Evidence Report

Chapter 1: Introduction

Background

Elevated blood pressure (BP), also termed hypertension, is a common, powerful, and independent risk factor for cardiovascular diseases (CVD) and kidney disease. BP-related CVD include cerebrovascular disease (or stroke), coronary heart disease (CHD), heart failure, and peripheral artery disease. The risk relationships are progressive and graded such that the risk of these diseases rises throughout the range of BP including BP in the non-hypertensive range.[1,2]

Approximately 25 percent of the adult U.S. population, about 50 million persons, has hypertension, defined as current use of anti-hypertensive medication, a systolic BP $\geq$140 mmHg, and/or diastolic BP $\geq$ 90 mmHg.[3] Less than half of adults have optimal BP defined as systolic BP < 120 mmHg and DBP < 80 mmHg. Hypertension disproportionately affects certain subgroups, particularly African-Americans and older-aged persons. With increasing age, the prevalence of hypertension rises such that over 50 percent of U.S. adults ages 60 years and older have hypertension. While hypertension affects both genders, men have a higher prevalence than women at younger ages, but the opposite is true at later ages (> approximately 50 years).

A compelling body of evidence from clinical trials has documented that drug therapy not only lowers BP but also prevents stroke, CHD and heart failure.[4,5] A complementary strategy to drug therapy for hypertension is non-pharmacologic, lifestyle therapy. A substantial body of research has documented that lifestyle modification can lower BP and prevent hypertension in non-hypertensive individuals who are not candidates for drug therapy but who nonetheless remain at risk for BP-related complications.[6]

In view of the epidemic of high BP and its complications, prevention and control of high BP continues to be a major national health priority. Governments, institutions, health care providers, insurers, private industry and non-profit organizations have committed substantial resources to research aimed at prevention and treatment of hypertension. Professional organizations and governmental bodies have developed guidelines to screen, diagnose, prevent and treat hypertension.[7] Health insurance companies typically cover the costs of anti-hypertensive care, including, to a variable extent, medication costs. Still, hypertension control rates have been unsatisfactory. In response, performance guidelines have been developed as a means to monitor and improve hypertension control.[8]

Despite this ongoing and massive effort to prevent BP-related complications, the most appropriate technique to measure BP remains uncertain, both to diagnose hypertension and to monitor therapy. Concomitantly, the enormous scope of the BP problem, the high aggregate costs of hypertension care, and the potential for medication side effects have spawned efforts to target therapy more effectively. Specifically, attention has focused on identification of lower risk individuals who might be candidates for less aggressive therapy and higher risk individuals who should receive more aggressive therapy. Measurement of BP outside of the office or clinic setting has been proposed as an alternative to traditional BP measurements. Ambulatory BP (ABP) monitoring and self-measured BP (SMBP) monitoring are two measurement techniques that can record BP outside of the clinic setting and that might accomplish the above objectives.

Clinic Blood Pressure Measurements

BP as recorded in the office or clinic setting is the standard technique recommended for measurement of BP in routine medical care.[7] Such measurements have been used in the major observational studies that documented risk relationships between BP and clinical events and in most clinical outcome trials that documented the benefits of anti-hypertensive therapy. Ideally, the observer is trained and then retrained periodically. The standard technique includes use of a mercury sphygmomanometer (or a calibrated aneroid device or validated electronic device) and an appropriate size cuff. Prior to measurement, patients should rest quietly in the seated position for several minutes. At each visit, at least two readings should be obtained. Typically, BP measurements at a given visit are then averaged. Except for those individuals with extremely high BP, the diagnosis of hypertension and adjustments in medication should then be based on the average of readings across two or more visits. Numerous national and international professional organizations have prepared guidelines for measurement of clinic BP.[7]

Clinic BP measurements have several limitations, even if they are measured according to established guidelines.[9] First, clinic BP measurements exhibit enormous variability, which hinders accurate classification and which frustrates providers and patients. Contributing to this variability are short-term variability (within clinic visit), diurnal variability (within the same day), and long-term variability (across an extended period of time, days or weeks). One solution is to measure BP across several visits, spaced several days or weeks apart. Another limitation is that BP measured in the clinic may not be a representative estimate of usual BP outside the clinic setting.[10] Commonly, BP rises in the clinic setting, in response to the observer and/or other aspects of the medical environment. An alerting reaction appears to trigger this response. The difference between measurements obtained in and outside the clinic setting leads to confusion over the diagnosis of hypertension and the need to start or modify therapy. The problem is exacerbated by the practical requirement for cutpoints to diagnose and treat hypertension despite the fact that BP is a continuous, unimodal distribution. In the end, because of misclassification, there is potential both for undertreatment of persons with high blood pressure and overtreatment of those with low blood pressure. Unfortunately, there are additional limitations because clinic measurements often do not conform to established guidelines.[11] Specific limitations include lack of observer training, inadequate rest period prior to initial measurement, use of inappropriate sized cuffs, rapid deflation of cuff, incorrect position of patients, insufficient number of BP measurements and visits, and awkward position of the observer and/or manometer.

Over the past several years, stationary automated devices and aneroid devices have increasingly replaced mercury sphygmomanometers in the clinic setting. Aneroid devices are inexpensive but still require an individual, typically a health care provider, to manually inflate a cuff and record the appearance and disappearance of Korotkoff sounds. In contrast, fully automated devices require minimal technical skills, that is, only placement of a cuff and initiation of a reading. The convenience of automated readings and the potential to avoid training and retraining of technicians has made automated readings extremely popular. An additional reason leading to greater use of aneroid and automated devices stems from concerns over mercury toxicity.[12] Specifically, to reduce the amount of mercury released into the environment and to

minimize the risk of accidental mercury exposure, government officials have encouraged health care officials to eliminate mercury from health care settings.

Self-measured Blood Pressure (SMBP)

SMBP devices include mercury sphygmomanometers, aneroid manometers, semi-automatic devices, and fully-automatic electronic devices. Automatic devices measure BP using an oscillometric technique in which systolic and diastolic BP are estimated from the pattern of vibrations in the cuff as it is deflated. This technique is quite different from the usual auscultatory technique in which systolic BP is estimated as the point of appearance of Korotkoff sounds and diastolic BP as the point of disappearance. Fully automated devices are popular because the patient does not have to inflate the cuff, listen for the appearance and disappearance of Korotkoff sounds, and read measurements off a column or dial. Hence, these devices appeal to individuals with hearing or visual impairments, or limited dexterity. Although numerous, perhaps, hundreds of SMBP devices are on the market, very few have been independently validated. In a recent review of published validation studies, only 23 devices had undergone validation testing; of these, only five were recommended by the European Society of Hypertension.[13]

SMBP devices provide an opportunity to record BP during awake hours, outside of the artificial setting of the medical office or clinic. Ideally, the patient is trained to record BP using a standard technique. Occasionally, physicians may observe the patient recording a BP measurement in the clinic and then perform a cross check of readings. While the medical literature has documented that patients can record BP accurately, there have been concerns about the accuracy of readings, the completeness of reports submitted to physicians, and the potential for biased readings based on selective reporting.[14]

The presentation of SMBP data is extraordinarily variable. Commonly, patients at their own initiative provide written lists of readings to their physicians at office visits. However, recent innovations have greatly enhanced the potential utility of SMBP devices to synthesize and present data. Contemporary SMBP devices have the capacity to store and download readings via phone or computer. Data can then be synthesized from which reports are generated and then transmitted to the patient and/or physician.

SMBP has several potential uses.[14] Repeated measurements, if averaged, should provide a more precise estimate of usual BP than occasional measurements obtained in the clinic. As a substitute for clinic BP, SMBP monitoring could then be used to adjust anti-hypertensive drug therapy and thereby reduce the need for frequent clinic visits and their associated costs and inconvenience. The extent to which physicians, or patients, use SMBP data to adjust medication is unclear. Self-measurement of BP has also been proposed as a means to improve adherence with treatment. In addition, self-measurement of BP theoretically provides a means to diagnose ‘white coat hypertension (WCH)’, also termed ’non-sustained’ or ‘office’ hypertension. This pattern refers to an elevation of clinic BP in the hypertensive range but normal or low BP outside the clinic setting. Individuals with WCH may be at comparatively low risk for BP related complications in comparison to individuals with sustained BP. An important issue is whether the risk of WCH exceeds that of non-hypertensives.[10]

Ambulatory Blood Pressure (ABP) Measurement

ABP monitoring is a non-invasive, fully automated technique in which BP is recorded over an extended period of time, typically 24 hours. The required equipment includes a cuff, a small monitor (attached to a belt), and a tube connecting the monitor to the cuff. Usually, a trained technician places the device on the patient, provides instructions to the patient, and then downloads data from the device when the patient returns. Most, but not all, ABP devices use an oscillometric technique. Compared to SMBP, relatively few ABP devices are on the market. However, in contrast to SMBP devices, most currently available ABP devices have undergone validation testing, as recommended by the American Association of Medical Instrumentation (AAMI) or the British Hypertension Society (BHS). In a review of validation studies by O'Brien et al, 24 devices had undergone validation testing and 16 were recommended.[13]

During a typical ABP monitoring session, BP is measured every 15-30 minutes over a 24 hour period including both awake hours and asleep hours. The total number of readings usually varies between 50 and 100. BP data are stored in the monitor and then downloaded into device-specific computer software. The raw data can then be synthesized into a report that provides mean values by hour and period [daytime (awake), nighttime (asleep), and 24 hour BP], both for systolic and diastolic BP. The most common output used in decision making are absolute levels of BP, that is, mean daytime, nighttime, and 24 hour values. Because of the expense of ABP equipment (up to $5,000 for a monitor, cuff set and software), the requirement for technicians, the inconvenience and logistics of placing and removing ABP devices, and until recently, the lack of reimbursement, it is uncommon for ABP monitoring to be done frequently.

In addition to mean absolute levels of ABP, certain ABP patterns may predict BP-related complications. The patterns of greatest interest are 'white coat hypertension' and 'non-dipping' BP. Using both daytime and nocturnal ABP, one can identify individuals, termed 'non-dippers', who do not experience the decline in BP that occurs during sleep hours. Usually, nighttime (asleep) BP drops by 10 percent or more from daytime (awake) BP. Research has suggested that individuals with a 'non-dipping' pattern (less than 10 percent BP reduction from night to day) may be at increased risk of BP-related complications compared to those with a normal dipping pattern.[15]

Although ABP could be used to monitor therapy, the most common application is diagnostic, that is, to ascertain an individual's usual level of BP outside the clinic setting and thereby identify individuals with WCH. In addition to detection of WCH, ABP devices may be used to identify individuals with a 'non-dipping' BP pattern and to evaluate apparent drug resistance, hypotensive symptoms to medications, episodic hypertension, and autonomic dysfunction.[7] Use of ABP monitoring has been controversial. First, few prospective studies have determined whether this technology predicts cardiovascular disease outcomes and whether this technology provides additional information beyond that provided by routine clinic measurements.[16] Second, insurers have been concerned that health care providers might overutilize ABP. Third, it has been unclear whether SMBP monitoring is a satisfactory and less expensive alternative to ABP monitoring. Accordingly, health insurers have been reluctant to reimburse for ABP monitoring. Recently, however, the Centers for Medicare and Medicaid Services has decided to cover use of ABP to diagnose WCH.

Scope and Purpose of Report

This evidence report summarizes and examines the evidence supporting the clinical utility of non-invasive ABP and SMBP monitoring. Although these technologies have been proposed for use in several settings, the focus of this report was the evaluation and management of adults with elevated BP. Patient populations included in this report were non-pregnant adults with BP in the non-hypertensive or hypertensive range.