

Effects of a feedback procedure on beliefs about symptoms and treatment adherence in hypertensive patients

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ABSTRACT

Hypertension is a major health problem, and noncompliance with treatment has been identified as the predominant reason for failure of hypertension therapy. Although it is generally assumed to be a silent disease, many hypertensive patients develop false beliefs concerning specific symptoms they use to estimate if their blood pressure (BP) is high. These false beliefs should be modified in order to improve control of the disease. The study presents a feedback procedure applied in a sample of 60 hypertensive patients expressing beliefs in false symptoms associated with their BP. After application of the procedure, 88% of the patients modified or eliminated their beliefs in false symptoms, and we found significant differences ($p < .05$) in the reports of adherence to pharmacological treatment before and after receiving the feedback procedure, as well as a significant improvement in the reports of difficulties with the other treatment elements (diet, exercise, control of emotions). The therapeutic possibilities of an easy procedure to apply within the healthcare setting is discussed.

Key words: hypertension, adherence, false beliefs, symptoms, feedback.

Novelty and Significance

What is already known about the topic?

- Many hypertensive patients develop false beliefs concerning specific symptoms they use to estimate if their blood pressure (BP) is high, in spite of having been instructed by healthcare personnel about the asymptomatic nature of their disease.
- The use of feedback is a simple procedure to modify false beliefs that has already shown its efficacy with diabetic patients.

What this paper adds?

- This is the first study carried out with hypertensive patients who present beliefs in false symptoms, showing that such beliefs can be totally or partially altered by means of a feedback procedure applied in the patients' natural context.

Body signals are of great value to maintain health and prevent and treat disease (i.e., Roales-Nieto, 2000, 2004). An important line of research has become consolidated with studies conducted with various types of patients concerning the variables related to the discrimination of signals and the oral reports of them, as well as their functions for health and disease (for a review, see Roales-Nieto, 2004). The repertoires of perception of symptoms and their reports are affected by different variables in addition to the disease itself, such that certain signals can acquire the functions of “symptoms” due to

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personal health-related experiences, knowledge of the organism's functioning, models of disease to which one has been exposed, and cultural influences.

From the psychological viewpoint, in blood pressure (BP), there is a complex interaction between the disorder -high blood pressure and its instability- environmental or context variables (health care center, family, social, cultural variables...), and the variables contributed by the individual as such (e.g., beliefs, schema of values, sensitivity to contingencies, capacity of discrimination, etc.) (Roales-Nieto, 2004).

Pioneer studies (e.g., Pennebaker, Gonder-Frederick, Stewart, Elfman, & Akelton, 1982) pointed out the important role that the perception of symptoms plays in chronic diseases, and this phenomenon has been the object of considerable research, with diabetes and hypertension being the most studied diseases. For example, diverse studies have confirmed that diabetic patients use the symptoms they perceive to estimate changes in their levels of blood sugar and to make decisions about their self-care (e.g., Cox, Gonder-Frederick, Antoun, Cryer, & Clarke, 1983; Cox, Gonder-Frederick, Pohl, & Pennebaker, 1985; Gonder-Frederick & Cox, 1984; O'Connell, Hamera, Knapp, Cassmeyer, Eaks, & Fox, 1984; Roales-Nieto, 1988; Roales-Nieto & Vílchez, 1993; Ybarra & Roales-Nieto, 2004). Although high BP is a condition that has no clear and contrasted physiological signals associated with its changes (e.g., Galton, 1973), numerous studies have confirmed the presence of false beliefs in hypertensive patients, as a large majority of such patients say that they perceive symptoms that indicate their level of blood pressure and that they use as a guide take their medication, in spite of having been instructed by healthcare personnel about the asymptomatic nature of their disease (e.g., Baumann & Leventhal, 1985; Brondolo *et al.*, 1999; Higgins, 1995; Leventhal, Meyer, & Nerentz, 1980; Hasford, 1992; Kaplan & Lieberman, 1999; Kottke, Tuomilehto, Puska, & Salomen, 1979; Meyer, Leventhal, & Gutmann, 1985; Nyklicek, Bingueroles, Van Heck, Kamphuis, Van Poppel, & Van Limpt, 1997; Pennebaker, Gonder Frederick, Stewart, Elfman, & Akelton, 1982; Pennebaker & Watson, 1988; Péres, Magna, & Viana, 2003; Robinson, 1969; Sharkness & Snow, 1992; Stewart & Olbrisch, 1986; Suls, Wan, & Costa, 1995; Tibblin, Bengtsson, Furunes, & Lapidus, 1990; Wilson *et al.*, 2002; Woods, Elias, Schultz, & Pentz, 1978).

Other studies have explored beliefs in false symptoms considered as elements to estimate the real level of BP and their effects on adherence to treatment, establishing that false beliefs in symptoms are a very important phenomenon for the correct treatment of hypertension (e.g., Brondolo *et al.*, 1999; Cantillon, Morgan, Simpson, Bartolomé, & Shaw, 1997; Granados & Roales-Nieto, 2007; Granados, Roales-Nieto, Moreno, & Ybarra, 2007; Higgins, 1995; Kjellgren *et al.*, 1998; Meyer *et al.*, 1985; Patel & Taylor, 2002; Peltzer, 2004; Sharkness & Snow, 1992; Schoenberg, 1997).

The process of formation and consolidation of hypertensive patients' false beliefs has been explored (e.g., Baumann & Leventhal, 1985; Bulpitt, Dollery, & Carne, 1976; Granados, Roales-Nieto, Gil-Luciano, & Moreno, 2014 under review; Meyer, Leventhal, & Gutmann, 1985), as well as the types of signals that are established as symptoms (e.g., Baumann & Leventhal, 1985; Bulpitt, Dollery, & Carne, 1976; Cirillo, Stellato, Lombardi, De Santo, & Covelli, 1999; Fuchs, Moreiras, Moraes, Bredemeier, & Cardozo, 1994; Kjellgren *et al.*, 1998; Meyer, Leventhal, & Gutmann, 1985; Morgan & Watkins, 1988; Péres, Magna, & Viana, 2003; Shapiro, Miller, King, Gincherau, & Fitzgibbon,

1982; Siegrist, Matschinger, & Motz, 1987; Weiss, 1972). Very few studies have explored ways to modify or eliminate false beliefs, and the impact of changing or eliminating beliefs about treatment adherence has not been analyzed. An example of an attempt to analyze the possibilities of changing false beliefs is the pioneer study of Greenstadt, Shapiro, and Whitehead (1986), who analyzed in 72 healthy male volunteers the ability to discriminate variations in diastolic BP (DPB), which improved when employing a simple feedback procedure consisting of providing the participants with the real result of their BP. Also, Barr, Pennebaker, and Watson (1988) and Baumann, Zimmerman, and Leventhal (1989) carried out a similar study, but none was made with hypertensive patients who showed false beliefs in symptoms.

The present study intends to test a procedure to modify false beliefs about symptoms in hypertensive patients by means of the identification of the body signals to which they attribute the value of symptoms, the estimation of the level of real BP, and the use of feedback of the level of real BP. It is a simple procedure to modify false beliefs that has already shown its efficacy with diabetic patients (e.g., de la Fuente & Roales-Nieto, 1994; Luzoro y Roales-Nieto, 1993; Roales-Nieto, 1988; Roales-Nieto, de la Fuente, Luzoro, 1994; Roales-Nieto & Vílchez, 1993; Ybarra & Roales-Nieto, 2004) and which is applied for the first time to hypertensive patients in this study.

METHOD

Participants

Participants were hypertensive patients who were receiving regular medical care in a Primary Care Center in the city of Almería (Spain). Eligible patients had to meet three criteria. Firstly, they should not be over 65 or under 18 years of age. Secondly, patients with disorders that could present symptoms (e.g., diabetes, asthma, cardiovascular disease and dislipidemias) were excluded. Thirdly, patients should be classified as “symptomatic” according to the protocol developed by Granados, Roales-Nieto, Gil-Luciano, and Moreno (2014 under review). Symptomatic patients were defined as patients who report beliefs in symptoms associated with high BP (symptoms that the patient believes are associated to his/her high BP).

The study sample was selected from among the total group of patients with a diagnosis of hypertension (96) who met the three inclusion criteria. The final sample comprised 60 eligible patients who agreed to participate; 36 eligible patients refused to participate due to difficulties to attend the meetings. All patients were informed that the purpose of the study was to “achieve a better understanding of the experiences of patients with the disease”.

The study protocol was approved by the ethics board of the corresponding health district. Oral and written consent was obtained from the patients who were willing to participate.

Instrument and Measures

The following instruments were used:

Questionnaire of Blood Pressure Beliefs 2 (Cuestionario de Creencias de Hipertensión 2 -CCH2), a simplified version of the CCH1 (Granados Gámez, Roales-Nieto, & Ybarra, 2006), which was used to collect data in the last appointment. This questionnaire has an interview format, specifically elaborated for this study, in which all the questions of the CCH-1 that were irrelevant to this study were eliminated. The final questionnaire was made up of 10 questions covering the two goals of data collection (see Annex 1).

A *Blood Pressure Monitor* (Nissei WS 520), recommended for domestic use, was employed as a complement to medical control. It measures BP (diastolic and systolic) and heart rate. The monitor could memorize and store the values of 30 trials and the values could not be altered by the patient. Its features are: oscillometric method, precision ± 3 mmHg (cuff pressure) and $\pm 5\%$ of reading (heart rate); application pressure 180 mmHg (fixed), range of measurement from 50 to 250 mmHg for systolic BP (SBP) and from 40 to 180 mmHg for DPB, and 40 to 160 beats per minute for heart rate.

Scale of Symptoms-Hypertension (SSH), designed in a card form for this study (see Annex 2), it measures the symptoms that the patient associates with high BP, the estimated values of BP (on a scale with three values: low, normal, or high), the reasons why the patient estimates those values, and the real BP value obtained by means of the BP monitor.

Design

The study used an A-B design although, being a preliminary study, data analysis was carried out taking the group as a whole, and establishing pre-post comparisons. All the participants underwent the same procedure and the same type of measures. As independent variable, we used the training system described in the Procedure section, and as dependent variables, we used both the patients' report of symptoms and of adherence behavior.

Procedure

The feedback training procedure had the following phases (an outline of the application phases of feedback is shown in Figure 1):

Initial interview: once the patients had agreed to participate in the study, they were instructed in the use of the BP monitor and how to complete the cards, according to an established instruction protocol. A trial test was conducted, repeating the task until they showed they had understood the procedure and could perform it well, and solving any doubts raised by the patients. Lastly, participants were informed that they could go to the health center if they had any problem, and that they should not manipulate the apparatus except for the given instructions. Next, they received the BP monitor and the cards scheduled for a mandatory daily measure (numbered 1 to 10, first training phase), as well as additional unnumbered cards they should use whenever they decided to measure their BP because they believed that it was high (unscheduled measurements).

They were told that they could perform these measures whenever they wanted to or if they suspected that their BP was high, regardless of the time or the place.

Follow-up appointment 1: in this session, the patients delivered the completed cards and the BP monitor (which was returned to them after registering the data stored in the memory of the apparatus). Next, the patients received 10 new mandatory cards that they should fill in every two days and a block of unnumbered cards for unscheduled trials (second training phase).

Follow-up appointment 2: the participants handed in the completed cards and the BP monitor (which was returned to them after registering the data stored in the memory of the apparatus). Next, they received 5 new mandatory cards that they should fill in every three days and a block of unnumbered cards for unscheduled trials (third training phase).

Final appointment: the participants handed in the completed cards and the BP monitor and then completed the CCH-2. After completing the questionnaire, the participants were informed of all the study details in which they expressed interest.

The reliability of the real BP values was guaranteed by the registry in the memory of the device, which allowed knowing the actual BP readings (Diastolic Blood Pressure -DBP- and Systolic Blood Pressure -SBP) and the order of trials. The sealing system of the apparatus prevented its manipulation.

To determine the validity of the measures of the BP monitor, we performed a control with a second BP measure following the traditional auscultatory method (with a Ligman stethoscope and a Primus 630 SK manual BP monitor), taking the measure at the brachial artery of the same arm on which the BP was measured with the BP monitor. After comparing the values obtained in 20 trials by both methods, the results showed a reliability higher than 99%.

		Day:	1	2	3	4
Day:	1 2 3 4 5	Trial number:	—	1	—	2
Trial number:	1 2 3 4 5	Schedule:	—	A	—	M
Schedule:	M A E A M	Day:	5	6	7	8
		Trial number:	—	3	—	4
		Schedule:	—	M	—	E
		Day:	9	10	11	12
Day:	6 7 8 9 10	Trial number:	—	5	—	6
Trial number:	6 7 8 9 10	Schedule:	—	A	—	E
Schedule:	A M E A M	Day:	13	14	15	16
		Trial number:	—	7	—	8
		Schedule:	—	M	—	A
		Day:	17	18	19	20
		Trial number:	—	9	—	10
		Schedule:	—	E	—	M

Notes: M= Morning; A= Afternoon; E= evening; —= No trial.

Figure 1. Outline of the application of the feedback training phases.

RESULTS

The results of the analyses carried out on the data provided by the 60 patients show the symptoms registered by the patients during the period of self-measurement at home using the SSH scale. Their responses to the CCH-2 questionnaire, which assesses the presence of false beliefs and the effect of the procedure on the report of treatment adherence, were subsequently analyzed.

A total of 2223 reports of symptoms were performed, taking into account all the trials carried out; the most frequently reported symptom was pain in the head/neck (34.7%), followed by a feeling of dizziness (18.1%), fatigue (15.4%), and tachycardia (13%). The majority of these reports (55.6%) were recorded when the patients felt that their BP was high, although 31.6% of the reports of symptoms were made when they felt that their BP was normal. Correspondence between the BP values recorded by the participants on the cards and those registered in memory of the BP monitor was observed, finding a correlation of .992 (*t* statistic for related samples, $p = .000$, $SD = 2.14$, for the real SBP-written SBP pairs, and $SD = 1.75$ for the real DPB-written DPB pairs). The patients related the reported symptoms to a high BP estimation in 19% of the trials (it was actually high in 63.3% of them).

One of the main goals of this study was to verify whether the feedback procedure could weaken false beliefs. To determine whether the patients maintained the same beliefs, we compared the reports of symptoms before and after feedback. Table 1 shows that an important number of patients changed the report of their beliefs about symptoms. The final data indicate that only 11.7% of the patients persisted in their false beliefs, nearly one half of the patients (48.3%), reported a radical change in their beliefs, whereas another 40% changed their beliefs, expressing doubts about the value of the signals reported in the previous phase as predictor symptoms of their BP. Taking the group as a whole, the chi-square contrast statistic indicates a statistically significant difference ($p < .01$) between the data about beliefs at the beginning and at the end of the study.

In order to analyze the possible effect of experience with the condition on the modification of beliefs, Table 1 shows the distribution of the patients who changed their beliefs, those who maintained them, and those who modified them as a function of the time elapsed since their diagnosis.

No differences were found in the tendency to change or modify beliefs as a function of time interval since the diagnosis, as the groups of patients with greater

Table 1. Results of the application of feedback on the report of beliefs (in percentages).

	Final report on symptoms		
	Patients maintaining beliefs	Patients eliminating beliefs	Patients modifying beliefs
Patients < 6 m from diagnosis ($n = 13$)	8%	38%	54%
6m / 2 years from diagnosis ($n = 23$)	13%	52%	35%
> 2 years from diagnosis ($n = 24$)	12.5%	50%	37.5%
Total sample ($N = 60$)	11.7%	48.3%	40%

experience did not show more resistance to change than did groups of more recent patients. According to the non-parametric Kruskal Wallis test, the group differences were nonsignificant, $\chi^2= 1.872$, $p= .846$.

The results indicated a significant improvement in all the reports of adherence to treatment after the application of the feedback procedure. Specifically, using the McNemar Test, statistically significant differences were found ($p <.05$) between the reports of adherence to pharmacological treatment before and after receiving the feedback procedure. Likewise, although 45.7% of the participants reported having problems adhering to the diet at the beginning of the study, no patient reported this problem at the end of the procedure, revealing statistically significant pre-post differences ($p <.05$). Significant differences were also found in the reports of problems to adhere to the physical exercise plan (whereas 39% of the patients reported prefeedback problems to adhere to exercise, only 2% reported postfeedback problems, $p <.05$); and between the pre and post reports of problems concerning control of emotions (56.5% of the participants reported prefeedback problems and 2% reported postfeedback problems, $p <.05$).

In order to explore the possibility that the effects of the feedback procedure pervade the values of real BP, we performed an analysis of the evolution of the measures of this variable. The comparison of the mean DPB at the beginning and at the end of the feedback procedure shows a statistically significant decrease ($p <.05$) with a mean prefeedback DPB of 81.98 mmHg ($SD= 10.96$ mmHg), whereas at the end of treatment, it was 80.29 mm/Hg ($SD= 8.59$, $p=. 007$). However, the SBP data did not reach statistical significance; the mean initial SBP was 130.78 mm/Hg ($SD= 15.24$) and final SBP was 128.49 mm/Hg ($SD= 14.32$).

DISCUSSION

The main goal of the study was to test the effects of simple intervention procedure on the beliefs about false symptoms related to BP maintained by hypertensive patients, and to ascertain its effects on the behavior of treatment adherence. The symptoms reported by the participants across the trials were similar to those reported in previous studies (Granados & Roales-Nieto, 2005, 2006), confirming that beliefs in false symptoms are a generalized phenomenon among hypertensive patients.

Studies in biofeedback, (i.e., Barr, Pennebacker, & Watson, 1988; Luvorsky *et al.*, 1976; Vidergar, Lee, & Goldma, 1983) have shown that people are able to learn how to more accurately estimate SBP levels. But these studies were carried out with normotensive participants and in experimental conditions that are not generalizable to the case of hypertensive patients who hold false beliefs about symptomatology that allows them to estimate the value of their BP. In fact, Baumann and Leventhal (1985) found that, when participants were provided with feedback about the inaccuracy of their BP estimates, an important resistance towards changing in their beliefs about their ability to perceive BP modifications was observed. However, this study was also conducted with people without a diagnosis of hypertension, so that its results cannot be generalized to the case of diagnosed hypertensive patients in medical treatment.

This is the first study carried out with hypertensive patients who present beliefs in false symptoms, showing that such beliefs can be totally or partially altered by means of a feedback procedure applied in the patients' natural context (the follow-up medical consultation and at home). The long period of self-measures at home has allowed us to obtain considerable additional data on different variables. One of them refers to the values of real BP recorded by the patients, and its analysis has allowed us to determine that approximately one half of these cases was not properly controlled, presenting high BP values. In fact, approximately one half of these uncontrolled patients presented measures that fall within the levels of risk. Likewise, the results of the DBP values registered by this sample of patients are similar to those found previous studies (e.g., Banegas *et al.*, 1998) in Spanish population aged between 35-64 years.

The effect that the feedback procedure has shown on the beliefs is of great clinical importance. Firstly, because it is a procedure that can alter a type of risk behavior that negatively affects adherence to treatment, as shown by the data of this study and those of prior studies (Granados & Roales-Nieto, 2007; Granados *et al.*, 2007). Secondly, because it is a simple procedure that is very easy to apply in the normal ambulatory healthcare setting, and it can be applied by the nursing staff attending to this type of patients.

The results of this study have shown that the patients who changed their beliefs in false symptoms presented better reports of adherence. Moreover, an indirect way to reveal the improvement in adherence are the results in the values of real BP, with significant differences between the mean DPB levels before and after the feedback procedure.

However, the methodological limitations of this preliminary study advise us to be cautious about reaching conclusions until replications have been conducted that include control groups and procedures to control adherence aside from participants' reports.

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ANNEX 1

Questionnaire of Blood Pressure Beliefs 2 (CCH-02)

Objetiv 1: To find out if the patient remains beliefs in symptoms associated with his/her Blood Pressure (BP).

Questions:

1- "Do you think you can tell when your BP is up?" Yes No

If the answer was Yes to ask:

2- How do you know if your BP is high?

Objetiv 2: Getting data on treatment adherence.

Questions:

3- Have you ever taken the prescribed treatment? Yes No

If the answer was No to ask:

4- Have you ever stopped taking the medication? Yes No

If the answer was Yes to ask:

5- Why did?

6- Have you ever dropped the dose of prescribed medication? : Yes No

If the answer was Yes to ask:

7- Why did?

8- Do you have any problem or difficulty following the prescribed treatment? Yes No

If the answer was Yes to ask:

9- What aspects of treatment are difficult to follow?	1- Diet plan Yes <input type="checkbox"/> No <input type="checkbox"/> 2- Exercise plan Yes <input type="checkbox"/> No <input type="checkbox"/> 3- Medication Yes <input type="checkbox"/> No <input type="checkbox"/> 4- Emotional reactions Yes <input type="checkbox"/> No <input type="checkbox"/> 5- BP selfmeasure Yes <input type="checkbox"/> No <input type="checkbox"/>
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ANNEX 2

Trial # _____	Date and time: _____
1. Please indicate if you are going on JUST RIGHT NOW something that follows...	My pulse is racing <input type="checkbox"/> I'm hungry <input type="checkbox"/> My stomach hurts <input type="checkbox"/> I'm tired <input type="checkbox"/> My skin is cold and clammy <input type="checkbox"/> I'm dizzy <input type="checkbox"/> It hurts the neck or head <input type="checkbox"/> I feel like I have a fever <input type="checkbox"/> I feel my face hot <input type="checkbox"/>
If you notice other sensations that are not among the above, please indicate how it is: _____ _____	
2. How do you think your blood pressure is right now?	Low <input type="checkbox"/> Normal <input type="checkbox"/> High <input type="checkbox"/>
3. Why do you think that your blood pressure is as you indicated? _____ _____	
4. Now, take your blood pressure and record the result here:	Systolic: _____ Dyastolic: _____