Clinical Abstracts

BpTRU Medical Devices,
a Division of MFC Industrial Ltd.
# 2012 BpTRU Clinical Abstracts

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OVERALL ACCURACY OF THE BpTRU--AN AUTOMATED ELECTRONIC BLOOD PRESSURE DEVICE.

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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.


COMPARISON OF THE AUTOMATED NON-INVASIVE OSCILLOMETRIC BLOOD PRESSURE MONITOR (BpTRU) WITH THE AUSCULTATORY MERCURY SPHYGOMANOMETER IN A PAEDIATRIC POPULATION.

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BACKGROUND: To directly compare the accuracy of the BpTRU (an automated oscillometric blood pressure device) with standard auscultatory mercury sphygmomanometer in a pediatric population. DESIGN: The BpTRU was connected in parallel with a standard mercury sphygmomanometer. Two observers measured the blood pressures at the same time as it was being measured by the BpTRU. The observers and the BpTRU were all blinded from each other. METHODS: For each of the demographic data--subject age, sex and arm sizes--the mean, standard deviation (SD) and range was calculated. The difference between the mean BpTRU readings and the reference standard measurements (observer average) was calculated with SD and ranges. The percentage of measurements within 5, 10 and 15 mmHg agreement was expressed. RESULTS: From the 36 subjects recruited aged 3-18 years, 162 pairs of sitting blood pressures were included. The difference between the mean BpTRU readings and the reference standard measurements (as determined by the observers) was 1.45+/−5.67 mmHg for systolic blood pressures, and -3.24+/−7.39 mmHg for diastolic pressure and 0.20+/−2.47 bpm for heart rate. CONCLUSION: The BpTRU is of similar accuracy in measuring blood pressure in children as it was in an adult population.

THE BpTRU AUTOMATIC BLOOD PRESSURE MONITOR COMPARED TO 24 HOUR AMBULATORY BLOOD PRESSURE MONITORING IN THE ASSESSMENT OF BLOOD PRESSURE IN PATIENTS WITH HYPERTENSION.

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BACKGROUND: Increasing evidence suggests that ABPM more closely predicts target organ damage than does clinic measurement. Future guidelines may suggest ABPM as routine in the diagnosis and monitoring of hypertension. This would create difficulties as this test is expensive and often difficult to obtain. The purpose of this study is to determine the degree to which the BpTRU automatic blood pressure monitor predicts results on 24 hour ambulatory blood pressure monitoring (ABPM). METHODS: A quantitative analysis comparing blood pressure measured by the BpTRU device with the mean daytime blood pressure on 24 hour ABPM. The study was conducted by the Centre for Studies in Primary Care, Queen’s University, Kingston, Ontario, Canada on adult primary care patients who are enrolled in two randomized controlled trials on hypertension. The main outcomes were the mean of the blood pressures measured at the three most recent office visits, the initial measurement on the BpTRU-100, the mean of the five measurements on the BpTRU monitor, and the daytime average on 24 hour ABPM.

RESULTS: The group mean of the three charted clinic measured blood pressures (150.8 (SD10.26) / 82.9 (SD 8.44)) was not statistically different from the group mean of the initial reading on BpTRU (150.0 (SD21.33) / 83.3 (SD12.00)). The group mean of the average of five BpTRU readings (140.0 (SD17.71) / 79.8 (SD 10.46)) was not statistically different from the 24 hour daytime mean on ABPM (141.5 (SD 13.25) / 79.7 (SD 7.79)). Within patients, BpTRU average correlated significantly better with daytime ambulatory pressure than did clinic averages (BpTRU r = 0.571, clinic r = 0.145). Based on assessment of sensitivity and specificity at different cut-points, it is suggested that the initial treatment target using the BpTRU be set at <135/85 mmHG, but achievement of target should be confirmed using 24 hour ABPM. CONCLUSION: The BpTRU average better predicts ABPM than does the average of the blood pressures recorded on the patient chart from the three most recent visits. The BpTRU automatic clinic blood pressure monitor should be used as an adjunct to ABPM to effectively diagnose and monitor hypertension.

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CONVENTIONAL VERSUS AUTOMATED MEASUREMENT OF BLOOD PRESSURE IN PRIMARY CARE PATIENTS WITH SYSTOLIC HYPERTENSION

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Objective To compare the quality and accuracy of manual office blood pressure and automated office blood pressure using the awake ambulatory blood pressure as a gold standard.
Design Multi-site cluster randomised controlled trial. Setting Primary care practices in five cities in eastern Canada.
Participants 555 patients with systolic hypertension and no serious comorbidities under the care of 88 primary care physicians in 67 practices in the community.
Interventions Practices were randomly allocated to either ongoing use of manual office blood pressure (control group) or automated office blood pressure (intervention group) using the BpTRU device. The last routine manual office blood pressure (mm Hg) was obtained from each patient’s medical record before
enrolment. Office blood pressure readings were compared before and after enrolment in the intervention and control groups; all readings were also compared with the awake ambulatory blood pressure.

Main outcome measure Difference in systolic blood pressure between awake ambulatory blood pressure minus automated office blood pressure and awake ambulatory blood pressure minus manual office blood pressure.

Results Cluster randomisation allocated 31 practices (252 patients) to manual office blood pressure and 36 practices (303 patients) to automated office blood pressure measurement. The most recent routine manual office blood pressure (149.5 (SD 10.8)/81.4 (8.3)) was higher than automated office blood pressure (135.6 (17.3)/77.7 (10.9)) (P<0.001). In the control group, routine manual office blood pressure before enrolment (149.9 (10.7)/81.8 (8.5)) was reduced to 141.4 (14.6)/80.2 (9.5) after enrolment (P<0.001/P=0.01), but the reduction in the intervention group from manual office to automated office blood pressure was significantly greater (P<0.001/P=0.02). On the first study visit after enrolment, the estimated mean difference for the intervention group between the awake ambulatory systolic/diastolic blood pressure and automated office blood pressure (−2.3 (95% confidence interval −0.31 to −4.3)/−3.3 (−2.7 to −4.4)) was less (P=0.006/P=0.26) than the difference in the control group between the awake ambulatory blood pressure and the manual office blood pressure (−6.5 (−4.3 to −8.6)/−4.3 (−2.9 to −5.8)). Systolic/diastolic automated office blood pressure showed a stronger (P<0.001) within group correlation (r=0.34/r=0.56) with awake ambulatory blood pressure after enrolment compared with manual office blood pressure versus awake ambulatory blood pressure before enrolment (r=0.10/r=0.40); the mean difference in r was 0.24 (0.12 to 0.36)/0.16 (0.07 to 0.25)). The between group correlation comparing diastolic automated office blood pressure and awake ambulatory blood pressure (r=0.56) was stronger (P<0.001) than that for manual office blood pressure versus awake ambulatory blood pressure (r=0.30); the mean difference in r was 0.26 (0.09 to 0.41). Digit preference with readings ending in zero was substantially reduced by use of automated office blood pressure.

Conclusion In compliant, otherwise healthy, primary care patients with systolic hypertension, introduction of automated office blood pressure measurement into routine primary care significantly reduced the white coat response compared with the ongoing use of manual office blood pressure measurement. The quality and accuracy of automated office blood pressure in relation to the awake ambulatory blood pressure was also significantly better when compared with manual office blood pressure. Trial registration Clinical trials NCT 00214053.


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**TAKING BLOOD PRESSURE: TOO IMPORTANT TO TRUST TO HUMANS?**

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The measurement of blood pressure in the physician’s office is subject to a number of observer errors and also to the “white-coat effect.” Automatic devices that measure blood pressure without a human observer in the room can eliminate many of these problems. We argue for greater use of these devices in the physician’s office.

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**MEASURING BLOOD PRESSURE IN THE OFFICE SETTING: MANUAL AND AUTOMATED OFFICE MEASUREMENTS IN RELATION TO AWAKE AMBULATORY BLOOD PRESSURE MONITORING**

Marshall Godwin*, Richard Birtwhistle, Dianne Delva, Miu Lam, Ian Casson, Susan MacDonald and Rachelle Seguin

Background. Automated blood pressure (BP) devices are commonly used in doctor’s offices. How BP measured on these devices relates to ambulatory BP monitoring is not clear.
Objective. To assess how well office-based manual and automated BP predicts ambulatory BP.

Methods. Using data on 654 patients, we assessed how well sphygmomanometer measurements and measurements taken with an automated device (BpTRU) predicted results on ambulatory BP monitoring. We assess positive and negative predictive values and overall accuracy. We look at different cut-points for systolic (130, 135 and 140 mmHg) and diastolic (80, 85 and 90 mmHg) BP.

Results. A single automated office BP (AOBP) assessment provides superior predictive values and overall accuracy compared to three manual office BP assessments. For systolic BP, the predictive values are <69% for any of the cut-points while the positive predictive values for the single automated measurement is between 80.0% and 86.9% and the overall accuracy gets as high as 74% for the 130 mmHg cut-point. For diastolic BP, the automated readings are also more predictive but in this case, it is the negative predictive values that are better, as well as the overall accuracy.

Conclusions. Based on the results, we suggest that 135/85 mmHg continue to be used as the cutpoint defining high BP with the BpTRU device. However, future research might suggest that values in a grey zone between 130–139 mmHg systolic and 80–89 mmHg diastolic be confirmed using ambulatory BP monitoring. As well, three AOBP assessments might produce much greater accuracy than the single AOBP assessment used in the study.

Family Practice, Oxford University Press, 2010, Aug 18

AUTOMATED BLOOD PRESSURE MEASUREMENT IN ROUTINE CLINICAL PRACTICE

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OBJECTIVE: To compare blood pressure measurements taken in routine clinical practice using an automated recorder, the BpTRU (VSM MedTech Ltd, Coquitlam, Canada), with readings taken by a conventional mercury sphygmanometer.

METHODS: Fifty consecutive patients [28 women, 22 men; mean (+-SD) age 62+-16 years] referred to a specialist for management of hypertension had blood pressure taken on the first visit in random order using both a mercury sphygmomanometer and an automated device. RESULTS: The mean initial automated reading (mmHg) taken with the observer present (162+-27/85+-12) was similar to the mean manual blood pressure taken in duplicate (163+-23/86+-12). Both values were higher (P<0.001) than the mean of the next five readings taken with the automated recorder when the patient was resting quietly alone (142+-21/80+-12). Women exhibited a greater fall in blood pressure with the automated device than men.

CONCLUSIONS: Use of an automated blood pressure recorder can eliminate some of the white-coat effect associated with readings taken by a mercury sphygmomanometer.

BP MEASUREMENT WITH AN AUTOMATED OSCILLOMETRIC DEVICE (BpTRU) IS A VALID SUBSTITUTE FOR CLINIC MERCURY SPHYGMOMANOMETER READINGS.

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Use of mercury sphygmomanometer is being phased out due to environmental concerns from potential mercurial toxicity. To date, there is no consensus about valid replacement for its use. Currently, Ambulatory Blood Pressure Monitoring (ABPM) is considered the gold standard for accurate BP assessment in outpatient settings. Among 73 patients followed in 3 hospital-based practices, we compared BP readings from an automated oscillometric device (BpTRU) with ABPM readings and mercury sphygmomanometer readings taken by physicians (MDBP). We hypothesized that BpTRU readings would be highly correlated with mercury sphygmomanometer readings taken by physicians. The protocol included a 24 hour ABPM, 3 MDBP, and 6 BpTRU readings, taken on 2 consecutive days. Using ABPM as a gold standard, the BpTRU and MDBP readings were compared to ABPM readings. Agreement between the BP readings was evaluated using descriptive measures, Bland-Altman plots, and intra-class coefficient. Thirty percent of the systolic and 39% of the diastolic MDBP readings were higher than the corresponding ABPM, readings, while only 23% of the systolic and 19% of the diastolic BpTRU readings were higher than ABPM. The absolute difference in mean SBP and DBP between ABPM and BpTRU was 10.93 and 10.75 mm hg respectively. Similarly, the difference in mean SBP and DBP between ABPM and MDBP was 10.42 and 10.73 mm hg. The intra-class coefficients between ABPM and BpTRU was 0.89 (SBP) and 0.60 (DBP); while a coefficient of 0.89 (SBP) and 0.64 (DBP) was found between ABPM and MDBP. We conclude that the agreement and correlation between BpTRU readings and ABPM are similar to that of MDBP and ABPM, with BpTRU having fewer proportions of higher readings than MDBP when compared to ABPM. Thus, BpTRU may serve as a valid substitution for mercury sphygmomanometer in outpatient settings.


AUTOMATED ASSESSMENT OF BLOOD PRESSURE USING BpTRU COMPARED WITH ASSESSMENTS BY A TRAINED TECHNICIAN AND A CLINIC NURSE.

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OBJECTIVE: To determine the accuracy and reproducibility of a new automated blood pressure manometer (BpTRU) relative to auscultatory blood pressure assessed by a research nurse and to that assessed by a clinic nurse.

METHODS: Firefighters in a cohort study had blood pressure assessed on up to five occasions with BpTRU and by a trained research technician. Patients in an internal medicine clinic had blood pressure assessed by
the clinic nurse and by BpTRU. The absolute values of blood pressure, reproducibility and effect on hypertension classification were compared with the different methods.

RESULTS: The research technician readings were higher than the BpTRU readings at visit 1 (3.0/2.7 mmHg, P<0.0001) but the readings converged by visits 4-5 because of a greater reduction in the research nurse readings. The BpTRU readings had similar reproducibility and classification of hypertension as the research technician but did not exhibit terminal digit preference while the research technician readings did. The BpTRU had substantially lower readings (8/7 mmHg) and fewer hypertensive readings than those of the nurse in the internal medicine clinic.

CONCLUSIONS: This preliminary study found that the BpTRU had desirable characteristics that suggest that it would be a suitable replacement for auscultatory assessment of blood pressure in clinical practice. A large confirmatory study performed in a usual clinic setting is required.


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(TM) 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+/−5.1 mmHg, and for diastolic blood pressure it was 4.8+/−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.


USE OF AN AUTOMATED BLOOD PRESSURE RECORDING DEVICE, THE BpTRU, TO REDUCE THE "WHITE COAT EFFECT" IN ROUTINE PRACTICE.

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BACKGROUND: Patients often exhibit higher blood pressure (BP) readings in the doctor’s office, a phenomenon known as the white coat effect. This study examines the presence of a physician in the examining room as a possible factor in provoking a white coat effect. METHODS: Blood pressure measurements taken by an automated BP recording device, the BpTRU (VSM MedTech Ltd., Vancouver, BC, Canada) with the patient alone in the examining room, were compared with the following: (1) BP taken
by the patient's family physician; (2) BP taken on the first visit to a hypertension specialist; (3) BP measured by a trained research technician and (4) the mean awake ambulatory BP (ABP). The BpTRU and trained research technician readings were taken outside of the office (treatment) setting in an ABP research unit.

RESULTS: Blood pressure readings (mm Hg, mean +/- SEM) taken by the BpTRU (155 +/- 5/88 +/- 2) tended to be lower than for the family physician (166 +/- 4/89 +/- 3) and the hypertension specialist (174 +/- 5/92 +/- 2; P < .001). However, BP taken by the trained research technician (158 +/- 4/90 +/- 2) was similar to the value obtained by the BpTRU. The mean awake ABP was lower (P < 0.01) than the other four BP values.

CONCLUSIONS: Use of an automated BP recording device outside of the office (treatment) setting can partly eliminate the white coat effect. A similar finding was observed with readings taken by a trained research technician under similar conditions. Referral of patients to nonoffice settings for automated BP recordings may provide a more accurate estimate of a patient's BP status, with partial elimination of the white coat effect associated with readings taken by a physician.


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WORK-SITE HYPERTENSION PREVALENCE AND CONTROL IN THREE CENTRAL EUROPEAN COUNTRIES.

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Compared to Austria, cerebrovascular stroke (CVS) mortality is three times higher in Hungary, and twice as high in Slovakia. We hypothesized that this is due to better treatment and control of hypertension in Austria. To test this hypothesis, we carried out a cross-sectional survey of ‘blue collar’ employees on work sites in each of these countries. Blood pressure screening was carried out at three work sites in Austria, one in Hungary and one in Slovakia. A standardized protocol was followed in each of these countries. The BpTRU(TM) measuring instrument was used to provide accurate reproducible readings and eliminate interobserver error. After the exclusion of missing data and women, the study population included 323 males screened in Austria, 600 in Hungary, and 751 in Slovakia. The mean ages of the respondents ranged from 35 to 42 years. The prevalence of hypertension was 29% in Austria, 28% in Hungary and 40% in Slovakia. Of those identified as hypertensive, 73% in Austria, 45% in Hungary and 67% in Slovakia were newly diagnosed as a result of this screening. Of those treated for hypertension, 10% in Austria, 15% in Hungary and 5% in Slovakia were controlled. The differences in CVS mortality cannot be explained by better control of hypertension in Austria but indicate the involvement of other determinants.