Journal of Psychosomatic Research 74 (2013) 433–438

Contents lists available at SciVerse ScienceDirect

Journal of Psychosomatic Research

Are there consequences of labeling patients with prehypertension? An experimental study of effects on blood pressure and quality of life

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ARTICLE INFO

Article history:
Received 19 October 2012
Received in revised form 18 January 2013
Accepted 22 January 2013

Keywords:
Prehypertension
White coat hypertension
Ambulatory blood pressure monitoring
Quality of life
Blood pressure

ABSTRACT

Objective: The prehypertension classification was introduced to facilitate prevention efforts among patients at increased risk for hypertension. Although patients who have been told that they have hypertension report worse outcomes than unaware hypertensives, little is known about whether or not prehypertension labeling has negative effects. We evaluated the effects of labeling individuals with prehypertension on blood pressure and health-related quality of life three months later.
Methods: One hundred adults (aged 19 to 82 [mean = 40.0] years; 54% women; 64% racial/ethnic minorities) with screening blood pressure in the prehypertensive range (120–139/80–89 mm Hg) and no history of diagnosis or treatment of elevated blood pressure were randomly assigned to either a "Labeled" group in which they were informed of their prehypertension, or an "Unlabeled" group in which they were not informed. Subjects underwent office blood pressure measurement, 24-hour ambulatory blood pressure monitoring and completed self-report questionnaires at baseline and at three months.
Results: Multilevel mixed effects regression analyses indicated that changes in the white coat effect, office blood pressure, mean daytime ambulatory blood pressure, and physical and mental health did not differ significantly between the two groups. Adjusting for age, sex, race/ethnicity and body mass index did not affect the results.
Conclusion: These findings suggest that labeling patients with prehypertension does not have negative effects on blood pressure or quality of life. Additional research is needed to develop approaches to communicating with patients about their blood pressure that will maximize the clinical and public health impact of the prehypertension classification.

Introduction

About one-third of U.S. adults have prehypertension [1], which is associated with an increased rate of progression to hypertension and increased cardiovascular disease (CVD) risk compared with normotension [2–6]. Prior to the publication of the Seventh Report of the Joint National Committee on High Blood Pressure (JNC 7) [7], blood pressures (BP) in this range (120–139/80–89 mm Hg) were classified as "normal" or "high–normal" [8]. Though it is not a disease category, the prehypertension classification was introduced to facilitate early identification of patients at increased risk for hypertension. Current treatment guidelines recommend counseling patients with prehypertension on the importance of lifestyle modification to reduce BP and prevent or delay progression to hypertension; the safety and efficacy of pharmacologic treatment in this group is the subject of ongoing investigation [9–13]. As the pros and cons of treating BP to lower targets are debated [14], an important question to address is whether or not labeling patients with prehypertension has unintended negative consequences that could limit the potential benefits of early identification of elevated BP.

Observational studies of "hypertension labeling" have demonstrated a broad range of negative outcomes among patients who are aware of their hypertension status compared with those who are hypertensive but unaware of the diagnosis. Increases in work absenteeism [15–18], higher levels of physical symptoms [18,19] and distress [20–23], and lower health-related quality of life [23–28] have been reported, and are not explained by BP elevation itself or by drug treatment, suggesting that the psychological effects of being labeled likely play a significant role. Much of the previous

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http://dx.doi.org/10.1016/j.jpsychores.2013.01.009

work on hypertension labeling has been limited by observational designs, which leave open a number of alternate interpretations such as the possibility that health declines or new physical symptoms prompt patients to seek medical attention and thus increase the opportunity for hypertension to be detected and diagnosed. The only published experimental studies of hypertension labeling demonstrated increased office BP among young men who were labeled as hypertensive following screening compared with those who were not informed of their diagnosis [29,30]. Ambulatory BP monitoring (ABPM) was not performed, so whether or not the increase was limited to the office setting (i.e., the white coat effect) is unknown. The white coat effect is defined as a transient increase in BP in the office setting relative to the usual BP, most often measured as the average daytime ABP [31], and is a source of measurement error that can affect clinical decision making. In a previous observational study using ABPM, we found that the white coat effect was larger, on average, among aware versus unaware hypertensives, and this difference was partly explained by elevated anxiety in the office setting [32]. The white coat effect might be particularly problematic among patients with prehypertension as it could contribute to the misdiagnosis of hypertension and unnecessary drug treatments.

The objective of the present study was to evaluate the effects of prehypertension labeling on the white coat effect and health-related quality of life three months later. One-hundred subjects, unaware of having elevated BP, were randomly assigned to either a "Labeled" group in which they were informed of their prehypertension status, or an "Unlabeled" group in which they (initially) were not informed. We hypothesized that subjects in the Labeled group would demonstrate greater increases in the white coat effect (i.e., higher office BP without changes in average daytime ABP), and greater reductions in health-related quality of life than those in the Unlabeled group.

Method

Study population

The target study population was healthy adults who were previously unaware of having elevated BP. Two recruitment strategies were used: (1) referrals from an internal medicine practice at Columbia University Medical Center (CUMC), and (2) advertisements for free BP screenings posted around the CUMC complex. Persons who responded to study advertisements or who were flagged by the physician (S.F.) were screened by a research assistant to determine eligibility. To avoid any possible labeling effect of participation, the research assistant described the purpose of the study as examining different ways that physicians talk to patients about their health; BP measurement was included in the explanation of procedures but was not the focus.

Screening and study visits were conducted in a private patient examination room. The primary inclusion criterion was a resting BP, defined as the average of the last two of three BP measurements taken by the research assistant using an automated device (BpTRU, VSM Medtech, Model BPM-100), in the prehypertension range according to JNC 7 guidelines (120–139/80–89 mm Hg). To limit the sample to newly identified prehypertension, potential subjects were excluded if they reported ever having been informed of having elevated BP (i.e., hypertension, high BP or prehypertension) by a physician or ever having been prescribed antihypertensive medications. Those who reported a history of cardiovascular disease, diabetes or kidney disease were also excluded. Eligible subjects who wished to participate provided written informed consent and were scheduled for the baseline visit. The study protocol was approved by the CUMC Institutional Review Board and the study was conducted from July, 2009 through August, 2011.

Study procedures

Baseline visit

The research assistant measured the subject's height and weight and instrumented him/her with a Spacelabs 90207 ABP monitor (Spacelabs, Redmond, WA), a validated oscillometric device. After fitting the subject with an appropriately sized cuff on the non-dominant arm, the research assistant performed standard calibration procedures. As described below, the average of three resting calibration measurements taken with the ABP monitor served as the office BP measure used to calculate the white coat effect for each study visit. The ABP monitors were programmed to collect and record (without display) BP data every 30 min for 24 h, after which time subjects used prepaid mailers to return the equipment. Subjects also completed a battery of questionnaires at baseline, including demographic data, medical history and health-related quality of life using the SF-12 measure [33].

Randomization

Upon completion of the baseline visit, subjects were randomly assigned to one of two groups: (1) Unlabeled, in which the physician informed them of their BP level but *did not* give them a "prehypertension" label; or (2) Labeled, in which the physician informed them of their BP level and discussed prehypertension with them. A statistician determined group assignments using a computer-generated algorithm. The research assistant, who remained blinded, provided one of the study physicians (three in total) with the top envelope from a stack of pre-prepared, sealed envelopes with the group assignment and corresponding script. The scripts for both groups were developed in collaboration with several physicians to be as realistic as possible with regard to length and content of feedback.

> *UNLABELED*: "First, let me explain that a person's blood pressure varies for a lot of reasons, like drinking coffee or running around a lot or being stressed. Your blood pressure today is in the high normal range, but we don't pay much attention to a single reading. We'll measure your blood pressure again three months from now to see how you're doing."*LABELED*: "First, let me explain that a person's blood pressure varies for a lot of reasons, like drinking coffee or running around a lot or being stressed. *Your blood pressure today is in what is called the 'pre-hypertension' range*. This doesn't mean that you have hypertension, and you don't need to take medication at this point. However, it does mean *that you are at increased risk for developing hypertension in the future*. Hypertension is a serious condition that can cause stroke, heart disease, or kidney disease, and it must be treated. To prevent your blood pressure from increasing to that level, there are things you can do, like losing weight, exercising more, and eating less salt. If your blood pressure does increase in the future, I might recommend that we consider treating you with anti-hypertension medication. We'll measure your blood pressure again three months from now, and if it's still high, we'll discuss how to proceed."

The decision to inform subjects in both groups of their BP may result in a smaller labeling effect than if one group was provided no feedback at all. However, this control condition is more consistent with a real clinical encounter in which patients are often told their BP level when it is measured and given minimal feedback when it is below the threshold for hypertension. The question addressed in this study was whether the prehypertension label and accompanying risk information have an impact on patients above and beyond the minimal feedback they typically receive.

3-Month visit

Subjects were scheduled to complete a follow-up visit three months after their baseline visit. At this time 24-hour ABPM and self-report