Accuracy Evaluation of Blood Pressures Measured by the CSI Model 6000 Health Management Unit

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ABSTRACT

The CSI Model 6000 Health Management Unit incorporates a monitoring technique utilizing both auscultatory and oscillometric methods. It additionally incorporates the K2 high frequency signal component of the wideband pulse, a component which relates closely to the Korotkoff sounds. These independent measurements are simultaneously analyzed mathematically using a computer driven algorithm to derive systolic and diastolic blood pressure values. Blood pressures measured on 320 subjects were compared with cuff sphygmomanometry measured simultaneously by a blinded observer trained to measure blood pressures at the bleed down declination rate set by the unit. The mean systolic BP was 114.49 ± 16.702 mm Hg for the CSI unit and 111.78 ± 15.05 mm Hg for the observed. The mean diastolic BP was 73.65 ± 11.85 mm Hg for the CSI and 75.67 ± 27.65 mm Hg for the observed. Correlation coefficients of 0.909 ($p < 0.0001$) and 0.919 ($p < 0.0001$) were obtained. The CSI Model 6000 provided highly accurate automated monitoring of BP which would be useful in the management and screening of blood pressures.

High blood pressure is established as a risk factor in cardiovascular disease that is independent of other risk factors. According to the Center for Disease Control, Behavioral Risk Factor Surveillance System Fact Sheet, about 1 in 4 American adults, 1 in 3 African Americans, 1 in 5 Hispanics and Native American, and 1 in 6 Asians/ Pacific Islanders have high blood pressure. The 7th Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure estimates that approximately 50 million in the United States have high blood pressure (hypertension). The importance of early detection, treatment, and control cannot be overemphasized. Untreated and poorly managed blood pressure control increases risk for heart disease, stroke and kidney disease. Accurate and regular testing of blood pressures in adults is required for monitoring of control and also for early detection. Almost a third of persons with hypertension are unaware of their condition. Of those with hypertension, only 60 percent are being treated and only 34 percent have achieved good control of their blood pressure.

Recommendations for accurate blood pressure measurements at regular intervals, with proper feedback to the individual may not be easily achieved. The impracticality of properly screening the adult population using trained personnel within the time constraints of the usual medical care system is a problem that cannot be ignored.

Automated blood pressure monitoring does not require measurements by skilled personnel and avoids measurement problems that result from differences in observer skills. In addition it permits automatic recording of results, something that manual auscultatory sphygmomanometry of the external brachial pulse does not offer. A variety of methods for sensing the external pulse such as piezoelectric crystal microphones for wideband auscultatory measurement, and oscillometric methods, where sensor placement is not critical have been used. Single application of these methods have not eliminated the problems observed in measurement.

The CSI Model 6000 Health Management Unit (Company) incorporates a monitoring technique utilizing both the auscultatory and oscillometric methods. It additionally incorporates the K2 high frequency signal component of the wideband pulse, a component which relates closely to the Korotkoff sounds. These independent measurements are simultaneously analyzed mathematically using a computer driven algorithm to derive systolic and diastolic blood pressure values.

The purpose of this study is to evaluate the accuracy of blood pressure measurements obtained by the CSI Model 6000 Health Management Unit (CSI 6000).

Description of Equipment:

The CSI 6000 provides a non-invasive blood pressure monitoring system that automatically measures blood pressure. Blood pressure is measured with the subject comfortably seated in front of a touch-screen. By passing the left arm through a fixed automated cuff assembly and resting the elbow on the table of the unit, the upper arm is properly positioned at heart level and in the cuff for sensing the external pulse. The blood pressure monitoring is started by the subject responding to the instructions on the high resolution 15-inch touch-screen color monitor and touching "start". The system is automatically activated and the blood pressure cuff closes to comfortably wrap the upper arm

The sensors for the unit are positioned on the inside of the cuff to be approximately medial of the cubital fossa when the cuff is closed around the upper arm. The air bladder inside the cuff is then automatically inflated to rapidly raise pressure to occlude the brachial artery. The maximum cuff pressure is 160, 190, 220, or 250 mmHg that is determined by the auscultatory sounds (heart rate). This is followed by a bleed down of pressure. By using a continuously variable flow valve, bleed down rate can be closely varied according to heart rate. In the normal heart rate range of 60 to 100 bpm the rate of bleed down is 3 mmHg per second. For higher heart rates the bleed down is increased and for lower heart rates the bleed down rate is decreased. Maximum bleed down rate is 6 mm/sec.

The sensors record auscultatory, oscillometric, and K2 results which are collected independently of each other and processed simultaneously by an algorithm, comparing the independent measurements for similarity. All values are dynamically stored in the 10.8 gigabyte hard drive memory. A minimum of two of the three measurements must be within the agreement range of ±4 points. If not the test is unsuccessful and a message "Test failed, inconsistent results". Measurements (maximum of 3 and minimum of 2) are averaged and produce the final result. Results (systolic and diastolic blood pressure values and averaged heart rate) are printed out for the subject.

The unit is calibrated to function at cuff pressure variations within ± 1% over the full range of 40 – 250 mmHg. There is an automatic zero pressure verification to adjust for atmospheric pressure, temperature and humidity variability.

Methods:

Blood pressures were manually measured simultaneously with the automatic measurement of the CSI unit. The automatic blood pressure monitoring was activated for each subject by the blood pressure technician and not by the subject. The trained observer used a high acoustic sensitivity stethoscope and read pressures on a remotely mounted 6 inch diameter aneroid gauge. Because the bleed down rates were faster than with the usual manual auscultatory measurements, the observer was carefully trained

prior to the tests to listen for the Korotkoff sounds at the bleed down rates of the unit. The bell of the stethoscope was applied near the subject's cubital fossa for listening to the Korotkoff sounds while the CSI unit automatically pressurized and bled-down. The systolic and diastolic values were recorded on paper. At the completion of the automatic procedures of the CSI unit, the observer was instructed on the touch-screen to input the manually read values by using a touch-sensitive keypad on the screen. Only after observer data was thus inputted did the results from automatic monitoring become displayed, thus ensuring blinding of the observer from the automatic measurements. A printout was automatically produced and given to the subject.

Subjects were adult volunteers who were students, staff, faculty or visitors of the Loma Linda University School of Public Health. Recruitment was done by printed announcements at strategic entrances to the school and enrollment was limited to the first successful 320 measurements. Incentives of $5 gift certificates were given to each participant. All recruitment and testing was completed in January of 2005.

Manually read blood pressures were compared with the averaged reading from the automatic measurements of the CSI unit. Simple linear regressions, correlation coefficients, slopes and "y" intercepts were used to evaluate accuracy. A significance level was set at $p< 0.5$.

Results:

A total of 349 measurement attempts were made resulting in 320 successful measurements by the CSI unit. These 320 successful observations were utilized for the accuracy evaluation. Thirty failures occurred where repeated measurement was not successful. The mean systolic blood pressure measured by the CSI unit was 114.49 ± 16.70 mmHg. The mean manually measured systolic BP was 111.78 ± 15.05 mmHg. The mean diastolic CSI unit BP was 73.65 ± 11.84 mmHg. The mean manually measured diastolic BP was 71.41 ± 11.98 mmHg.

Figure 1 shows Pearson product-moment correlation coefficients, regression lines and equations for systolic blood pressures.

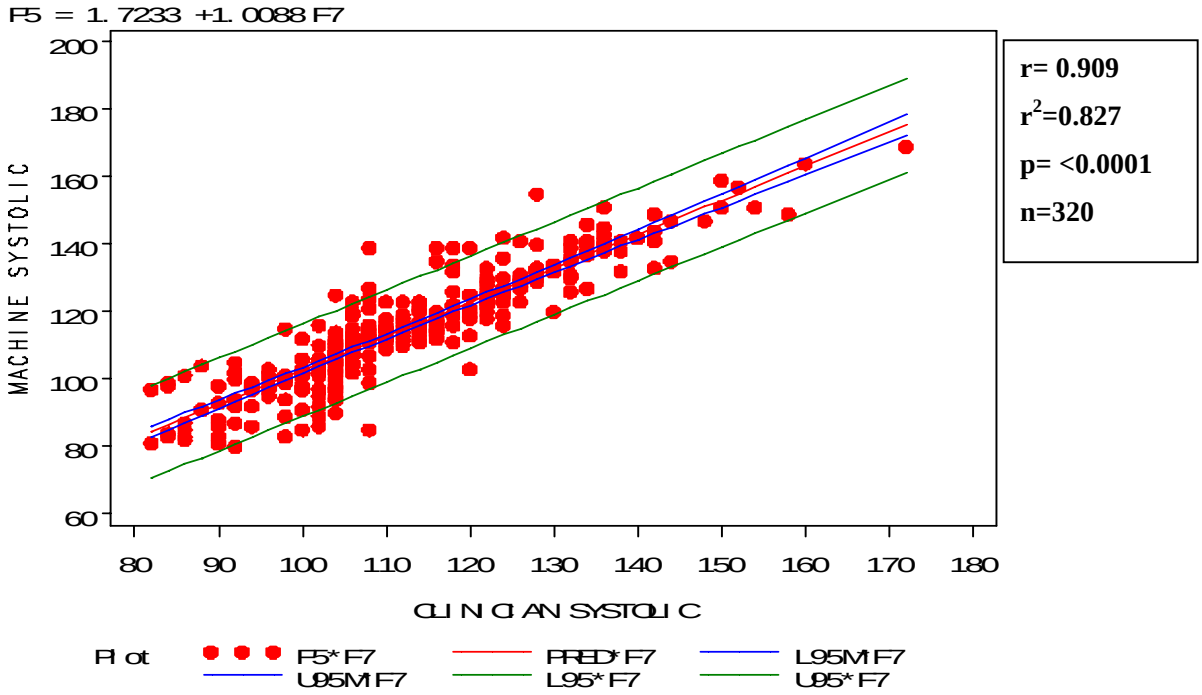
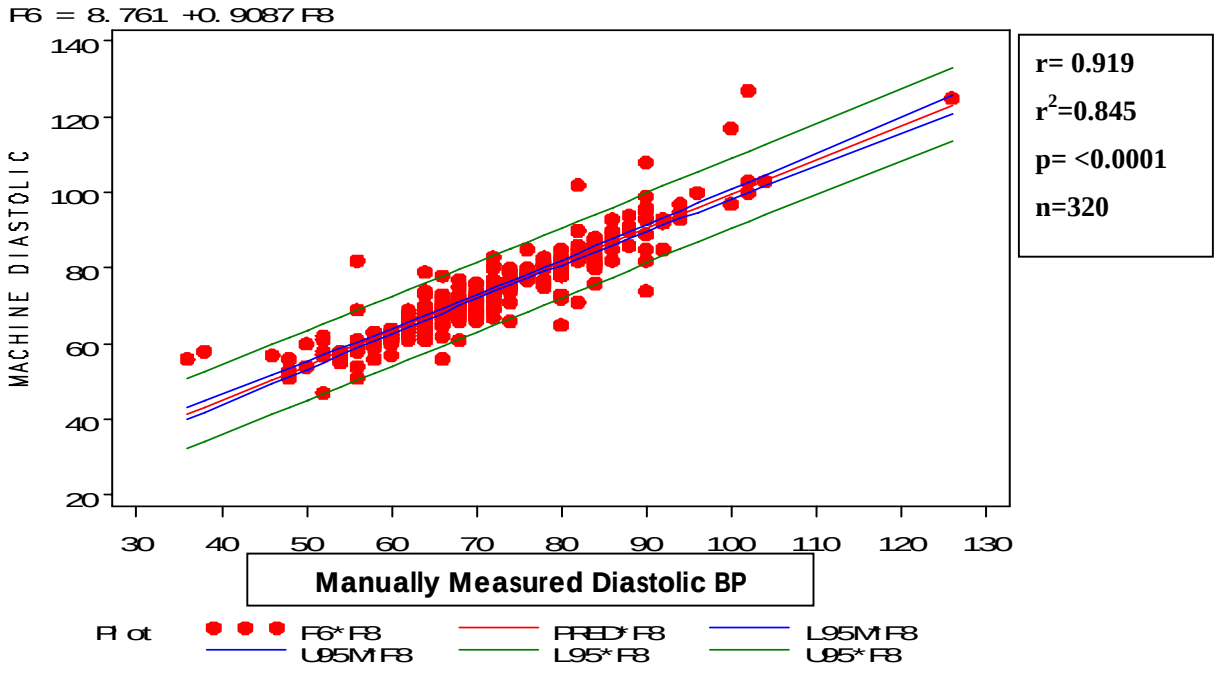


Figure 2 shows Pearson product-moment correlation coefficients, regression lines and equations for diastolic blood

pressures.



The results obtained showed a high correlation between the blood pressure values measured by the CSI unit and the manually obtained values. Pearson product-moment correlation coefficients were 0.909 and 0.919 for the systolic and diastolic blood pressures respectively. The r^2 which shows the strength of association between the CSI unit values and the manually obtained values were 0.827 and 0.845 respectively. A significance level of $p < 0.0001$ was obtained for both the systolic and diastolic measurements.

Discussion:

The upwardly spiraling cost of health care has spurred serious discussion on changes necessary to salvage a highly dysfunctional system of health care delivery. Problems of accessibility, high cost treatments, the uninsured, and the out of control rise in health insurance premiums have been part of the driving forces behind this thinking. The increase in obesity, diabetes, hypertension, cancer, and cardiovascular diseases can only place an enormous burden on this strained system. Prevention of these diseases will reduce this burden and perhaps provide the opportunity to the system to deliver better services to those that need it. Central to this approach is the need for individuals to have more personal involvement in their personal health care. Hypertension is one of the areas where this has the best possibility. Early detection and close management of hypertension requires that individuals should have easier access to accurate blood pressure monitoring. However accurate blood pressure measurements at regular intervals, with proper feedback to the individual may not be easily achieved. The time constraints and the resources available in the usual medical care setting make this recommendation difficult to achieve.

Automated blood pressure monitoring which has been available for many years, avoids the need for skilled personnel and the problem of time constraints. By using automatic auscultatory techniques and oscillometric methods, these units have attempted to increase accuracy. The CSI Model 6000 incorporates both the auscultatory and oscillometric methods, and additionally, the K2 high frequency signal component of the wideband pulse, a component which relates closely to the Korotkoff sounds. These independent measurements are simultaneously analyzed mathematically using a computer driven algorithm to derive highly accurate systolic and diastolic blood pressure values. It has a large touch-screen which provides simple and easy operation by subjects and printed results are provided. From our study, the CSI Model 6000 was shown to provide highly accurate automated monitoring of BP and is a useful tool in the management and screening of blood pressures.