Clinical decision-making in hypertension using an automated (BpTRU™) measurement device

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Mercury sphygmomanometers are being removed from clinical practice in the United States due to environmental concerns about mercury toxicity. Accurate blood pressure measurement is central to high-quality hypertension management. In this study of 106 patients, the BpTRU™ device was compared to nurse blood pressure measurements that complied with all the JNC VII/American Heart Association guidelines in evaluation of a random casual blood pressure. The intermethod difference in systolic blood pressure was $+1.8 \pm 5.1$ mmHg, and for diastolic blood pressure it was $4.8 \pm 5.1$ mmHg (both $P<0.001$). For the primary study end point of clinical decision-making, there was 92% (97/106) agreement between the hypertension nurse specialist and the BpTRU™ (kappa 0.8280, 95% confidence interval, 0.721–0.9350). The oscillometric blood pressure measurement with the BpTRU™ is recommended as a replacement for poorly performed auscultatory blood pressure measurement in clinical practice.

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Introduction

Accurate blood pressure measurement is the foundation of the diagnosis and treatment of hypertension. Since the introduction of the Riva-Rocci mercury manometer in 1896, auscultatory blood pressure measurement has been the standard in clinical practice. The mercury manometer is being removed from clinical practice, as was the mercury thermometer, because of valid concerns about mercury toxicity.1,2 Its usual replacement, the aneroid manometer, has been found to be a satisfactory replacement if properly maintained.3 Unfortunately, whether one uses the mercury manometer or the aneroid manometer, the seemingly simple task of auscultatory blood pressure measurement in clinical medicine is fraught with sources of error that may lead to misdiagnosis or mistreatment of the hypertensive patient.4,5 Human-induced errors in blood pressure measurement include incorrect positioning of the patient, inappropriate cuff usage, inadequate rest period, overly rapid deflation rate, digit bias, digit preference, and lack of multiple measurements.6–11 These errors occur in large part due to the failure of training of doctors and nurses in the importance of these different factors that affect blood pressure determination.12–14 In light of the increasingly aggressive goals set for blood pressure control in JNC VII,15 confidence in the accuracy of the blood pressure measurement by both the physician and the patient is critical to the successful implementation of these guidelines. Given the increasing time pressures in clinical practice, it is unlikely that time is going to be set aside for multiple blood pressure measurements according to American Heart Association/JNC VII criteria and for training and retraining of these harried practitioners.

The oscillometric method of blood pressure determination has led to the availability of multiple automated devices for blood pressure determination. Many automated oscillometric devices have been validated as accurate by AAMI/BHS/Modified International Protocol standards.16 Hla et al demonstrated that an automated blood pressure recorder (Infrasonde Model RS2) compared very favourably to a trained observer in systolic blood pressure determination in the elderly. The hypothesis of this study is that a validated automated oscillometric device (BpTRU™) could provide the same high-quality blood pressure measurement as a
Study design

A total of 106 patients who were sent to the Division of Hypertension for a 6-h ambulatory blood pressure monitoring to evaluate an elevated casual blood pressure gave verbal consent to participate in this study. All patients in this study were ≥18 years of age. Each patient was taken to the nurse specialist’s office (CN), an office especially configured for an accurate blood pressure measurement. The following data were obtained by direct questioning or by review of the electronic medical record: age, gender, height, weight, systolic blood pressure, diastolic blood pressure, presence of diabetes, renal failure, proteinuria, atherosclerotic heart disease, smoking, dyslipidaemia, family history of ASHD, and referral source. In 104 of the 106 subjects, the referring physician had measured the patient’s blood pressure prior to ordering the 6-h ambulatory monitor. This was considered the ‘referral blood pressure’. All blood pressure measurements were carried out according to JNC VII criteria by a trained hypertension nurse specialist (CN). In brief, according to the JNC VII criteria, the subjects were seated in a chair with back support and their feet on the ground and the arm placed comfortably on a table at heart level. There was 5 min of rest in a quiet room preceding the blood pressure measurements. The appropriately-sized cuff, based on the patient’s arm circumference, was placed on the upper arm, 5 cm above the upper arm. Any patient with a history of ongoing atrial fibrillation or with an irregular heart rate at the time of study evaluation was excluded from the study.

The BpTRU™ device was connected via ‘Y’ tubing to an aneroid sphygmomanometer (Tycos) that had been maintained by protocol, as reported by Canzanello et al.[3] Immediately prior to this study, the aneroid manometer was validated, as described by Canzanello et al., using the Digimano 2000™ device and found to be accurate. The aneroid device read zero prior to inflation and demonstrated needle movement from 60 to 240 mmHg when inflated in 20 mmHg increments. At no point did the aneroid manometer deviate by more than 2 mmHg from the Digimano standard. During the study, the BpTRU™ device controlled cuff inflation and deflation. The BpTRU™ performed six blood pressure measurements at 3-min intervals with the first reading being discarded. The hypertension nurse specialist simultaneously auscultated three blood pressures following JNC VII/American Heart Association (AHA) guidelines beginning with the second BpTRU™ measurement. A minimum of three nurse specialists and three BpTRU™ blood pressure readings were available for each patient.

Statistical methods

For each study patient, mean values for systolic blood pressure and diastolic blood pressure and heart rate were obtained for the BpTRU™ and the hypertension nurse specialist. The mean median, standard deviation, and range as well as a 95% prediction interval summarized intermethod differences. The empirical correspondence between diagnoses provided by each method (<140/90 mmHg—Yes or No) was tabulated as two-way tables for each pair of methods and compared by McNemar’s test for systemic differences. Bland–Altman plots were made to compare the difference in systolic blood pressure and diastolic blood pressure seen between the two methods.

Results

The demographic characteristics for the 106 (57 women and 49 men) patients in this study are summarized in Table 1. The mean age of the patients was 62.8 ± 13.3 years (R: 18–85). The mean height was 169.3 ± 10.8 cm (R: 147–193 cm) and the mean weight was 82.9 ± 20.6 kg (R: 47.1–165.7 cm). The mean arm circumference was 30.2 ± 4 cm (R: 21–39.2 cm). The mean referral systolic blood pressure was 151.8 ± 22.5 mmHg (R: 74–212) and diastolic blood pressure was 83.5 ± 12.4 mmHg (R: 38–110).

For the primary study end points of clinical decision-making, there was 92% (97/106) agreement between the hypertension nurse specialist (kappa 0.8280, 95% confidence interval, 0.721–0.9350). In 55 patients, the two methods indicated that blood pressure was <140/90 mmHg; and in 42 patients, both methods indicated that it was not (Figure 1). In the two patients where the nurse indicated that the blood pressure was <140/90 mmHg and the BpTRU™ did not, the disagreement was with both systolic blood pressure and diastolic blood pressure in one patient. In the second patient, the disagreement was only in diastolic blood pressure (Table 2). In the reverse case, where the BpTRU™ indicated the

Table 1 Patient demographics at study entry

<table>
<thead>
<tr>
<th>N=106</th>
<th>Mean:</th>
</tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>62.8 ± 13.3</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>169.3 ± 10.8</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>82.9 ± 20.6</td>
</tr>
<tr>
<td>Arm circumference (cm)</td>
<td>30.2 ± 4</td>
</tr>
<tr>
<td>Referral SBP (mmHg)</td>
<td>151.8 ± 22.5</td>
</tr>
<tr>
<td>Referral DBP (mmHg)</td>
<td>83.5 ± 12.4</td>
</tr>
</tbody>
</table>
patient was in control and the nurse did not, the disagreement in all seven patients was in systolic blood pressure. Among the 106 study patients, the mean systolic blood pressure was $137.7 \pm 20.2$ mmHg ($R: 92–210$) for the hypertension nurse specialist and $135.9 \pm 20$ mmHg ($R: 94–208$) for the BpTRU™. The intermethod difference for systolic blood pressure was $+1.8 \pm 5.1$ mmHg ($P<0.01$). For diastolic blood pressure, the mean for the hypertension nurse specialist was $74.1 \pm 12.1$ mmHg ($R: 41–110$), while the BpTRU™ mean diastolic blood pressures was $78.9 \pm 11.6$ mmHg. The intermethod difference for diastolic blood pressure was $-4.8 \pm 5.1$ mmHg ($P<0.001$). Even though there were larger methodologic differences in measured diastolic blood pressure than between systolic blood pressure, there was little impact of these differences in clinical decision-making with the BpTRU™. Bland–Altman plots of systolic blood pressure (Figure 2) and diastolic blood pressure (Figure 3) showed excellent agreement between the gold standard nurse and the BpTRU™.

### BpTRU Study: Results

- **Is the Patient < 140/90 mm Hg?**
  - **BpTRU**
    - NO 42
    - YES 7
  - **GSN**
    - YES 2
    - YES 55
  - 92% Agreement

**Figure 1** Agreement on diagnosis of hypertension: BpTRU™ compared to hypertension nurse clinician.

**Table 2** BpTRU™: Patients with disagreement

<table>
<thead>
<tr>
<th>Normal by nurse BP</th>
<th>Avg of SBP</th>
<th>Avg of DBP</th>
<th>Normal BPM 100 BP</th>
<th>Avg of SBP</th>
<th>Avg of DBP</th>
</tr>
</thead>
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<tr>
<td>0</td>
<td>144.0</td>
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<td>1</td>
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<tr>
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<tr>
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<tr>
<td>0</td>
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<td>86.0</td>
<td>0</td>
<td>135.0</td>
<td>95.6</td>
</tr>
</tbody>
</table>

**Figure 2** Bland–Altman plot of agreement of systolic blood pressure.

**Figure 3** Bland–Altman plot of agreement of diastolic blood pressure.
Discussion

After a century of use, the mercury sphygmomanometer is being replaced in clinical medicine due to serious concerns about the impact of mercury on health.\textsuperscript{1,2} The debate has begun as to what method will be used to determine blood pressure in the diagnosis and management of hypertension. Currently, the two choices are the aneroid sphygmomanometer and automated oscillometric devices. The accuracy of aneroid manometers can be precise if they are subjected to, as reported by Canzanello \textit{et al},\textsuperscript{3} previously described regular surveillance using a protocol. The clinical blood pressure measurement with an aneroid device contains all the same opportunities of failing to follow JNC VII/AHA guidelines for blood pressure measurement that have occurred with mercury manometers.\textsuperscript{4,5} Reduction in errors in auscultatory blood pressure measurement due to incorrect patient positioning, digit bias, incorrect deflation rate, and lack of rest time prior to blood pressure measurement occur commonly in clinical practice.\textsuperscript{6–11} Reduction in these observer errors and correct interpretation of phase 1 and phase 5 Korotkoff sounds requires intensive training.\textsuperscript{12,13} In addition, it has been shown that these skills are easily lost so that frequent reassessment and retraining is required.\textsuperscript{14}

In a previous study, the BpTRU\textsuperscript{7}, an automated oscillometer device, was found to be a highly accurate device for the measurement of systolic blood pressure and diastolic blood pressure.\textsuperscript{15} Mattu \textit{et al} found that in using the AAMI protocol, the intermethod difference was $-0.62 \pm 6.96$ mmHg for systolic blood pressure and $-1.48 \pm 4.80$ mmHg for diastolic blood pressure. Using the British Hypertension Society guidelines, it received a grade for systolic blood pressure/diastolic blood pressure of A/A.\textsuperscript{18} Our study confirmed the accuracy in measurement found in the Mattu \textit{et al} study with intermethod difference for systolic blood pressure of $+1.8 \pm 5.1$ mmHg and for diastolic blood pressure, $-4.8 \pm 5.1$ mmHg. Bland–Altman plots of systolic blood pressure (Figure 2) and diastolic blood pressure (Figure 3) confirm excellent agreement between the BpTRU\textsuperscript{7} and the gold standard nurse blood pressure determinations that do not vary as a function of the blood pressure level. Our intermethod difference for diastolic blood pressure is not as small as that reported by Mattu \textit{et al}. This may be due to the wider range of blood pressure required in the Mattu \textit{et al} study by the BHS protocol\textsuperscript{19} for blood pressure measurement device validation.

This study focused on the utility of the BpTRU\textsuperscript{7} in clinical decision-making. The physician, when confronted with a random casual blood pressure, must decide whether this patient has hypertension (is the blood pressure $\geq 140/90$ mmHg?). The standard for diagnosis of hypertension is repeated to obtain AHA/JNC VII quality blood pressures over several office visits. In our study, we found that in 97/106 patients (92%), the BpTRU\textsuperscript{7} gave the same answer as the gold standard nurse blood pressure measurement. There were nine patients in whom there was disagreement. In two patients, the nurse indicated that the patient was normotensive while the BpTRU\textsuperscript{7} disagreed. In one patient, they disagreed about both systolic blood pressure and diastolic blood pressure; and in the second, they disagreed only about the diastolic blood pressure. In the other seven patients, the BpTRU\textsuperscript{7} indicated they were $<140/90$ mmHg and the gold standard nurse found all seven to have systolic blood pressure $\geq 140$ mmHg, while both methods agreed that diastolic blood pressure was $<90$ mmHg. None of the patients with disagreements had arrhythmias, which might interfere with oscillometrically measured blood pressure.

Oscillometric blood pressure determination is being increasingly recognized as a valuable and accurate tool for blood pressure management. Similar to our study, Hla \textit{et al}\textsuperscript{22} have demonstrated that an automated blood pressure recorder (Infrasonde Model RS2) can provide as accurate a systolic blood pressure measurement as a trained observer. In addition, the Infrasonde eliminated digit bias seen in the clinical providers blood pressure determinations in the 36 elderly patients in that trial. Reflecting the increasing acceptance of validated oscillometric devices, several large multi-centre hypertension studies, such as the HOT Study\textsuperscript{20} and the ASCOT,\textsuperscript{21} have used oscillometric devices as the method of blood pressure measurement. Devices used are those that have passed the AAMI or British Hypertension Society published validation studies.\textsuperscript{36} The BpTRU\textsuperscript{7} and other validated devices increase the accuracy of blood pressure measurement by reducing observer errors such as digit bias, zero preference, incorrect deflation rates, and failure to perform multiple blood pressure measurements. As seen in this study, they offer blood pressure measurements comparable to the highly trained nurse without the need for extensive training and retraining. The BpTRU\textsuperscript{7} offers the practising clinician the ability to improve the care of hypertensive patients without increased personnel costs. By discarding the first blood pressure recording, the BpTRU\textsuperscript{7} may reduce the impact of the office pressor or ‘white coat’ effect. Campo \textit{et al}\textsuperscript{22} have shown that six blood pressure measurements using an oscillometric device reduced the incidence of white coat hypertension from 33.1 to 11.3%. Other features of the BpTRU\textsuperscript{7} that enhance its value to the practising clinician include its rugged construction (over 100 000 inflations without malfunctions) and self-zeroing function, which verifies the validity of the device before each measurement.\textsuperscript{23}

A potential weakness in this study is the use of the aneroid manometer as the comparator for the BpTRU\textsuperscript{7} device. Canzanello \textit{et al}\textsuperscript{3} have shown that a well-maintained aneroid manometer, even in a busy
clinical practice, can have an instrument failure rate of less than 0.5%. Other studies that have shown lesser degrees of accuracy with aneroid devices were in situations where a rigorous calibration and validation protocol were not being followed.24,25 Indeed, it has been underappreciated that even the mercury manometer may become highly inaccurate without careful maintenance and calibration.25 Thus, a use of the well-maintained aneroid manometer in our study should not have impacted the accuracy of blood pressure determination.

Conclusions

In this study and others, the BpTRU™ automated oscillometric blood pressure measurement devices have been shown to measure systolic blood pressure and diastolic blood pressure accurately. More important than the accuracy of an isolated blood pressure determination is the utility of the method of multiple automated determinations at one visit in clinical care. In this study, the BpTRU™ agreed 92% of the time with a trained hypertension nurse specialist following AHA/JNC VII guidelines. It should be kept in mind that both methods used in this study are superior to the casual blood pressure determinations reported in clinical practice. The BpTRU™ offers the practising clinician the accuracy of a trained hypertension nurse observer without the expense of retraining or revalidation personnel, a significant cost savings in a busy clinical practice. The replacement of the mercury manometer due to environmental concerns offers a unique opportunity to improve hypertension management. Validated oscillometric devices offer the ability to improve blood pressure measurement in the hypertensive patients. Removal of mercury sphygmomanometers, similar to the removal of mercury thermometers, offers the unique opportunity to abandon imprecise auscultatory blood pressure measurement and switch to accurate oscillometric devices such as the BpTRU™.

References

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