



Home Blood Pressure Monitoring and Hypertension Control

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Abstract

Hypertension affects approximately 65 million individuals in the United States and it is a leading modifiable risk factor for cardiovascular diseases. It is an independent predictor of all-cause mortality. Despite recent improvement in the global trend of hypertension, high blood pressure (BP) still remains a huge public health and economic burden and the percentage of uncontrolled BP still remain high and unacceptable. Home blood pressure monitoring (HBPM) is increasingly being recognized as having a significant contribution to BP control when compared to conventional BP monitoring. It has also been shown to have better reproducibility and prognostic predictive value, and reduce the cost of care associated with hypertension. It is therefore imperative to understand the barriers to successful adoption and implementation of HBPM and address such barriers through evidence-based interventions.

Keywords: Hypertension; Home blood pressure monitoring; Blood pressure; Hypertension control

Introduction

Hypertension affects approximately 65 million individuals in the United States (U.S.) [1] and it is a leading modifiable risk factor for cardiovascular diseases [2,3] and mortality [4]. In 2010, hypertension was estimated to cost the U.S. 76.6 billion dollars in health care services, medications and missed work days [5]. Global cost of suboptimal blood pressure (BP) in 2001 was 370 billion US dollars representing about 10% of the world's overall health care expenditures [6]. It was estimated that it will cost nearly 1 trillion U.S. dollars if current global BP levels persist over a 10 year period, and indirect cost could be as high as 3.6 trillion U.S. dollars annually [6], making hypertension one of the most important challenges facing public health.

While there has been no significant change in prevalence of hypertension over the years [2,7], there has been some improvement in the trend of BP control nationally. Hypertension control increased from 25% in 1999-2000 to 33.1% in 2003-2004,¹ and to 50.1% in 2007-2008 [2]. Similar rates of control were also reported in Canada (13.2% in 1992 to 64.6% in 2009), European countries such as Denmark (57% of treated patients are controlled), and in Italy whose current control rate is 35% [2]. Despite these improvements in BP control, the percentage of uncontrolled still remains high and unacceptable.

An interesting development over the years has been the concept of self-measured home blood pressure monitoring (HBPM). For many years, medical office BP readings have been the standard for diagnosing and managing hypertension, however, monitoring BP outside of providers' offices is increasing among individuals with hypertension and health care providers [8]. In 2008, the American Heart Association and others published the "Call to Action on Use and Reimbursement for Home Blood Pressure Monitoring" which states that "Home blood pressure monitoring should become a routine component of blood pressure measurement in the majority of patients with hypertension" [3]. Studies have reported an increase in the proportion of hypertensives achieving target BP control when HBPM was used rather than standard office BP monitoring [9,10]. The additional BP control achieved by HBPM is likely due to increased awareness among hypertensives of their condition as a result of self-monitoring and increased compliance to provider-recommended lifestyle modifications and medications [2,11,12]. HBPM has also been reported to have better reproducibility and prognostic value [13], stronger predictor of cardiovascular risks [4] and lesser mean adjusted cost for hypertension care than office BP monitoring [14,15]. This review paper will examine the feasibility

of widespread implementation of HBPM, the cost effectiveness of implementation, and the impact on hypertension-related morbidity and mortality.

Review Literature

There is continuous fluctuation in BP levels during the day and even at night and these fluctuations are due to interplay of various hormonal, neuroendocrine and physical factors [16]. BP levels have been reported to dip at certain period of the night, might be slightly elevated on waking up, and varies with different levels of exertion, state of mind and stress experience [17]. The diagnosis of hypertension has traditionally been made by elevated BP measurements taken at least on two separate clinic visits, but given the amount of variability in individuals' BP in a 24-hour period, a single office BP reading might not reflect, and may even give misleading and inadequate information regarding the true BP of a patient. There is a growing consensus for the need to measure BP outside the providers' office to supplement and also to provide an average BP measurement during routine daily activity. The growing consensus has led to the increase in the use of HBPM by physicians and patients over the past decades. The number of patients monitoring their BP at home has increased by about 17% between the year 2000 and 2005, and the proportion of patients owning a BP monitor has increased from 49% in 2000 to 64% in 2005 [18], suggesting increasing awareness for HBPM.

In a recent study of 1,350 hypertensive patients, 66% were found to use HBPM regularly [19]. In a similar study, 70% of participants (n=103) reported monitoring their BP at places other than their providers' offices [8]. 41.6% monitored their BP at homes, 48% reported monitoring their BP at the pharmacy, 32.4% monitored their BP at the fire station, 24.8% used BP monitors in a large retail store and 20.9% monitored their BP at a family member's home. Though less than half

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Received February 21, 2015; **Accepted** March 23, 2015; **Published** March 30, 2015

Citation: Akinseye OA, Akinseye LI (2015) Home Blood Pressure Monitoring and Hypertension Control. Primary Health Care 5: 182. doi:10.4172/2167-1079.1000182

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of the study participants monitored their BPs at home, the findings signifies that patients are comfortable monitoring their BP outside of healthcare offices.

HBPM and BP control

Adequately controlled BP in hypertensive patients is associated with reduced hypertension-related cardiovascular morbidity and mortality, and regression of hypertension induced target organ damage. There is an ongoing public health effort through the Healthy People 2020 objectives to achieve a significant amount of hypertensive individuals with controlled BP. Over the past 3 decades, BP control among the population has increased gradually, so also is the use of HBPM in hypertensive patients. There is a growing consensus that BP measurements taken by patients at home are often lower compared to regular office BP measurements. In a meta-analysis of 18 randomized controlled clinical trial, HBPM resulted in greater BP control and achievement of BP targets than regular office based BP monitoring [9]. In another meta-analysis of 37 randomized controlled trials with 9,446 participants, systolic BP improved with HBPM (-2.63mmHg; 95% CI, -4.24, -1.02); diastolic BP also showed improvement (-1.68mmHg; 95% CI, -2.58, -0.79) when compared with clinic-based BP measurement [20]. Filippi et al.[2] studied the effect of implementing a simple, multifaceted improvement strategy by having 18 General Practitioners agree to use (1) HBPM in their non-controlled hypertensive patients, (2) add a new drug in non-controlled but adequately adherent patients and (3) use occasional direct and indirect contacts to decrease missing BP recordings and increase therapeutic adherence. They found that extensive use of HBPM and the use of direct and indirect contact to improve therapeutic compliance increased the BP control rate to over 80% in this hypertensive population.

HBPM has also proved effective in controlling BP in majority of African Americans (AA), a minority group that has higher prevalence and greater severity of hypertension when compared to other ethnic groups, and suffer disproportionately from the associated cardiovascular disease [21]. In a study of 33 AA with uncontrolled BP despite pharmacological treatment for greater than 1 year, significant decreases ($p \leq 0.001$) in mean systolic and diastolic BPs were noted in HBPM group and 60% achieved BP control within 1 month [22]. A pilot study of 26 AA examining the effect of nurse-managed HBPM with telemonitoring of result to providers compared to nurse-managed community-based monitoring found that both groups had a clinically and statistically significant drop in both systolic and diastolic BP at 3 month follow up, but also noted that the HBPM group demonstrated the greatest improvement in both systolic and diastolic BP [23].

There are several factors that may be contributing to the BP controlling effect of HBPM. The variability in human BP is mostly mediated by neural and hormonal changes that fluctuates with different daily activities, emotions and stress level. Though it has been recommended that BP should be taken after 5 minutes of rest in a sitting position, this approach, which is intended to relax the patient prior to BP measurement, might not reveal the ideal BP when compared to BP taken in a relaxed environment at home. Individuals who monitor their BP at home are also likely to be more aware and involved in management of their hypertension, which also improves compliance with recommended medical and lifestyle interventions and provides the patient with a sense of being in control of their medical condition.

However, there are few studies that did not show that HBPM results in better BP control when compared to office based BP measurements. A randomized clinical trial sought to evaluate how HBPM affects the

treatment of hypertension as compared to office-based BP monitoring. 400 participants with diastolic BP of 95 mmHg or more as measured at physicians' offices were enrolled and followed up for 1 year. The authors noted that BP measurements were higher in HBPM group than in the office BP group with the mean baseline-adjusted systolic/diastolic differences between the HBPM group and office based BP groups averaging 6.8/3.5 mmHg and 4.9/2.9 mmHg respectively [15]. Data from another observational study comparing the effect of HBPM on hypertension management also found that systolic pressures remained significantly higher in HBPM group compared to usual office based BP monitoring group [24]. This calls for further prospective studies to establish the impact of HBPM on BP control.

HBPM and BP reproducibility

HBPM provides a more representative estimate of an individual's BP, and several studies have reported that it shows good reproducibility which allows it to provide better estimate of the impact of BP treatment and predicts cardiovascular outcome more effectively.

Sakuma et al.[25] compared the reproducibility of home BP with that of casual screening BP measurement over a period of 1 year in residents of Ohasama, in Japan. A total of 136 untreated subjects without cardiovascular complications were studied. The reproducibility of HBPM over time was superior to that of the usual BP measurement. The correlations between the first and second BP measurements of the subjects were significantly higher for the HBPM group, and the mean differences between the first and second home BP were significantly smaller than those for the usual BP group [25]. The authors discussed the clinical significance of HBPM for the diagnosis and treatment of hypertension and as a tool for evaluating the efficacy of antihypertensive drugs. The above findings were supported by data from another study that compared reproducibility of ambulatory, home, and clinic BPs in 13 untreated mildly hypertensive and 14 normotensive subjects. HBPM had a better reproducibility and was superior to clinic BP [26]. In a study of 16 borderline hypertensive patients, home BP readings were obtained 6 weeks apart. The measurements were highly reproducible and detected minor changes in BP during treatment [25,27]. The above findings of higher reproducibility of BP measurements by HBPM is significant in evaluating individuals with white-coat hypertension (BP that is higher only when taken at a provider's office) or masked hypertension (BP that is higher outside of the health professional's office) and preventing unnecessary treatment or the lack thereof respectively.

HBPM and prognostic value of cardiovascular diseases and mortality

Hypertension is an independent predictor of various cardiovascular diseases and mortality and its detection and control cannot be effective without accurate and practical BP measurements. Office BP measurement has been the standard for diagnosing and monitoring effectiveness of therapy in hypertensive patients and will likely remain the cornerstone for diagnosis and management of hypertension, but it is known to have several limitations, such as poor reproducibility, presence of white-coat effect and observer bias [13]. Several studies have reported the superior prognostic value of HBPM when compared to office based BP measurement. In a study of 1,913 subjects aged 40 years or older followed for an average of 8.6 years for their survival status, HBPM was independently associated with an increase in the risk of cardiovascular mortality when compared to office based BP measurement [13]. A prospective nationwide study on 2,081 randomly selected subjects aged 45 – 74 years investigated whether HBPM

was strongly associated with cardiovascular events (cardiovascular mortality, nonfatal myocardial infarction, nonfatal stroke, hospitalization for heart failure, percutaneous coronary intervention, or coronary artery bypass graft surgery) and total mortality than is office BP. Mean follow-up year was 6.8. HBPM (HR, 1.22; 95% CI, 1.09 - 1.37), not office BP was predictive of cardiovascular events. Systolic HBPM was the sole predictor of total mortality (HR, 1.11; 95% CI, 1.01 - 1.23) [4]. The above finding was supported by a recent study which showed that when HBPM and office screening BP values were simultaneously incorporated into the statistical analysis as continuous variables, only the average of multiple HBPM values was significantly and strongly related to cardiovascular mortality risk, and the average of two initial HBPM values was better related to the mortality risk than were office screening BP values [28].

Bobrie et al. [29] assessed the prognostic value of HBPM versus office BP measurement in a cohort of 4,939 hypertensive patients followed up for a mean of 3.2 years. For each 10 mmHg increase in systolic BP in HBPM group, the risk of cardiovascular event increased by 17.2% and each 5 mmHg increase in diastolic BP increased that risk by 11.7%. In a multivariate model with patients having controlled hypertension (normal home and office BP) as the referent, the hazard ratio of cardiovascular disease was 1.96 in patients with uncontrolled hypertension (high BP with both methods), 2.06 in patients with normal office BP and elevated home BP, and 1.18 in patients with elevated office BP and normal home BP [29].

From the above studies, it can be said that HBPM has specific advantages and a stronger predictive factor for cardiovascular diseases and mortality in the general population and specifically in the hypertensive population.

HBPM and Cost Savings

Wang et al. [5] reviewed the literature on the costs and cost-effectiveness of adding HBPM into routine BP screening in adults. The authors comprehensively reviewed and analyzed 14 original articles that included cost outcomes and compared two or more modalities of BP measurement. The review suggested that existing evidence supports the cost-effectiveness of incorporating HBPM following an initial clinical-based diagnosis of hypertension. Another study examined if HBPM will reduce cost of care compared to regular office BP monitoring without compromising BP control. They found that HBPM patients made 1.2 fewer hypertension-related office visits than usual care patient and the mean adjusted cost for physician visits, telephone calls, and laboratory tests associated with hypertension care was 29% less than in the office BP group [14].

An insight into the cost-saving impact of HBPM on a national scale was provided in a recent study. The study reported that the estimated medical cost per 1000 subjects per 5 years is US\$10.89 million if HBPM is not incorporated in the management of hypertension. The estimated cost is US\$9.33 million per 1000 subjects per 5 years when HBPM is incorporated in hypertension management [30]. The cost saving mechanism is likely due to avoidance of treatment in patients with white-coat hypertension, prevention of hypertension related complications such as strokes and by improving the prognosis of hypertension. However, in a recent study that examined the direct and patient time costs associated with several interventions, including HBPM on hypertension management, the interventions are said to be cost-additive to the health care system and thrice-weekly home BP monitoring resulted in patient time costs that surpassed the cost of the intervention [31]. There is need for further cost analysis studies on

the comparative effect of HBPM and office BP monitoring on overall hypertension-related care cost.

Barriers to Implementation

The number of patients monitoring their BP at home was about 55% as at 2005[18]. In a recent study that examined the attitudes of primary care physicians (PCP) and their hypertensive patients towards the use of HBPM, while majority of PCPs encouraged HBPM, only 13% of PCPs preferred HBPM for diagnostic purposes and only 19% will use HBPM to guide therapy [32]. The study reported that 80% of patients received no advice from their provider about the device to purchase and only 8% received training on use of the device.

The slow reimbursement of physicians by insurance companies for efforts spent on implementing HBPM and educating their patients might not provide incentives to providers to adopt HBPM program. Physicians who get paid by patients' office visit are also less likely to adopt HBPM unless they are being reimbursed for data collection, analysis and BP medication adjustments based on the values collected by HBPM. There is lack of evidence that HBPM is cost beneficial for insurers, however a recent study estimated the cost-benefit ratios and both short- and long-run return on investment for HBPM compared with clinic BP monitoring. The results suggested that reimbursement of HBPM is cost beneficial from an insurer's perspective for diagnosing and treating hypertension. Depending on the insurance plan and age group categories considered, estimated net savings associated with the use of HBPM range from \$33 to \$166 per member in the first year and from \$415 to \$1364 in the long run (10 years). Return on investment ranges from \$0.85 to \$3.75 per dollar invested in the first year and from \$7.50 to \$19.34 per dollar invested [33].

In another study, clinicians were also supportive of HBPM, but reported collection of follow-up data from enrolled patients as a common challenge [34]. Also the degree of reliability of patients' reporting of self-measured BP values have been found to be variable and unpredictable and may have profound effect on usefulness of HBPM [35]. This was further reproduced in other studies [36-38], with Wagner et al. [38] reporting that a third of study participants failed to self-report accurately. Given that self-report of BP measurements to providers by patients may be variable and unpredictable, Rifkin et al. [39] evaluated the impact of real-time, wireless BP telemonitoring on older patients with kidney disease and hypertension. They found that telemonitoring of home BP readings led to greater sharing of data between patients and clinic and there was significant improvement in BP control compared to the self-reporting group. This is consistent with analysis of data from a multicenter randomized clinical control trial which showed that HBPM with telemonitoring of BP readings to a secure website for review by providers resulted in clinically important BP reduction among patients with uncontrolled hypertension, and tele-monitored measurements were perceived to be more accurate and improve reliability of shared data [40]. Other studies have also reported improved BP control using HBPM with telemonitoring when incorporated with a patient support system [41,42]. However, a cost-effectiveness analysis comparing the costs of HBPM with telemonitoring with costs of conventional office BP monitoring showed that telemonitoring of HBPM was more effective but also more costly compared with usual monitoring of office BP within a 6 month period [43].

Another barrier is the need for infrastructure to implement home monitoring. The ideal way is telemonitoring the readings in real time to a secure health portal for review by the patient and provider. However, this requires collaboration across multiple sectors and has been difficult

to achieve practically. Some obvious challenges include the costs of data transmission via public and or private networks, available bandwidth, and the need to devise and validate new data analysis methods required to interpret the mass of data produced by telemonitoring [44].

Gaps Identified In Literature Review

Despite the encouraging body of evidence regarding HBPM, there were some gaps identified in the literature that will need further investigations. The evidence of the effect of socioeconomic, sociodemographic and literacy status of individual hypertensive patients on the reliability of BP measurements reported to providers is scarce. In a recent study, clinicians who were supportive of HBPM, reported that collection of follow-up data from enrolled patients was a challenge [34]. It is also important to note that the degree of reliability of patients' reporting of self-measured BP values have been found to be variable and unpredictable and may have profound effect on usefulness of HBPM [35]. Studies are needed to evaluate the impact of socioeconomic, sociodemographic and educational status on the variability of reporting self-measured BP values.

While there has been an increase in the use of HBPM by physicians and patients over the past decades, adoption among providers is still slow. As stated earlier, only 13% of primary care providers prefer HBPM for diagnostic purposes and 19% will use HBPM to guide therapy [32]. Intervention studies such as incentivizing adoption and use of HBPM by providers and reimbursing providers on time spent in analyzing and making medication adjustment based on HBPM values are scarce. Such intervention studies will help determine if appropriate reimbursement of providers' effort might improve the adoption and implementation of HBPM.

It can be said that HBPM will theoretically reduce the cost associated with hypertension care, given that it may reduce number of office visits and prevent unnecessary treatment of patients with white-coat hypertension; however, a recent study found several interventions, including HBPM on hypertension management to be cost-additive and that thrice-weekly home BP monitoring resulted in patient-time costs that surpassed the cost of the intervention [31]. In addition, costs related to the validation of BP device and training of patient in proper use of the BP device including recording or transmitting the BP measurements are additive [18]. Most studies evaluating the cost of implementing HBPM did not account for these several hidden or offsetting costs.

Most studies evaluating the cost impact of HBPM also did not account for the cost of additional medications that providers might have started patient on due to the frequent reporting of BP values. A randomized clinical trial sought to evaluate how HBPM affects the treatment of hypertension as compared to office-based BP monitoring. The authors found that more HBPM than office monitored patients had stopped antihypertensive drug treatment with no significant difference in the proportions of patients progressing to multiple-drug therapy [15]. This finding was consistent with that of the HOMERUS trial which found that HBPM group used less antihypertensive medication than the office based BP group [45]. Identification of white-coat hypertension and subsequent discontinuation of antihypertensive drug treatment might explain the less intensive drug treatment in HBPM group [15]. However, both studies reported lesser BP control in the HBPM group compared to the office BP group but acknowledged that had the recommended HBPM target of 135/85 mmHg been used [46], BP values similar to those of the office-based values could have been achieved. The rationale was that the use of a threshold value of 140/90mmHg for treatment in the HBPM group led to less drug prescription compared to

the office-based group and subsequently higher BP values in the HBPM group. Although these studies suggested that HBPM does not lead to additional BP lowering medications, further prospective studies are needed to determine the impact of HBPM on changes in hypertension medication regimen especially when the recommended target of 135/85 mmHg is used, and the cost impact.

Conclusion

Hypertension remains a huge public health and economic burden globally despite recent improvement in the trend of BP control. It is an independent predictor of cardiovascular disease and all-cause mortality. The efforts directed at achieving maximal BP control across populations are well directed and are impacting reduction in the morbidity and mortality associated with hypertension. Increase in public awareness of hypertension, increased knowledge of hypertension's pathophysiology, and availability of newer medications to adequately control BP have contributed to the improvement of the national trend seen in BP control as noted in the review above; however, the percentage of the uncontrolled still remains high.

The impact of HBPM in achieving BP control is increasingly being recognized. Multiple studies have shown its superiority in achieving BP control compared to conventional BP monitoring. It has better reproducibility and prognostic predictive value, and if widely adopted and implemented, can have significant impact on individual and population level BP control. It may improve public health by reducing the health and economic burden associated with hypertension related morbidity and mortality. There is also need for more enlightenment of healthcare providers and their hypertensive patients on the benefits of HBPM, and insurance companies should be advised on the evidence supporting HBPM reimbursement. It is imperative to understand the barriers to successful adoption and implementation of HBPM and address such barriers through evidence-based interventions. There is need for further studies to add to the body of evidence on the prognostic value and clinical benefits to patients, providers' practice and public health as a whole, so as to increase implementation and improve adoption of HBPM.

Acknowledgement

The paper was originally submitted as a graduate course work at Brooklyn College, New York. We will like to acknowledge Professor David Balk of Brooklyn College for his effort and guidance in putting the original coursework together.

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