Comparison Between an Automated and Manual Sphygmomanometer in a Population Survey

Martin G. Myers1, Natalie H. McInnis2, George J. Fodor2 and Frans H.H. Leenen2

BACKGROUND
An automated sphygmomanometer, the BpTRU, was used in a blood pressure (BP) survey of 2,551 residents in the province of Ontario. Automated BP readings were compared with measurements taken by a mercury sphygmomanometer under standardized conditions in a random 10% sample.

METHODS
BP was recorded in 238 individuals in random order using both a standard mercury device and an automated BP recorder, the BpTRU. All subjects rested for 5 min prior to the first BP reading, which was then discarded. The mean of the next three readings was obtained using the mercury device whereas the BpTRU was set to record a mean of five readings taken at 1 min intervals with subjects resting alone in a quiet room.

RESULTS
The mean s.d. BP with the automated device was 115 ± 16/71 ± 10 mm Hg compared to 118 ± 16/74 ± 10 mm Hg for the manual BP (P < 0.001). A systolic BP ≥140 mm Hg was present for 16 automated and 19 manual readings. Similarly, the diastolic BP was ≥90 mm Hg for 9 automated and 14 manual readings. Linear regression analysis showed that automated BP was a significant (P < 0.001) predictor of both manual systolic and diastolic BP.

CONCLUSION
Conventional manual BP readings can be replaced by readings taken using a validated, automated BP recorder in population surveys. The slightly lower readings obtained with the BpTRU device (in the context of reduced observer–subject interaction) may be a more accurate estimate of BP status.


Blood pressure (BP) surveys in the community have generally been performed using mercury sphygmomanometry. This approach requires extensive training for health professionals in order to standardize procedures for BP measurement, so that accurate readings can be taken for thousands of subjects by different study personnel. Rigorous programs for monitoring quality control also need to be initiated in order to ensure continued compliance with the study protocol for BP measurement until the survey is completed. The net result is an estimate of the BP status of a population based upon conventional BP readings, but obtained at great expense with extensive human resource efforts in training and execution.

The Ontario Survey on the Prevalence of High Blood Pressure (ON-BP) decided to consider alternatives to the conventional measurement of BP using the mercury sphygmomanometer, in order to simplify the process of evaluating the BP status of a large number of individuals in the community. An attractive alternative was the use of a validated automated BP recording device, which is designed specifically for the office or clinic setting. The most widely studied device to date is the BpTRU (BpTRU Medical Devices, Coquitlam, BC, Canada) which is able to perform five readings with subjects resting quietly and alone in an examining room, thus decreasing subject–observer interaction, reducing anxiety and decreasing observer measurement error, all of which would tend to give a better estimate of an individual’s BP status. In hypertensive populations, the BpTRU has been shown to reduce the white-coat effect with readings exhibiting a significantly higher correlation with the mean waking ambulatory BP, the current gold standard for assessing BP status, compared to BP readings obtained in routine clinical practice.1,2 Mean BpTRU readings have exhibited a close approximation to the manual BP in both validation studies3,4 and in clinical practice.5

The ON-BP was undertaken to record the BP of about 3,000 randomly selected subjects residing in the community in the province of Ontario. In a random sample of 10% of participants, BP readings were taken with both the BpTRU and a mercury sphygmomanometer under similar standardized conditions in order to compare the automated BP readings with the conventional standard for BP surveys, the mercury device.

METHODS
Patient population. Adult residents of the province of Ontario, aged 20–79 years, were randomly selected for enrollment in
the ON-BP survey using census data from Statistics Canada. Both men and women with and without high BP were eligible for the survey. Potential subjects were contacted by home visits to see if they were interested in participating in the survey and attending a BP clinic (see Leenen et al. for more details6). A total of 2,551 individuals attended the special clinic for BP measurement. One of every 10 participants was selected to have their BP recorded using both the BpTRU device and a standard mercury sphygmomanometer. The order in which the devices were used was determined by the individual’s study number; those subjects with even last digits were measured with BpTRU first and those with odd last digits were measured with the mercury device first. The left arm circumference was measured and the appropriate cuff size was used for each device.

**BP measurement.** Manual BP was recorded by a registered nurse or registered nurse practitioner using a Baumanometer sphygmomanometer (W.A. Baum, Copiague, NY) according to the procedures of the Canadian Hypertension Education Program.7 Subjects remained seated with the back supported and left arm at heart level. They were allowed to rest for 5 min in a quiet room before the first reading was taken; this was then discarded. Three more readings were taken, each 1 min apart and the mean value and heart rate were recorded for each individual. Automated BP readings were obtained using the BpTRU (model BPM 300) after patients rested alone in a quiet room for 5 min. The device was set to take six readings at 1 min intervals with the first reading being discarded. The mean automated BP reading and heart rate were noted for each subject. The device was positioned in such a way as to prevent the subject from seeing the readings as they were taken. There was a 2-min break between automatic and manual BP readings. All measurements were obtained under similar conditions except for the two different BP recording techniques used.

**Data analysis.** Mean manual and automated systolic and diastolic BP values were tabulated as histograms showing the number of participants for each 5 mm Hg interval of BP. A paired t-test was used to assess the differences between the manual BP and automated BP readings. Delta values were calculated as manual systolic BP—automated systolic BP and manual diastolic BP—automated diastolic BP. A one way analysis of variance was used to analyze the differences between delta systolic and delta diastolic by age and cuff size. To assess the differences between males and females an independent t-test was used to analyze the delta systolic and delta diastolic values. A linear regression analysis was performed to examine the relationship between the automated and manual BP readings with the automated systolic and diastolic BPs as the independent variables. All data was analyzed using SPSS version 15.0.

**RESULTS**

A 10% sample (n = 238) of the entire survey population participated in this sub-study. The subjects in this sub-study comprised 96 males and 142 females, mean (±s.d.) age 50 ± 15 and 47 ± 15 years, respectively. Fifty-nine subjects remembered being told by a health professional that they had hypertension and, of these, 42 were receiving antihypertensive drug therapy.

Individual readings for systolic and diastolic BP for each of the two methods were tabulated and displayed as frequency histograms (Figures 1 and 2). Diastolic BP was ≥90 mm Hg for 14 manual and 9 automated BP readings. Systolic BP was ≥140 mm Hg for 19 manual and 16 automated measurements. Each data set was normally distributed.

Mean (±s.d.) BP taken with the automated BpTRU device was 115 ± 16/71 ± 10 mm Hg compared to 118 ± 16/74 ± 10 mm Hg for the manual BP readings (P < 0.001). Parameters such as age, sex, and cuff size did not predict the differences in systolic and diastolic BP between the automated and manual measurements. For the automated/manual order of readings, the automated and manual values (mm Hg) were 116 ± 14/72 ± 9 and 118 ± 15/75 ± 10, respectively. The corresponding results for participants having manual BP followed by automated BP readings was 113 ± 17/70 ± 11 for the automated versus 117 ± 17/74 ± 10, for the manual BP. The differences between systolic manual readings and systolic automated readings were significantly (P < 0.01) smaller when automated was used first.

The comparison of the manual versus the automated readings showed a high coefficient of correlation (r²) for systolic BP (r² = 0.84) and diastolic BP (r² = 0.70) readings (Figure 3). Linear regression analysis showed that the automated systolic BP is a significant predictor (β = 0.93, P < 0.001) of manual systolic BP with a regression equation (Adjusted systolic BP = 11.4 + 0.93 x
Automated Recording Devices for BP Surveys

The benefits of taking readings using an automated device such as the BpTRU are generally applicable to population surveys such as the ON-BP. Thus, one would anticipate lower mean BP values for the automated device compared to conventional manual readings obtained by a nurse, which is what was observed in the Ontario survey. In this instance, manual readings exceeded automated readings by 3/3 mm Hg.

This difference represents the white-coat effect for a random sample of adult residents residing in Ontario. A similar difference was observed in hypertensive patients when manual readings recorded by a research technician outside of the treatment setting were compared with the mean automated readings taken using the BpTRU device. In this instance, the manual readings were 3/2 mm Hg higher with the mercury sphygmomanometer.

These differences between automated and manual readings are substantially less than reported for other hypertensive populations, when the manual readings were taken by physicians. Under these circumstances, the “white-coat reaction” tends to provoke a greater pressor response. In a series of 50 hypertensive patients referred to a specialty hypertension centre for their management, the mean manual office BP was 20/5 mm Hg higher than the mean of five automated BpTRU readings. Similarly, Beckett and Godwin noted a difference of 11/3 mm Hg between the last routine office BP taken by a patient’s own family physician and the mean automated BpTRU value. In a population survey of persons 65 years of age and older with hypertension, Kaczorowski and colleagues found systolic BP readings (taken in a community pharmacy using the BpTRU device), produced a mean value 9 mm Hg lower than the last routine office BP taken by the subject’s own family doctor.

In the above studies, the automated readings were taken with the BpTRU device with subjects resting alone in a quiet room in order to minimize factors that tend to provoke a white-coat reaction. However, if one performs the automated readings and manual BP measurements under standardized conditions, the mean values are quite similar. In a formal validation study reported by Wright, mean BpTRU values for systolic and diastolic BP differed from reference readings taken with a standard mercury device by only –0.2 ± 4.3/–1.4 ± 4.2 mm Hg, respectively. In a study in clinical practice, the mean ± s.d. of two readings taken using a mercury sphygmomanometer (163 ± 23/86 ± 12) was similar to the first BpTRU reading taken in the presence of the observer (162 ± 27/85 ± 12). Thus, automated readings taken with the BpTRU device closely approximate conventional measurements recorded with a mercury sphygmomanometer when taken under similar conditions.

In this subset of the ON-BP survey, the mean BP was substantially lower than in previous studies involving hypertensive patients. Estimates of the cut-point for normal BP for routine manual versus automated (BpTRU) values are still preliminary but the available data suggest conventional office BP at 140/90 mm Hg is equivalent to an automated reading of 135/85 mm Hg taken in the office with subjects resting alone in a quiet room. In the present subset, 8.0/5.9% would be designated as being hypertensive according to a cut-point of <140/90 mm Hg for normal manual BP and 9.7/8.0% with a normal automated BP set at <135/85 mm Hg. The number of subjects in this subset of the ON-BP was too small to provide reliable comparative estimates of normal versus abnormal cut-points for a diagnosis of hypertension with the two methods of measurement.

Linear regression analysis of the automated and manual BP data provided a “correction factor” to convert the automated readings obtained in the survey into comparable manual BP readings. This conversion makes it possible to compare data derived from BP surveys performed using an automated BP recorder with previous surveys that have employed manual BP measurement techniques. According to the linear regression in this sample from the ON-BP survey, automated systolic BP readings of 120 and 140 mm Hg are equivalent to manual readings of 123 and 142 mm Hg, respectively. Automated diastolic BP readings of 80 and 90 mm Hg are equivalent to manual readings of 82 and 90 mm Hg, respectively.

DISCUSSION

The automated BpTRU device was designed to minimize the impact of observer–subject interaction on the measurement of BP in the office/clinic setting. This approach removes several aspects of bias associated with conventional BP measurement using mercury sphygmomanometry. The role of the observer in recording the BP is eliminated and replaced with a validated, accurate, digital device programmed to take readings at specific time intervals, thus eliminating imprecision due to factors such as digit preference, too rapid deflation of the cuff, or reading up or down to influence the patient’s BP status. The absence of the observer from the room during readings also precludes conversation between the subject and the observer, which is a factor known to increase the BP. Many individuals exhibit a fall in BP within a minute or two after being left alone in a quiet room especially in the context of a treatment setting such as a doctor’s office or clinic.

Figure 3 | A linear regression analysis was performed to examine the relationship between the automated and manual blood pressure (BP) readings with the automated systolic and diastolic BP as the independent variables. The $r^2$ values for systolic and diastolic BP are 0.84 and 0.70, respectively ($P < 0.001$).
The results of the ON-BP have demonstrated that conventional manual BP readings taken using mercury sphygmomanometry can be replaced by a validated, automated recorder. If the BpTRU minimizes the white-coat effect it would not be surprising to see lower BP readings in participants with high normal or mild hypertension readings, possibly indicating a lower prevalence of hypertension. Instead of underestimating hypertension, the automated readings may actually reflect the true hypertension status in the population, by minimizing the white-coat effect when one takes into account the close relationship between automated BP readings and mean waking ambulatory BP, the current gold standard for assessing cardiovascular risk.

Acknowledgment: This survey was supported by a Heart and Stroke Foundation of Ontario contract awarded to F.H.H.L. and G.J.F. F.H.H.L. holds the Pfizer Chair in Hypertension Research, an endowed chair, supported by Pfizer Canada, University of Ottawa Heart Institute Foundation, and Canadian Institutes of Health Research.

Disclosure: The authors declared no conflict of interest.