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Baseline medication adherence and blood pressure in a 24-month longitudinal hypertension study

Ryan Shaw and Hayden B Bosworth

Aim and objectives. We sought to identify the feasibility and predictive validity of an easy and quick self-reported measure of medication adherence and to identify characteristics of people with hypertension that may warrant increase attentiveness by nurses to address hypertensive self-management needs.

Background. Current control rates of hypertension are approximately 50%. Effective blood pressure control can be achieved in most people with hypertension through antihypertensive medication. However, hypertension control can only be achieved if the patient is adherent with their medication regimen. Patients who are non-adherent may be in need of additional intervention. **Design.** This secondary analysis evaluated the systolic blood pressure of patients who received usual hypertension management across 24 months at six-month intervals.

Methods. A longitudinal study of 159 hypertensive patients in two primary care clinics.

Results. In a sample of 159 patients receiving care in a primary care facility, baseline medication non-adherence was associated with a 6·3 mmHg increase in systolic blood pressure (p < 0.05) at baseline, a 8·4 mmHg increase in systolic blood pressure (p < 0.05) at 12 months and a 7·5 increase in systolic blood pressure at 24 months (p < 0.05) compared with adherent patients, respectively. Results also indicate a significant increase in systolic blood pressure across 24 months among people who identified as minority and of low financial status.

Conclusions. Non-adherence with antihypertensive medication at baseline was predictive of increased systolic blood pressure up to 24 months postbaseline.

Relevance to clinical practice. This study demonstrates the use of an easy-to-use questionnaire to identify patients who are non-adherent. We recommend assessing medication adherence to identify patients who are non-adherent with their anti-hypertensive medication and to be especially vigilant with patients who are minority or are considered low income.

Key words: blood pressure, longitudinal, medication adherence, nurses, nursing

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Introduction

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Over 74.5 million North Americans, one in three adults, are affected by hypertension, defined as blood pressure $(BP) \ge 140/90 \text{ mmHg or taking an antihypertensive medica-}$	with diabetes (American Heart Association 2006). Hyper- tension is the most common primary diagnosis in America (Cherry & Woodwell 2002), and current control rates are only at 50% (Egan <i>et al.</i> 2010).
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tion for non-diabetics and ≥130/80 mmHg for individuals

Background

Hypertension is a significant risk factor for cardiovascular disease (CVD). The relationship between BP and risk of CVD is continuous and independent of other risk factors. Even among normotensive individuals at age 55, there is a 90% lifetime risk of developing hypertension (Vasan *et al.* 2002).

Effective BP control can be achieved in most people with hypertension through lifestyle modification and antihypertensive drugs. Most people with hypertension require two or more hypertensive medications to achieve BP control (Black *et al.* 2001, Cushman *et al.* 2002). Recent studies suggest that nurse-administered self-management interventions can have positive economic impact and improve BP control, systolic BP and diastolic BP across 24 months compared with usual care (Bosworth *et al.* 2009, Reed *et al.* 2010).

However, even among the most diligent clinicians, hypertension control can only be achieved if the patient is adherent with their medication regimen. Patients who are non-adherent with their medication regimen may be in need of additional intervention. Poor adherence to BP drug therapy can translate into a greater risk of BP-related complications and increased health care expenditures (Flack *et al.* 1996).

Nurses are in a crucial position to identify patients who are non-adherent with their antihypertensive medication regimen and to target patients who may be in need of additional intervention to improve BP self-management. Identifying and addressing self-management interventions is a key role in nursing (Wagner 2000) and a major part of the national nursing agenda (National Institutes of Health 2006).

We sought to identify the feasibility and predictive validity of an easy and quick self-reported measure of medication adherence and to identify characteristics of people with hypertension that may warrant increase attentiveness by nurses to address hypertensive self-management needs.

Methods

This study is an analysis of the randomised usual care group (n = 156) from the Take Care of Your Blood Pressure (TCYB) trial. Recruitment occurred from May 2004–December 2005, with follow-up from November 2004–January 2008. Details on the study design and the interventions have been reported previously (Bosworth *et al.* 2008, 2009).

Blood pressure was measured at baseline and at six-month intervals for 24 months. Patients received standard hypertension care from their primary care provider and underwent six-month outcome assessment measurements. Institutional Review Board approval was obtained from the Duke University Health System, and all patients provided written informed consent.

Outcomes and measurements

Demographics were obtained from patients and medical chart review at baseline (Table 1). Financial status was evaluated by asking patients to report whether they had enough money to pay bills only by cutting back on things or if they had difficulty paying bills (Bosworth *et al.* 2001). Health literacy was evaluated as a dichotomous variable defined as ≤ 8 th (≤ 60) vs. > 9th (> 61) on the Rapid Estimate of Adult Literacy in Medicine test; a 7-item word recognition test to provide a quick assessment of patient health literacy (Dewalt *et al.* 2004). Body mass index was calculated from a mean between self-reported weight and body weight abstracted from the medical record.

Blood pressure was measured at six-month time points over 24 months. At each time point, a research assistant who was blinded to the patient's group assignment obtained two BP measurements with a digital sphygmomanometer. The first BP measurement was obtained after patients were seated and rested for at least five minutes. The second was obtained 30 seconds after the first. The mean of the values was used as the outcome for that time point. We chose to examine systolic BP (SBP) for this study because SBP greater than 140 mmHg is a more important risk factor than diastolic blood pressure for the majority of people with hypertension (Izzo *et al.* 2000).

Table 1 Patient characteristics at baseline

	(n = 159)
Demographic	
Mean age (SD)	62 (12)
Race (%)	
White	45
African–American	54
Other	2
Male (%)	36
Married (%)	51
Lives alone (%)	25
Completed ≤12 year of school (%)	35
Low health literacy (%)	27
Employed (%)	36
Inadequate income (%)	20
No weekly exercise ≥20 min (%)	20
Current smoker (%)	18
Mean BMI (SD)	32.6 (8.5)
Medication non-adherence (%)	32
BP (mmHg)	
Controlled	72
Mean systolic BP (SD)	124 (18)
Mean diastolic BP (SD)	70 (10)

Medication non-adherence was assessed at baseline and months 6 and 24 using a five-item measure based on the Morisky scale ($\alpha = 0.86$). Response options ranged from strongly agree (1) to strongly disagree (4) and also included options for 'don't know' and 'refused'. The questions asked included the following: I sometimes forget to take my blood pressure medicine; I am sometimes careless about taking my blood pressure medicine; when I feel better, I sometimes stop taking my blood pressure medicine; if I feel worse when I take the blood pressure medicine, sometimes I stop taking it and; I have skipped doses in the past month. Consistent with prior research (Thorpe et al. 2009), a summary binary variable was created by coding those who responded 'strongly agree,' 'agree,' 'don't know,' 'refused,' or missing data to any of the five questions as 1 (non-adherent). This indicated a patient was not fully compliant with their medication regimen; otherwise patients received a value of 0 (adherent). The time frame of responding to medication adherence was the last month.

Statistical analysis

A correlation analysis (PROC CORR in sAs, version 9.2; SAS Institute Inc., Cary, NC, USA) was used to estimate which demographic variables were significantly correlated with blood pressure in the usual care group. A repeated linear regression model (PROC REG in sAs, version 9.2) was used to estimate the predictive validity of baseline medication adherence over 24 months. A general linear model (PROC MIXED in sAs, version 9.2) (Singer & Willet 2003) was used to estimate change in BP over 24 months between adherent and nonadherent medication users at baseline. The fixed effects for the model included a common intercept; the stratification variables included adherence and time (in months) and the following interaction term: adherence by month. The same subjects were used for each analysis.

Results

Of the 159 patients, 54% were African–American, 64% were female and 20% reported inadequate income. The mean age was 62 years old (Table 1). At baseline, mean systolic BP was 124 mmHg; 72% had their BP under control at baseline and 32% reported that they were non-adherent with their medication. Overall BP measurements were available for 128 (81%) of patients at 24 months of follow-up (Baseline 157; six months 144; 12 months 131; 18 months 129; 24 months 128).

There was no significant change in SBP between (p = 0.80) over 24 months in the sample. Non-adherence at baseline was predictive of the following: a 6.3 mmHg increase in SBP



Figure 1 Change in systolic blood pressure (mmHg) across 24 months by adherence at baseline.

(p < 0.05) at baseline; a 8.4 mmHg increase in SBP (p < 0.05) at 12 months; and a 7.5 increase in SBP at 24 months (Fig. 1) (p < 0.05).

A correlation analysis indicated that financial status and race were significantly (p < 0.05) correlated with SBP and medication adherence. There was no significant difference in SBP by gender (p > 0.05). Thus, we added these potential confounders to the model. Low financial status was indicative of a of 3.2 mmHg increase in SBP at baseline (p = 0.04). Race (minority status) was indicative of a 10.6 mmHg increase in SBP at baseline (p < 0.01), a 7.4 mmHg increase in SBP at 12 months (p < 0.05) and a 7.9 mmHg increase in SBP at 24 months (p < 0.05). When these variables were added to the model, both adherence and financial status were no longer significant indicators of increased SBP (p > 0.05).



Figure 2 Change in systolic blood pressure (mmHg) by race and baseline medication adherence.

However, minority status continued to indicate an 8.9 mmHg increase in SBP when all three variables were added to the model (p > 0.01) (Fig. 2).

Discussion

The purpose of this study was to understand whether medication adherence is a significant predictor of SBP over time and to identify characteristics of people with hypertension that may warrant increase attentiveness by nurses to address hypertensive self-management needs. As demonstrated by this study and consistent with the literature (Munger et al. 2007, Perreault et al. 2010), non-adherence is related to elevated BP (+6.3 mmHg at baseline). In this study, non-adherence continued to demonstrate elevated SBP over 24 months compared with patients who were adherent. Financial status was also an indicator of elevated SBP (+3.2 mmHg). Thus, financial status may be an additional factor to consider when targeting patients for hypertension management. Although adherence and financial status were significant predictors of elevated SBP, results from this study indicate that minority status was an even greater factor in elevated BP (+10.6 mmHg) at baseline. This is consistent with literature that shows that hypertension is greater among blacks than other races (Ong et al. 2007). Race was such a significant factor that when it was added to the statistical model, it accounted for the effect of medication adherence and financial status. In addition, results indicated that SBP did not vary over a two-year period in the sample studied even though at baseline 28% of patients had uncontrolled BP.

The modified five-item Morisky scale was reliable ($\alpha = 0.86$) and demonstrated predictive validity of up to 24months postbaseline. This is consistent with the literature that the Morisky scale has been shown to be reliable ($\alpha = 0.83$) (Morisky *et al.* 1986) significantly associated with blood pressure control and has good concurrent and predictive validity in primarily low income, minority patients with hypertension (Morisky *et al.* 2008). Other self-reported medication adherence measures have been used in research settings as well (Morisky *et al.* 1986, Shea *et al.* 1992, Kim *et al.* 2000). Consistent demonstration of validity and reliability in diverse populations is continually needed.

Medication adherence in relationship to BP and cardiovascular events has been well studied. Non-adherence has been documented to occur in over 60% of cardiovascular patients (Kravitz *et al.* 1993) leading to poor clinical outcomes, including rehospitalisation, subsequent myocardial infarction and increased mortality in various patient settings (Baroletti & Dell'Orfano 2010). Because of the relationship between antihypertensive medication nonadherence and elevated BP, non-adherence provides an opportunity to significantly improve BP management. In particular, clinicians need to be diligent and sensitive to the needs of individual needs of patients to promote optimal medication adherence. By identifying patients who are nonadherent to their antihypertensive medication regimen at baseline through a quick and easy questionnaire such as the short Morisky (Morisky et al. 1986) used in this study, clinicians can quickly and easily identify patients who are in need of additional intervention and follow-up. Assessing medication adherence may be particularly useful in certain minority groups. Minorities in particular have been shown to have higher rates of hypertension than others racial groups (Ong et al. 2007). As seen in Fig. 2, the elevated SBP was greatest in people who identified as both minority and were non-adherent with their antihypertensive medications.

Results that SBP in this study did not change over a 24-month period reflect that many patients with hypertension do not receive proper treatment. Over 75% of patients who receive hypertension treatment worldwide fail to reach normotension (BP < 140/90). This is a significant problem and warrants increased vigilance by physicians and nurses to appropriately adjust therapy and deliver proper management. This study was limited by being a secondary analysis of a larger trial where the purpose was to evaluate the effects of a home BP monitoring self-management intervention and nurse-administered behavioural intervention compared with usual care. Medication adherence was not the focus of the primary study.

Relevance to clinical practice

To surpass the Healthy People 2020 goal of reducing the proportion of adults with hypertension, multiple strategies are needed. The national guideline clearinghouse (NGC) advocates nurses as one approach towards hypertension management (Heart and Stroke Foundation of Ontario, Registered Nurses Association of Ontario 2005). NGC recommends that nurses assess and promote the adherence of patients' anti-hypertension treatment plan. The benefits of nurses delivering behavioural interventions and hypertension management to patients have been demonstrated (Bosworth et al. 2009, Reed et al. 2010). Based on the results from this study that demonstrate the predictive validity of a baseline medication adherence tool up to 24 months and a significant increase in SBP among non-adherent patients, we recommend nurses and other clinicians assess medication adherence to identify patients who are non-adherent with their hypertension medication. An easy-to-use questionnaire such as the Morisky is one tool that can be used to reliably gauge and predict medication adherence. By identifying non-adherent patients at baseline, additional behavioural interventions can be delivered, which focus on promoting medication adherence that can in turn potentially further improve blood pressure among hypertensive patients. In addition, increase vigilance is needed to target communities and groups that are known to have increased rates of hypertension, including minorities and those of lower income status. With approximately 65% of men and 80% of women who reach the age of 75 developing hypertension (National Center for Health Statistics 2008), strategies to reduce the prevalence of hypertension in the general public are greatly needed. Nurses are in a pivotal role to help manage and reduce the prevalence and burden of hypertension.

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Contributions

Study design: HBB; data collection and analysis: RS, HBB and manuscript preparation: RS.

Conflict of interest

No authors have a conflict of interest.

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