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BpTRU™ Blood Pressure Monitor for use in a Physician's Office

Summary

- ✓ **The BpTRU™ is an automated device that takes serial blood pressure (BP) measurements in a physician's office.**
- ✓ **Preliminary data from non-randomized, uncontrolled trials suggest that the average of five BpTRU measurements, taken while the patient is alone, more reliably reflects "resting" BP compared to manual measurements taken with a stethoscope and sphygmomanometer.**
- ✓ **BpTRU helps reduce the overestimation of BP due to improper measurement technique, or due to a patient's anxiety in a physician's presence ("white coat" effect).**
- ✓ **The BpTRU device can improve hypertension management by replacing conventional manual BP measurements, which are often poorly performed and inaccurate.**
- ✓ **BpTRU is more expensive than the manual manometers used in a physician's office. The serial measurement, taken in a private examining room, requires an average of six to 12 minutes, which could increase the duration of a patient's visit.**

The Technology

The BpTRU is a blood pressure (BP) monitor manufactured by VSM MedTech (Coquitlam BC) for use in a physician's office.

The device uses a BP cuff with an automated inflation and deflation mechanism. The cuff measures oscillations in the pulses in the upper arm, and uses a computer algorithm to calculate the systolic and diastolic BP. The initial reading is taken while a physician or nurse is present, and then discarded. Five additional measurements are subsequently taken at intervals of one to five minutes while the patient is alone in a room. These measurements, and the average of the last five readings are displayed to the nearest 1 mm Hg. The BpTRU device has been validated for accuracy by the British Hypertension Society, and the Association for the Advancement of Medical Instrumentation.[1]

Regulatory Status

All BpTRU models are licensed by Health Canada (BPM-100, May 2000; BPM-300 and BPM-300T, September 2002), and are indicated to measure systolic and diastolic BP and pulse rate in individuals ≥3 years of age.[2] The BPM-300T model also measures body temperature.

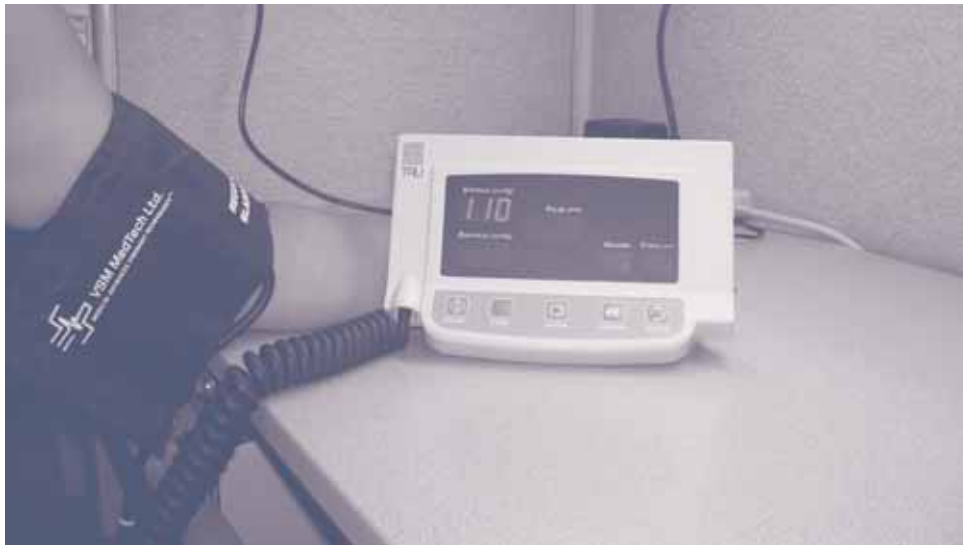

photo courtesy of Allison Kirby

BpTRU™ blood pressure monitor

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Patient Group

More than a fifth of Canadians have hypertension, which is one of the most common reasons for a patient to visit a physician's office.[3] Hypertension is a key modifiable risk factor for stroke, heart attack, heart failure, and premature death.[4] Hypertension management, however, is often suboptimal, and <15% of Canadians with hypertension have their BP well controlled.[5]

Drug treatment is required, usually for life, for persistent elevation of systolic or diastolic BP ≥140/90 mm Hg in a physician's office, or ≥130/80 mm Hg if diabetes or chronic kidney disease is present.[6]

Current Practice

National committees and experts emphasize the critical role of standardized, accurate, and reproducible BP measurements in the initial diagnosis of hypertension and its ongoing management.[7, 8]

The most common method of measuring BP in a physician's office involves listening for sounds with a stethoscope (auscultation) while using a mercury or aneroid (liquid-free) sphygmomanometer. Mercury devices are being phased out because of environmental concerns about toxicity.[9-11] Aneroid devices require regular maintenance and calibration; 30% to 40% of aneroid devices used by physicians have been shown to be out of calibration by ≥4 mm Hg, and 10% are out of calibration by ≥10 mm Hg.[12]

Up to 40% of patients experience an increase in BP at a physician's office, making clinic measurements an unreliable indicator of true BP control.[13,14] Three factors contribute to erroneous measurements. First, patients may be nervous about visiting a physician, producing the "white-coat effect," which can raise systolic and diastolic blood pressure by >20/10 mm Hg.[13] Second, while BP measurement by auscultation is one of the most common and basic medical assessments, errors often occur. These errors include failure to keep the arm at heart level, incorrect cuff size, failure to allow the patient to rest quietly for at least five minutes before taking the first measurement, deflating the cuff too rapidly, imprecise rounding of digits (digit bias), and lack of multiple measurements.[9,12] Finally, the patient and physician may engage in conversation just before or during the reading, which tends to increase BP.[11] The skills required for proper auscultatory measurement are easily lost, and frequent reassessment and retraining are required.[7,9]

A transiently elevated BP of ≥140/90 mm Hg in a doctor's office (when the ambulatory BP is normal) is called "white coat hypertension."[11] If BP is elevated in a physician's office, at least two more readings are recommended during the same visit.[6] The time constraints of a busy practice can contribute to errors if BP is not measured as meticulously as is recommended in guidelines.[7,13]

Ambulatory blood pressure monitoring (ABPM) over 24 hours is used to diagnose and monitor hypertension in difficult cases where there is uncertainty about BP measurements, a "white coat effect," or a lack of response to treatment. The widespread use of this test, however, is impractical, because it is expensive, time-consuming, and not always available.[7,14]

The Evidence

Several non-randomized trials have compared BpTRU measurements with manual auscultation or ABPM. Preliminary evidence suggests that BpTRU reduces the "white coat effect." After discarding the first measurement taken in the presence of a health professional, the average of five subsequent measurements taken while the patient is alone in a room more reliably reflects "resting" BP compared to auscultatory measurements taken with a stethoscope and a conventional sphygmomanometer.

In a study of 50 patients referred to a specialist for hypertension, BpTRU significantly reduced the "white coat effect" ($p<0.001$). The mean of five BpTRU measurements taken at one-minute intervals was significantly lower (142±21/80±12 mm Hg) than the first BpTRU reading taken in the presence of a health professional (162±27/85±12 mm Hg), or readings taken with a mercury manometer (163±23/86±12 mm Hg).[11]

A study of 107 adult hypertensive patients found that, compared with BP measurements obtained by a trained research nurse using a mercury manometer, the BpTRU significantly reduced the "white coat effect" (seven patients versus 39; $p<0.0001$) and "white coat hypertension" (one patient versus 13; $p<0.0001$).[7]

A cohort study found that BpTRU readings (at one-minute intervals) taken from 645 firefighters on five occasions were lower on the first visit (3.0/2.7 mm Hg, $p<0.0001$) compared to standardized manual readings, but the readings converged by the fourth or fifth visit. In addition, among 50 consecutive patients seen in a clinic for urgent general conditions or hypertension, BpTRU measurements were substantially lower (8/7 mm Hg) compared to auscultatory BP measurements taken by a nurse.[15]

A study of 481 known hypertensive patients found that the mean of five BpTRU measurements (140±17.71/79±10.46 mm Hg) taken at one- or two-minute intervals correlated significantly better with daytime ABPM (141.5±13.25/79.7±7.79 mm Hg) than did usual clinic auscultation measurements (150.8±10.26/82.9± 8.44 mm Hg).[14]

A study of 106 patients referred to a hypertension clinic for six-hour ABPM found a 92% agreement for the diagnosis of hypertension between a nurse specialist's mean measurement with an aneroid anometer (137.7±20.2/74.1±12.1 mm Hg), and the mean of five BpTRU™ measurements taken at three-minute intervals (135.9±20/78.9±11.6 mm Hg). No comparison was reported with the ABPM.[9]

No adverse effects were reported in published studies.

Although the BpTRU is simple to use and requires little training, measurement errors may occur if the patient is not properly situated or rested, if the wrong cuff size is used, or if the arm is not supported at heart level.[15]

One study that used the five-minute interval for BpTRU measurements in 107 hypertensive adults noted a substantial number of inaccurate classification of patients as normotensive when they were hypertensive, potentially leading to under-treatment.[7] The authors concluded that the five-minute interval setting should not be used in clinical practice.

Administration and Cost

The BpTRU is available in three models, with each measuring heart rate and BP in the same way. Three cuff sizes are included. The BPM-100 model costs C$900. The BPM-300, at C$1,150, also includes a rechargeable battery and a USB port. The BPM-300T, at C$1,375, has all of the BPM-300 features, with the addition of a body temperature component. Pediatric or extra-large adult cuffs cost C$24 and C$52 respectively (Kimberly Sasaki, VSM MedTech, Vancouver: personal communication, 2006 May 25). The device has an anticipated lifetime of at least 10,000 BP measurements.[16]

Concurrent Development

No randomized, controlled trials have compared BpTRU with other automated oscillometric BP monitors. Another validated, automated device available in Canada for office use is the Omron HEM-907XL (Omron Healthcare Inc., Bannockburn IL). It records a maximum of three readings without discarding the first measurement. The retail price is C$895, including a portable stand, four cuff sizes, and a rechargeable battery (Mark Rinker, Omron Healthcare, Inc. Burlington: personal communication, 2006 June 2).

Rate of Technology Diffusion

The BpTRU monitor is approximately five times more expensive than aneroid or mercury sphygmomanometers for office use. This could impede diffusion. No cost-effectiveness evaluations were identified. The phasing out of mercury manometers may encourage physicians to consider oscillatory devices such as the BpTRU.

Implementation Issues

A single measurement with a traditional sphygmomanometer may be sufficient for routine screening if the BP is normal or low. The BpTRU may be useful in assessing patients with borderline or elevated BP detected on screening, and for ongoing monitoring of borderline hypertensive patients, or those treated with anti-hypertensive drugs.

An expert committee comprising members of the Canadian Hypertension Society, the Canadian Coalition for High Blood Pressure Prevention and Control, and the Heart and Stroke Foundation of Canada recommends oscillometric BP monitoring in preference to auscultation. The committee recommends the BpTRU device for office use.[4]

Compared to sphygmomanometers, the BpTRU is easy to use and requires little training.[15] An advantage of the device is the consistency of the computer algorithm used to calculate BP compared with measurement by technique-dependent auscultation, which may vary from visit to visit.

Before the first reading is taken with any BP monitor, including the BpTRU, patients must rest quietly for at least five minutes after the cuff is placed on the arm. After this rest period, if the one- or two-minute interval is selected, the serial BpTRU measurement takes an additional six to 12 minutes, which could increase the duration of a patient's visit.

The device takes the BP measurement while the patient is alone in a room, which allows the health professional to do other tasks, and helps reduce the overestimation of BP created by the "white coat effect." However, freeing

up an examining room (or establishing a separate room) for the BP measurement could pose a challenge for clinics with limited space. In addition, any change to the traditional flow of patients through the clinic could serve as a barrier to implementation.

More controlled trials are needed to compare BpTRU measurements at specific interval settings to standard measurements taken by trained health care professionals across a spectrum of patients. This evidence is needed before specific recommendations can be made in guidelines about which BP monitor should be used preferentially in a physician's office. Preliminary evidence, however, indicates that automated oscillometric devices, such as the BpTRU, can improve hypertension management by replacing auscultatory BP measurement methods, which are often poorly performed, inaccurate, and misleading.[9,15]

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Reviewers: Marshall Godwin, MD, MSc, Memorial University; **James M Wright, MD, PhD,** University of British Columbia.

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