

Overall accuracy of the BpTRU™—an automated electronic blood pressure device

Gurdial S. Mattu^a, Balraj S. Heran^a and James M. Wright^{a,b}

Background The objective of this report is to combine the data from an earlier adult study with the data from a paediatric study in order to determine the overall accuracy of the BpTRU™ (BPM-100 model) as compared to the recognized standard, auscultatory mercury sphygmomanometer.

Design The individual blood pressure points recorded for both adult and paediatric studies were compared directly to its corresponding observer reference measurements from data collected and stored from the two separate studies. There were 255 sets of readings in the adult study and 162 sets from the paediatric study, which were combined to make 417 pairs of blood pressure readings for this study.

Methods The overall observer standard reference mean for the 417 measurements was calculated and the difference between this and the overall mean BPM-100 was calculated with SD and ranges. Measurements within 5, 10 and 15 mmHg agreement were expressed as percentages.

Results A total of 121 subjects were included for this study (85 from the adult study and 36 from the paediatric study). From these, 417 paired measurements were recorded. The mean difference between the BpTRU™ and the reference standard systolic blood pressure (BP) was

0.47 ± 5.40 mmHg with 89.2% measurements within 5 mmHg, 96.4% within 10 mmHg and 99.3% within 15 mmHg. The mean difference between the BpTRU™ and reference diastolic BP was -2.12 ± 5.93 mmHg with 81.1% within 5 mmHg, 92.1% within 10 mmHg and 97.6% within 15 mmHg.

Conclusion The BpTRU™ has been shown to be an accurate non-invasive blood pressure monitoring device in the general population over a wide range of ages (3–83 years). This combined study meets all requirements of the Association of Advancement of Medical Instrumentation and achieved a grade 'A' in the BHS protocol. *Blood Press Monit* 9:47–52 © 2004 Lippincott Williams & Wilkins.

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^aDepartment of Pharmacology & Therapeutics and ^bDepartment of Medicine, University of British Columbia, Vancouver, BC, Canada.

Correspondence and requests for reprints to James M. Wright, Department of Pharmacology & Therapeutics and Department of Medicine, The University of British Columbia, 2176 Health Sciences Mall, Vancouver, BC, Canada, V6 T 1Z3. Tel: +1 (604) 822 4270; fax: +1 (604) 822 0701; e-mail: jmwright@interchange.ubc.ca

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Introduction

The BpTRU™ (model BPM-100) is a non-invasive automated electronic blood pressure monitor that uses the oscillometric technique to determine the mean arterial pressure and then calculates the systolic and diastolic blood pressures from this. It records six measurements automatically, separated by a time period of 1 to 5 min set as required by the operator. It discards the first reading, which is normally taken with the observer present and then records and saves the remaining five readings plus the average of those readings.

Home blood pressure readings with an automated device have been shown to have greater predictive value than office blood pressures for mortality in a recent population-based observational study [1].

Hypertension has a major impact on our health services; it is the major risk factor for heart disease, stroke and renal

disease. Heart disease is the leading cause of death in the USA, with cerebrovascular disease being the third leading cause of death [2]. Joffres *et al.* [3] discuss the differences in awareness, treatment and control of hypertension between the USA and Canada, yet fail to emphasize the two very different settings for the blood pressure measurement, saying that these should have minimal impact. In contrast Gerin *et al.* [4] clearly emphasized the differences and concluded that an automated device would be better than both methods.

The most accurate technique for measuring blood pressure (e.g., intra-arterial catheterisation) is not practical or functional for the primary care physician who is the frontline for diagnosing, monitoring and managing hypertension. If performed correctly, office blood pressures with a mercury sphygmomanometer may be accurate; however, it has been shown that at least 20% of hypertension is misdiagnosed this way [5]. In addition

the difficulties of managing mercury spills is a growing concern such that many European countries and US cities have already banned mercury and others are set to follow suit [6,7].

Blood pressures recorded in the physician's office by the physician can be misleading and readings performed by the office nurse or the patient are more representative. In fact non-physician measurements result in less treatment initiation, change in type of medication or escalation of dose [8].

Correctly diagnosing and managing blood pressure clearly has a potential for impact on mortality, morbidity and health care costs. However, we can only be confident of achieving the benefits seen in the trials if we have a method of accurately recording blood pressures in a manner similar to that seen in the clinical trial setting.

The purpose of this study was to combine the data from two studies, one in a paediatric population and one in an adult population in order to determine the overall accuracy of the automated blood pressure monitor, BpTRU™ against the gold standard mercury sphygmomanometer. To achieve this, the study was assessed in accordance with the standard guidelines of the AAMI SP10-1992 provided by the Association for the Advancement of Medical Instrumentation (AAMI) and in accordance with the British Hypertension Society protocol-1993; the regulating bodies for validating these types of monitors.

Methods

Adult subjects were recruited from the Hypertension Clinic and affiliated primary care practices at the University of British Columbia during September and October 1999. The paediatric subjects were recruited from British Columbia's Children's Hospital and also family practice offices during June to August 2001.

Details of all ethical approval, consent acquired, inclusion, exclusion criteria and target population requirements can be obtained from the companion paper [9] and the two original adult publications [10,11].

In the adult population two experienced nurses were used whose blood pressure reading skills were tested prior to the initiation of any data collection. Similarly in the paediatric population three experienced nurses rotated as the two observers.

The set-up was the same for both studies with the BpTRU™ being connected in parallel with the Trimline precision standard mercury sphygmomanometer (Trimline Medical Products, Branchburg, New Jersey, USA) and the Nonin finger pulse oximeter (Onyx, Nonin Medical Inc.,

Plymouth, Minnesota, USA) being connected to the other arm or alternate body part. The observers, who were seated opposite the standard mercury sphygmomanometer, were blinded by a curtain between them and also blinded to the BpTRU™ device. One of them would palpate the brachial pulse and put the diaphragm of the dual-headed stethoscope over it. The only difference between the two population sub-groups was that the paediatric subjects were allowed to sit on the laps of their accompanying parent or guardian.

All data recorded by the BpTRU™ device was simultaneously saved onto a computer from which subsequent analysis could be performed. From the 121 subjects recruited for this study, 417 data points were obtained, all of which were used in our study having already conformed to the inclusion and exclusion criteria specified in the previous studies.

Data analysis

After combining the 85 adult subjects (at least 18 years of age) and the 36 paediatric subjects (from 3–18 years of age), a total of 121 subjects were included. For each of the included measurements, distribution of blood pressures was determined and expressed as the number and percentages of systolics > 180 mmHg, between 100 and 180 mmHg and < 100 mmHg. Included in this was an expression of the mean, standard deviation and range of blood pressures in the population group.

From the 417 measurements the mean, standard deviations and range of blood pressure and heart rate was also determined for observer I and observer II. Subsequently, the mean of the two observers was also calculated and became known as the reference standard measurement. Agreement of readings within 5 and 10 mmHg was also expressed. Similarly, the mean, standard deviation and range of blood pressure were also determined for the BpTRU™ device.

To assess the accuracy of the device, the mean difference and standard deviation, between the BpTRU™ and the reference standard was determined as per the ANSI/AAMI SP10-1992 standard [12]. Subsequently, in order to reflect this accuracy in the clinical setting, the subject mean difference with standard deviation was also determined (subject mean BpTRU™ measurements minus the subject mean reference measurements). The percentage agreement of measurements within 5, 10 and 15 mmHg was also expressed in order to represent the requirements of the British Hypertension Society protocol [13].

Results

Included subjects

There were a total of 121 subjects included from the two studies (85 from the adult study [10] and 36 from the

paediatric study [9]). Of these 67 (55.4%) were male subjects and 54 (44.6%) were female subjects. The average age of included subjects was 33.1 years of age, ranging from 3–83 years. Details of included and excluded subjects can be seen in the original adult study [10] and the paediatric companion paper [9]. All of the target population requirements for each study were met, except the hypertensive criteria specified in the paediatric study (discussed in the paediatric paper) [9].

Included blood pressure measurements

From the 121 subjects included there were a total of 417 reference standard systolic readings obtained. Of these, 27 (6.5%) were greater than 180 mmHg, 253 (60.7%) were between 100 and 180 mmHg, and 137 (32.8%) had systolic measurements less than 100 mmHg. Of the 417 reference standard diastolic readings twenty-five (6.0%) were greater than 100 mmHg and 108 (25.9%) were less than 60 mmHg with the remaining 284 (68.1%) between 60 and 100 mmHg. The overall average systolic blood pressure was 117.7 ± 29.23 mmHg (range 78–223.5 mmHg) and the overall average diastolic blood pressure was 71.5 ± 15.95 mmHg (range 45–119.5 mmHg). The overall mean heart rate was 77.1 ± 15.41 bpm (range 42–116 bpm) using the Nonin finger pulse oximeter.

Excluded blood pressure measurements

There were six subjects excluded because of technical errors made by the BpTRU™ device that did not allow for a minimum of three blood pressure readings to be recorded. More detailed explanations of all excluded subjects and measurements can be obtained from the previous publications [9–11].

Reference standard blood pressure readings

Observer agreement (or the mean difference between observer I and II), as recorded using a Trimline mercury sphygmomanometer, for the 417 systolic measurements was -0.26 ± 2.38 mmHg (range -10 to 10 mmHg). Of these 404 (96.9%) readings were within 5 mmHg. Similarly the observer agreement for the 417 diastolic blood pressure readings was -0.35 ± 3.27 mmHg (range -10 to 10 mmHg) with 378 or 90.6% being within 5 mmHg (see Table 1). Only a small percentage of

readings were outside the 5 mmHg agreement (mean values greater than 10 mmHg were excluded as one of the post-measurement exclusion criteria), however, the diastolic measurements had a larger number in this range. This highlights the difficulty of accurately measuring diastolic blood pressure, particularly in paediatric populations or young female adults where values are as low as 45 mmHg.

Measurements of BpTRU™ (model BPM-100)

Table 1 also shows that the overall mean systolic blood pressure recorded by the BpTRU™ was 118.2 ± 28.47 mmHg with a range of 77–221 mmHg, and diastolic blood pressure was 69.4 ± 16.3 mmHg (range 40–120 mmHg) for 417 measurements. The overall mean heart rate recorded by the BpTRU™ was 77.3 ± 15.33 bpm with a range of 42–116 bpm for the 417 readings.

Accuracy

The accuracy of the BpTRU™, or the mean difference between the BpTRU™ and the observer reference standard systolic blood pressure was 0.47 ± 5.40 mmHg which is well within the ANSI/AAMI SP10-1992 standard. Similarly the mean difference between the BpTRU™ and the reference diastolic blood pressure was -2.12 ± 5.93 mmHg which is also within the ANSI/AAMI SP10-1992 standard, as seen in Table 2. The mean difference of the observer reference and the BpTRU™ for the heart rate was 0.18 ± 2.20 bpm.

In Table 3 it can be seen that 372 (89.2%) systolic differences were within 5 mmHg, 402 (96.4%) were within 10 mmHg and 414 (99.3%) were within 15 mmHg. For the diastolic measurements 338 (81.1%) were within 5 mmHg, 384 (92.1%) were within 10 mmHg and 407 (97.6%) were within 15 mmHg. These determinants all fall within the British Hypertension Society (BHS) grade 'A' protocol. It can also be seen that the agreement of systolic measurements was better than that of the diastolic.

As stated previously the BpTRU™ is an automated device that records and calculates the average of five blood pressure measurements. It is intended for use in the physician's office in this manner. The subject mean

Table 1 Systolic, diastolic blood pressure and heart rate measurements for the two observers and the BpTRU™

	n	Systolic			Diastolic			Heart rate		
		Mean mmHg	±SD mmHg	Range mmHg	Mean mmHg	±SD mmHg	Range mmHg	Mean bpm	±SD bpm	Range bpm
Observer I (1)	417	117.6	29.13	78–224	71.3	15.82	44–119	77.1	15.41	42–116
Observer II (2)	417	117.9	29.34	76–223	71.6	16.25	43–120	77.1	15.41	42–116
Observer mean (ref)	417	117.7	29.23	78–223.5	71.5	15.95	45–119.5	77.1	15.41	42–116
Obs. agreement (1–2)	417	-0.26	2.38	-10 to 10	-0.35	3.27	-10 to 10	0	0	0
BpTRU™ readings	417	118.2	28.47	77–221	69.3	16.30	40–120	77.3	15.33	42–116
Accuracy (BpTRU™ - ref)	417	0.47	5.40	-18.5 to 22.5	-2.12	5.93	-22.5 to 17	0.18	2.20	-16 to 7

Table 2 Difference between the BpTRU™ and the reference standard measurements compared to the American National Standard for Electronic or Automated Sphygmomanometers

	n	Systolic		Diastolic	
		Mean difference (mmHg)	Standard deviation (mmHg)	Mean difference (mmHg)	Standard deviation (mmHg)
ANSI/AAMI SP10-1992		± 5.0	< 8.0	± 5.0	< 8.0
BpTRU™-100 minus reference standard	417	0.47	5.40	-2.12	5.93
Subject mean BpTRU™ minus reference standard	121	0.40	4.34	-2.00	5.15

Table 3 Performance of the BpTRU™ compared to the British Hypertension Society (BHS) grade 'A' protocol

	n	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Grade 'A' BHS standard		≥ 60%	≥ 85%	≥ 95%
BpTRU™ minus reference systolic blood pressure	417	89.2	96.4	99.3
BpTRU™ minus reference diastolic blood pressure	417	81.1	92.1	97.6
Subject mean BpTRU™ minus subject mean reference systolic blood pressure	121	75.2	98.3	100.0
Subject mean BpTRU™ minus subject mean reference diastolic blood pressure	121	71.1	92.6	98.3

difference was determined in order to reflect the accuracy of the device in the clinical setting. The subject mean difference for systolic blood pressures was 0.4 ± 4.3 mmHg, for diastolic -2.0 ± 5.1 mmHg and for heart rate was 0.2 ± 1.1 bpm. Of the systolic mean differences 91 (75.2%) subjects were within 5 mmHg, 119 (98.3%) were within 10 mmHg and 121 (100%) were within 15 mmHg. Of the diastolic mean differences, 86 (71.1%) subjects were within 5 mmHg, 112 (92.6%) were within 10 mmHg and 119 (98.3%) were within 15 mmHg agreement (see Table 3).

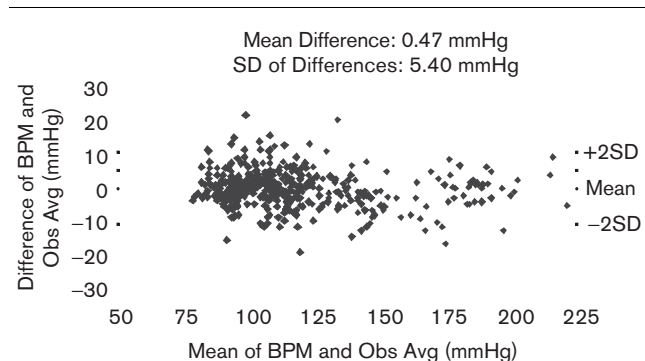
Bland–Altman plots displaying the difference of the BpTRU™ and the observer average for both systolic and diastolic pressures are shown in Figures 1 and 2, respectively [14].

Discussion

There have been several publications on the importance of taking accurate and reproducible blood pressures. Campbell and McKay [15] have illustrated the potential difficulties with inaccurate readings, demonstrating that consistent over-estimation of diastolic blood pressure by 5 mmHg would increase the diagnosis of hypertension in a physicians practice by 100% and conversely, under-estimating the diastolic blood pressure by 5 mmHg would reduce the diagnosis of hypertension by 62%.

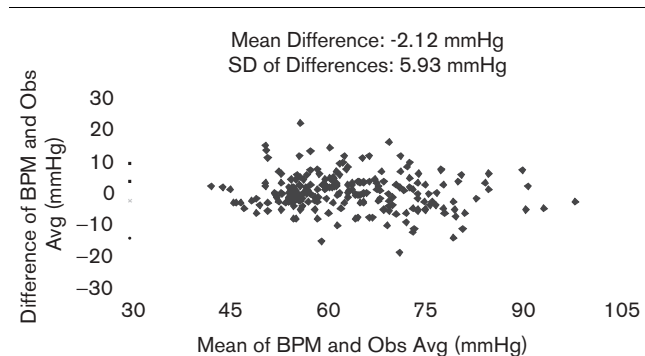
Blood pressure should be recorded bearing in mind the following factors [4,16–18]: (1) Patients should refrain from smoking or ingesting caffeine at least 30 min before having their blood pressures recorded. (2) Blood pressure should be recorded in a quiet and calm environment. (3) Patients should be seated with their backs well supported, feet flat on the ground and with the mid-point of the bare upper arm supported at heart

Fig. 1



Bland–Altman display of all systolic blood pressure measurements (n=417). BPM, BpTRU™ (model BPM-100) monitor; Obs Avg, observer average (reference standard).

Fig. 2



Bland–Altman display of all diastolic blood pressure measurements (n=417). BPM, BpTRU™ (model BPM-100) monitor; Obs Avg, observer average (reference standard).

level. (4) An appropriate-sized cuff (the bladder inside the cuff should be at least 80% of the arm circumference) should be placed on the upper arm of the patient 2–2.5 cm above the antecubital fossa. (5) Blood pressure measurements should only be recorded after at least 5 min of rest. (6) Measurements should be taken either with a regularly calibrated automated blood pressure device or mercury sphygmomanometer. (7) Inflate the cuff to at least 30 mmHg above the disappearance of the radial pulse of the arm from which pressures are being recorded. (8) Deflate the cuff at a linear rate of 2 mmHg/s. (9) Utilize the disappearance of sounds as the diastolic blood pressure. (10) At least two readings, at least 2 min apart should be taken at each visit. (11) At least two separate visits with blood pressure recordings are required to make the diagnosis of hypertension unless there is evidence of end-organ damage at the first visit.

The automated device assessed here saves time and makes it more likely that the above criteria will be followed: (1) Patients can be placed in a quiet room by themselves, avoiding the effects of the observer on the blood pressure. (2) Different cuffs supplied with the device are clearly marked to allow for the most appropriate cuff to be used according to arm size. (3) The device automatically calibrates to atmospheric pressure and ambient temperature before each measurement reducing errors of calibration. (4) The device inflates to 35 mmHg above the level of occlusion of the radial pulse so as not to miss auscultatory gaps. (5) The device has a linear deflation rate to provide consistency and reduce errors of detecting pulse waves. (6) The device has reproducible smooth inflation and deflation. (7) The device is calibrated to agree with disappearance of sounds to generate diastolic blood pressure. (8) The first measurement is discarded since the person starting the device is expected to still be in the room. (9) Five measurements are obtained at 1 to 5 min intervals with the average calculated to give the most representative measure of blood pressure.

With the advent of newer blood pressure measuring devices, there has been renewed interest in validation trials and standardization of these devices [19]. Recently, the European Society of Hypertension Working Group has used published data to devise a new International Protocol that it is hoped will encourage all device manufacturers to perform and adhere to minimum validation and approval protocols [20].

The device tested here met the requirements set by the governing bodies mentioned, which are far more rigorous than the new International Protocol. This study demonstrated that this device met these strict requirements over a wide range of subjects. The Bland–Altman plots demonstrate that the device is accurate over a wide range

of pressures with the expected increase in variability of differences at the lower pressures. Because we combined raw individual data rather than means and imputed standard deviations, the combined analysis is equivalent to doing an individual subject meta-analysis.

The BpTRU™ is the only non-invasive automated oscillometric blood pressure device currently available that has been tested in a population group with an age range of from 3 to 83 years. It has satisfied the criteria set out by the American National Standard for Electronic or Automated Sphygmomanometers, ANSI/AAMI SP10-1992 [12]. It has also achieved a grade 'A' according to the British Hypertension Society protocol for the evaluation of blood pressure measuring devices-1993 [13].

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