how to retrieve and read text messages on their mobile phone; and *f)* patients who gave their informed consent to participate in the study. The exclusion criteria were: *a)* patient on treatment with 2 or more antihypertensive drugs to control their blood pressure; *b)* patients with secondary HT; *c)* patients with known contraindications for any of the antihypertensive drugs to be used; *d)* patients whose clinical condition might have interfered with the study; *e)* patients unable to give their informed consent; *f)* patients participating in other research studies; and *g)* patients who lived with a person who was being treated with the same antihypertensive drug. Finally some withdrawal criteria were established: *a)* insufficient therapeutic effect necessitating an increase of more than 20% in the number of scheduled follow-up visits; *b)* patient´s decision to withdraw from the study; *c)* patient´s health compromised, in the physician's opinion, because of adverse effects or concomitant disease; and *d)* lack of cooperation or noncompliance with follow-up by the patient after inclusion.

Intervention

Each patient was given printed information about HT, and each was subscribed to a Short Message System (SMS) mobile telephone alerting system. Two messages were sent to the patient's mobile phone per week between 11:00 AM and 14:00 PM on randomly chosen weekdays from Monday to Friday during the 6-month study period. The aim of the messages was to provide information on HT, foment compliance, and good health and dietary habits, and remind patients to take their medication (table 1). The messages were sent randomly from an SMS platform programmed to generate random messages by Infociencia, S.L., and MyAlert, Inc. Receipt of the messages was free to participants in the study and independent of their telephone service operator.

Follow-up and Work Plan

Four visits to the health center were scheduled: the first appointment (inclusion) and 3 subsequent visits at 4, 12, and 24 weeks. *1.* First appointment: fulfillment of the inclusion and exclusion criteria was checked, the patient was given verbal and written information about the study, and informed consent was requested. The patient was questioned about his or her illness and given a physical examination. Weight and height were recorded, and 2 blood pressure measurements were taken. Verbal and printed health education information was provided. Single-dose antihypertensive treatment was prescribed, with medication to be taken each day on arising. The date of the prescription, number of tablets in the package, and day the first tablet was to be taken were recorded. A follow-up appointment was scheduled for 4

TABLE 1 Short Text Messages Sent to Mobile Phones During the Study

Messages to encourage compliance:
a) Always take your blood pressure pill when you get up in the morning
b) Remember that the effect of blood pressure pills wears off after 24 hours. Some patients have serious problems because they don't take their pill every day
c) Try to take your pills exactly as your doctor advised you. This ensures that your treatment will be useful
d) The secret to controlling blood pressure is to take your pill at the same time each day
e) Your blood pressure treatment is well tolerated. Ask your doctor if you think your pills might be making you ill
f) The aim of treatment is to reduce your blood pressure to below 14/9, or below 13/8.5 if you have diabetes.
g) You should never stop taking your blood pressure medicine even when you are taking other medicines or have another illness
h) Patients with hypertension who do not take their medicine according to their doctor´s instructions may develop cardiovascular disease
j) Always take your blood pressure medicine even when you have a cold, on weekends, or when you are traveling
k) Do not stop taking your blood pressure pills even when you are taking some other medication
l) Attend all follow-up visits your doctor schedules
Messages about lifestyle:
a) General: large meals are not good for your health, and neither are smoking or drinking
b) Blood pressure:
– Your blood pressure should be lower than 14/9
– High blood pressure may be a serious threat to your health
– Always attend follow-up appointments so your doctor can note changes in your blood pressure
– Hypertension is a risk factor for heart diseases
– If you keep your blood pressure under control, you will live longer
c) Sedentary lifestyles:
– A little exercise each day will help make your treatment more effective
– Taking a walk for about 40 minutes three or four times a week will improve your health
d) Diet:
– A healthy, balanced diet is the best guarantee for controlling your blood pressure
– Reduce fats and sugars in your diet
– Stay away from the salt shaker
– Adding salt to your food raises your blood pressure.
– Follow you doctor's advice about your diet
e) Drinking:
– Excess drinking is dangerous for your health
f) Smoking:
– Don't smoke. It's not worth it.
– If it's hard for you to quit smoking, ask your doctor for advice
– If you quit smoking you will feel a lot better

TABLE 2 **Analysis of Variables That Might Influence Compliance With Therapy in the Intervention and Control Groups***

	Intervention (N=34)	Control N=33)	*P*
Age, years	56.26±10.22	59.43±10.94	NS
Sex			
Men	52.9%	57.6%	NS
Women:	47.1%	42.4%	NS
Other illnesses	1.44±1.00	1.48±1.08	NS
Pills consumed	1.92±1.65	2.08±1.93	NS
Number of cardiovascula risk factors (CVRF)			
0	14.7%	15.2%	NS
1	55.9%	45.5%	
2	23.5%	33.3%	
3	2.9%	6.1%	
4	2.9%	–	
Initial Quetelet index	29.68±3.16	29.06±4.79	NS
Attended all appointments	25 (73.5%)	28 (84.8%)	NS
Number of patients taking other antihypertensive medication	5.8%	3.3%	NS

Results are expressed as the mean±SD or percentages.
*NS indicatesd non significance.

weeks later. The patient was instructed to bring to this appointment all the packages of the prescribed medication (used, partly used, and unused packages), and not to take the medication on the day of the appointment. Patients with HT in the IG were subscribed to the short text messaging program via a telephone call made by the physician or the patient to a toll-free (900) number.

2. First follow-up visit: 4 weeks after the start of treatment, blood pressure and weight were recorded, and the physician discreetly counted the number of tablets consumed to avoid patient-related bias. The patient was asked about the possible appearance of side effects. If the target blood pressure value was not reached, the physician-researcher considered adding another antihypertensive in the light of his or her clinical experience. A second medication was prescribed if necessary, and the second and third follow-up visits at the health center were scheduled for 12 and 24 weeks after the start of treatment.

3. Second follow-up visit: the procedure at this visit, 12 weeks after the start of treatment, was similar to that used for the 4-week follow-up visit.

TABLE 3 **Cumulative Percentage of Compliers at Each Appointment in the 2 Groups***

	Overall N =67	intervention N= 34	Control N= 33	*P*
Compliers 1st month	89.10%	92.0%	85.70%	.488
Compliers 3rd month	82.50%	77.30%	88.90%	.412
Compliers 6th month	82.10%	89.50%	78.9	.622

*P indicates difference between the groups in percentage compliance.

4. Final visit: the third and last follow-up visit took place 24 weeks after the start of treatment. The procedure at this visit was similar to that used for the 4-week and 12-week follow-up visits.

Main Outcome Measures

To evaluate compliance with treatment, we counted the number of tablets consumed,[3] and then calculated percentage compliance (PC) with the formula

$$\frac{\text{Total number of pills presumably consumed}}{\text{Total number of pills that should have been consumed}} \times 100$$

Individuals were considered compliers if PC was between 80% and 110%.[3] The data analyzed for this study were PC at the end of the study, cumulative PC at the end of follow-up (last follow-up visit or withdrawal), monthly PC, and change in PC from one follow-up visit to the next.

Statistical Analysis

The following statistical analyses were done:
– Similarity of the 2 groups was verified for age, sex, time since diagnosis, number of diseases, and number of tablets consumed, as variables that might influence compliance.
– The percentage of compliers and mean PC at the end of the study were compared between groups.
– The degree of control of HT was calculated. Control of HT was defined as values <140/90 mm Hg in patients without diabetes, and <130/85 mm Hg in patients with diabetes.
– The reduction in absolute risk (RAR) and in relative risk (RRR) was calculated, along with the number needed to treat (NNT) to avoid noncompliance.
– The chi-squared test was used for qualitative variables, and Students *t* test for quantitative variables. Statistical significance was said to exist when $P<.05$.

Ethical Considerations

The study was approved by the Primary Care Ethical Committee of the Jordi Gol i Gurina Foundation in Barcelona. Written informed consent was obtained and good clinical practice guidelines were followed.

Results

A total of 72 individuals (69.23% of the calculated sample) were recruited; 5 patients were excluded because they had no record of the number of tablets consumed. Usable results were available for 67 individuals (37 [55.2%] men and 30 [44.8%] women) with a mean age of 57.8±10.6

TABLE 4 Mean Percentage Compliance Overall and in Eeach Droup*

	Overall	Intervention Group	Control	*P*
First month	88.9±24.4	91.1±23.1	86.2±26.6	NS
Third month	89.7±16.2	91.5±12.0	87.6±20.1	NS
Sixth month	90.6±17.7	95.0±10.4	86.1±23.4	NS

Results are expressed as the mean ± standard deviation.
* *P*. Indicates Differences in percentage compliance between the groups.

TABLE 5 Mean Systolic (SPB) and Diastolic Blood Pressure (DBP) at Each Follow-up Appointment in the 2 Groups

	Intervention Group	Control Group	*P*
Initial SBP	158.5±13.9	162.1±13.9	NS
First month	143.6±14.7	145.7±11.8	NS
Third month	141.8±14.1	143.8±13.7	NS
Sixth month	139.4±13.1	138.3±9.5	NS
Initial DPB	95.6±7.9	95.4±6.8	NS
First month	86.94±9.8	86.0±7.0	NS
Third month	84.87±10.1	85.1±6.8	NS
Sixth month	84.94±10.4	83.1±5.6	NS

	Mean Decreases in Blood Pressure		Mean Decreases in Blood Pressure		
	mm Hg	*P*[a]	mm Hg	*P*[a]	*P*[b]
Initial-final SBP	19.1±14.4	<.001	23.7±13.1	<.001	.25
Initial-final DPB	10.6±7.9	<.001	12.3±7.5	<.001	.48

Results are expressed as the mean ± standard deviation.
* *P* indicates differences in mean decrease in blood pressure between the 2 groups.
[a] *P*, differences between groups in mean decrease from initial to final blood pressure.
[b] *P*, differences in mean decrease in blood pressure between the 2 groups.

years. The IG consisted of 34 individuals (18 men, 16 women) with a mean age of 56.3±10.2 years, and the CG consisted of 33 persons (19 men, 14 women) with a mean age of 59.4±10.9 years. At the start of the study there were no differences between groups in variables that might have affected compliance (table 2).

At the end of follow-up, compliers comprised 85.1% of the sample (CI, 74.9%-95.3%), i.e., 85.7% (CI, 70.5%-100.0%) in the CG and 84.4% (CI, 70.7%-95.3%) in the IG (*P*=NS, table 3). There were no differences between groups in PC at any of the visits. Mean PC at the end of follow-up was 90.2%±16.3% overall, 88.1%±20.8% in the CG and 91.9%±11.5% in the IG (table 4; *P*=NS). There were no differences in mean PC between groups.

Table 5 shows mean differences in blood pressure at each visit in the 2 groups; none of the differences between groups was significant. The decrease in SPB and DPB was significant in each group, with no difference in the mean decreases. The percentage of patients in whom blood pressure was controlled was 33.3% (CI, 17.2%-49.4%) in the CG and 44.1% (CI, 27.4%-60.8%) in the IG (*P*=NS) after 4 weeks. These figures were 36.4% (CI, 20.4%-52.8%) in the CG and 61.8% (CI, 45.5%-78.1%) in the IG (*P*<.05) after 12 weeks, and 51.5% (CI, 34.4%-68.6%) and 64.7% (CI, 48.6%-80.8%) respectively (*P*=NS) after 24 weeks. The percentage of patients whose blood pressure was controlled at the final follow-up visit was significantly higher in the CG.

Mean initial body weight was 79.8±13.6 kg in the CG and 82.0±10.9 kg in the IG (*P*=NS), and mean final body weight was 79.6±13.2 kg and 76.84±8.92 kg respectively. The decrease in body weight was significant in the IG (*P*<.001).

Discussion

The rate of noncompliance in this study was 14.9%. Although compliance was slightly higher in the IG, there were no significant differences between the two groups in PC or mean PC. If the sample had been larger and if the trend had remained stable, the differences would probably have reached significance. However, the effectiveness of the intervention was not supported by our data. In comparison to other studies, the percentage of compliers and percentage compliance were high in both of our groups, and only 15.6% of the patients in the IG had skipped 6 or more tablets each month of the study. Compliance was highest in both groups after 4 weeks of treatment, and decreased thereafter. Similar results have been reported in other studies of patients with HT[2] or dyslipidemia.[13]In Spain the prevalence of noncompliance ranges from 7.1% to 66.2% depending on the study.[14] In a review of all studies of compliance based on tablet counts published in Spain until 2001,[14] the weighted mean for noncompliance among all 2313 patients was 45%. In other clinical studies run in Spain, Márquez et al[2] found a noncompliance rate of 16.7%, Pertussa et al reported a figure of 54%,[15] Raigal et al set the figure at 52.6%,[16] and Tortajada et al[17] noted a rate of 45%. A number of reviews and metaanalyses have looked into strategies to improve compliance with HT treatment, including the review by Márquez et al[1] on compliance in general, a Cochrane review by Haynes et al,[4] and reviews published by Kravitz et al,[5] Roter et al,[6] and Haynes et al.[7] The strategies found to be effective in improving compliance and the degree of control of HT are: regular sessions of individual verbal and written health education; group health education sessions about HT; documents prepared according to specific methods; single-dose antihypertensive treatment regimens; diary cards for patients with HT; associating antihypertensive medication with a habitual daily activity; using medication dispensers; use of an alarm clock or other device to remind patients to take their medication; rewards for compliance with treat-

Discussion
Key points

What Is Known About the Subject

- **The magnitude of noncompliance with pharmacological treatment for hypertension in Spain is considerable, ranging from** 7.1% to 66.2%.
- **Strategies shown to improve compliance with therapy for hypertension in Spain are group health education sessions, on-demand interventions for patients outside the usual primary care setting, and motivational clinical interviews.**
- **There are no published studies that evaluate the effectiveness of an intervention aimed at improving compliance with mobile phone text messaging.**

What This Study Contributes

- **Noncompliers (patients who skipped 6 or more tablets during each month of the 6-month study period) made up 14.9% of all patients.**
- **The mobile phone text messaging intervention was not shown to be effective in improving compliance in patients with hypertension.**
- **However, some trends observed in this study suggest that it may be worthwhile to investigate this type of intervention further.**

ment better than 90%; on-demand primary care interventions outside the physician's office or health center, and motivational clinical interview. The best strategy consists of a combination of several of these individual approaches.[1] In Spain, Márquez et al[2] investigated the effectiveness of health education in group sessions with reminders sent by mail. After 2 years of intervention to improve compliance with HT therapy, the authors found that compliance was indeed better in the intervention group. Raigal et al[16] tested an intervention to improve knowledge about the disorder with oral and written health education materials. The CG received on-demand primary care (5 minutes per visit) and the intervention group attended scheduled visits (10 minutes per visit). After 14 weeks the difference between groups was significant (P=.01) for percentage compliance and reduction in blood pressure. A randomized clinical trial reported by Tortajada et al[10] compared the usual methods for HT therapy combined with telephone reminders to attend follow-up visits, versus these measures in combination with motivational interviews and an on-demand visit outside the usual setting of the follow-up visits. Significant differences were found for compliance and for the reduction in blood pressure. However, Zaragoza et al,[11] in a study of the effects of an initial home interview to foment compliance along with brief written instructions similar to those habitually provided by physicians, found that this intervention did not improve compliance. These authors concluded that brief counseling was not useful, and that instead, longer-term strategies and extensive written information about HT and antihypertensive treatment should be used.

The present study did not investigate the clinical relevance of the intervention, since no benefits were observed. However, the NNT with the strategies tested here were 2.49 according to Márquez et al,[2] 5.5 in a study by Tortajada et al[10], and 4 according to a report by Raigal et al.[16] When we analyzed the effect of the intervention on blood pressure values, we found no significant differences between the 2 groups at the end of the study. However, the percentage of patients who achieved good control at the third (and last) follow-up visit was significantly higher in the IG than in the CG. In the former, we noted a significant mean decrease in body weight as compared to the CG at the end of the study. This decrease may have been related with the SMS alerts received, as some messages—programmed to be sent between 11:00 AM and 13:00 specifically recommended healthy eating habits and exercise. However, this finding should be interpreted with caution, as in the long term (after 2 years, for example), the effect of most educational measures regarding weight control are found to be transient. When we examined the validity of the study and its biases, we noted a number of problems that need to be considered in order to interpret the results appropriately. Although the criteria for studies on compliance recommended by Haynes et al[7] were taken into account, some of them were not satisfied. For example, the diagnosis of HT was appropriate and in accordance with the JNC VI recommendations. The methods used to measure outcomes and to count the tablets consumed were those recommended by authorities at McMaster University in Canada,[7] although it would have been preferable to determine use of medication with unscheduled home visits. Our methods were nonetheless suitable given that the recommended method is a double-blind randomized clinical trial, with appropriate assurances that the groups are initially comparable, and with an analysis of compliance based on measures of the actual disease or disorder involved (blood pressure values, in this case). Follow-up data should have been available for more than 80% of the participants during a period of 6 months, and more than 50 patients per group should have been included in the final calculation of the magnitude of clinical relevance (RRR, RAR and NNT). Statistical significance should have been calculated with confidence intervals. These criteria were not satisfied in the present

study, as the final sample comprised less than 80% of the initial number of patients, and there were fewer than 50 individuals in each group. A larger sample would probably have improved the favorable results in the IG. Despite these biases, we feel it is worthwhile to report the findings and explain why it was not possible to obtain a larger sample.

The sample size makes it impossible to draw conclusions about the possible clinical relevance of the intervention, and the good results for compliance in the CG suggest that the participating researchers might not have been representative of the "average" Spanish primary care physician, since members of this collective, in general, have little interest in or motivation to participate in this type of study. The use of mobile phone messaging in motivated researchers who were already able to obtain high rates of compliance from their patients might not have revealed any additional benefits. Our impression was that the technology is difficult to implement in everyday practice, as it requires patients with HT who own a mobile phone, who know how to retrieve and read SMS messages, and who are preferably noncompliers with poorly controlled HT.

Regardless of the lack of evidence of effectiveness of this intervention, further research on the usefulness of this technology for health care is advisable given that there are currently 30 million mobile phone users in Spain, and it is likely that more than 40% of all persons with HT will own a mobile phone. These numbers make SMS alerts a simple technique to implement, at reasonable cost.

One of the challenges of future research in this area is to recruit a random sample of primary care physicians and train or otherwise motivate health professionals, to the extent necessary, to participate in studies of this type and to show an acceptable degree of adherence to procedural requirements. Once enough health professionals have been trained and motivated, patients should be recruited anew and randomized to one group or the other, and the study should be repeated with a sample large enough to provide useful data and to compensate for withdrawals and dropouts. Training in research procedures should not significantly influence the physicians' habits and practices in the long term regarding how they manage their patients with HT. This approach, arduous as it is, would improve the external validity of the results, and would ensure that if they were again found to be negative, this could be considered definitive evidence of a lack of effect of mobile phone text messaging to improve compliance with treatment in patients with hypertension.

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COMMENTARY

Noncompliance With Prescribed Medication

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Noncompliance with prescribed treatment is a well known phenomenon especially in chronic diseases, although its clinical consequences are not often assessed appropriately. The apparent safety of appropriate compliance with treatment in patients who are included in clinical trials has perhaps been one of the reasons why health professionals have failed to analyze in sufficient detail the impact of noncompliance on health outcomes.

The VI Report of the Joint National Commission on High Blood Pressure in the USA noted that only 27% of all patients with hypertension reduce their blood pressure to 140/90 mm Hg, and these poor results have been attributed mainly to noncompliance.[1] Canadian and European studies reached similar conclusions, and established that noncompliance with prescribed treatment is responsible for 50% of the failures of treatment for hypertension.[2,3]

Compliance is understood to be the extent to which the medication actually used matches the pharmacological treatment prescribed. Lack of compliance can thus arise from the patient´s initial rejection of treatment, changes in the dose or schedule, or early cessation of treatment. Noncompliance with antihypertensive treatment increases the risk of morbidity and mortality from cardiovascular disease. Restoring treatment can on occasion cause adverse effects such as tachycardia if calcium antagonists are used. Premature cessation of pharmacological treatment is more frequent in asymptomatic diseases that are not imminently life-threatening, as is the case with hypertension. This form of noncompliance places the patient at a level of cardiovascular and cerebrovascular risk similar to that associated with the lack of treatment.

For compliance to improve, problems that can interfere with compliance must be detected in a timely fashion. Although self-administered tests and checklists for self-reporting exist it is best to aim for effective communication and empathy during consultations, based on the classical model of self-change.[4] Predisposing factors can be related with the patient, the characteristics of his or her hypertension, the usually silent nature of this disorder, the complexity of the therapeutic regimen (the best is the enemy of the possible), problems in the patient's milieu, or problems with the health care system. The physician's actions should be guided by a realistic view of the circumstances, and messages need to be backed up with constant reinforcement and appropriate follow-up. If the health professional is able to establish, in collaboration with the patient, a shared, realistic treatment plan, the chances of success will be greater.[5]

Increasing patients' knowledge about hypertension is a necessary although not sufficient condition for improving compliance. Another basic need is for the physician to correctly interpret the symptoms of noncompliance. Thus the physician should ask whether the patient has taken all the medication prescribed, give instructions about the medication, and in particular, explain the need for treatment clearly.[6] Increasing the frequency of appointments, using active outreach systems for patients who miss appointments, and improving accessibility are all strategies that

Key Points

- Noncompliance with prescribed medication is the cause of 50% of all failures of hypertension treatment.
- Lack of compliance can arise from the patient's initial rejection of treatment, changes in the dose or schedule, or early cessation of treatment.
- Noncompliance places the patient with hypertension at a level of cardiovascular and cerebrovascular risk similar to that associated with absence of treatment.
- It is fundamental for the physician to correctly interpret the symptoms of noncompliance, ask whether the patient has taken all the medication prescribed, give instructions about the medication, and in particular, explain the need for treatment clearly.
- The effectiveness of postal and mobile phone reinforcement in enhancing compliance with antihypertensive treatment is still under evaluation.

contribute much to increasing compliance with treatment in patients with hypertension. Any postal system, Short Message System (SMS)—based technology or other type of approach may serve to provide support and reinforcement for these measures.

The article by Márquez Contreras and colleagues examines an original way to try to improve compliance with treatment for hypertension by sending messages and reminders over the patient´s mobile phone. One of the factors that might explain the absence of significant differences between the intervention and the control groups is the high rate of compliance in the latter group. The problem then is how to harmonize the internal validity of clinical trials with external validity. If we know that the mean rate of noncompliance with treatment for hypertension in Spain is 45%, the question we should be asking is this: why was the rate of noncompliance in this control group below 15%? The reason can easily be imagined. The participants did not represent "average" family doctors, probably because these professionals are little inclined to participate in this type of study. Physicians who take part in such research are likely to be interested in hypertension and cardiovascular disease, to be more highly trained, and to be more highly motivated than usual. In a way, what this study tells us is that even in a subgroup of especially motivated physicians, the use of SMS technology did not contribute much to the management of their patients' hypertension. Nevertheless, it is a highly pertinent project as the use of SMS technology can be expected to continue to spread throughout the population. This may mean that the use of these communications systems will become more common—hence the need for further research into their potential to improve compliance with pharmacological treatment for hypertension. We should not neglect the opportunity to evaluate this and other ingenious, novel and original methods for enhancing compliance with treatment for hypertension and reducing mortality from cardiovascular diseases.

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