

Comaprison Between OMRON HEM-7203 and HEINE GAMMA G5 Sphygmomanometer in a Population Survey

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Abstract—The rapidly expanding number of automated devices and the necessity of replacing the manual sphygmomanometer, has raised concerns about the accuracy of blood pressure (BP) values measured by monitors. Our on-going research compared the use of HEINE GAMMA G5 aneroid vs. OMRON HEM-7203 automated sphygmomanometer, before implementing a study-wide transition to the automated sphygmomanometer. BP of 74 normal and hypertensive individuals was measured in random order, under standardized conditions, using both types of devices. The study found no statistically significant difference for systolic and diastolic BP of normal and hypertensive subjects, using the automated BP monitor. Aneroid BP readings can be replaced by readings taken using a validated automated BP recorder in population surveys. The slightly lower readings obtained with the automated device (in the context of reduced observer-subject interaction) may be a more accurate estimate of BP status.

Keywords-blood pressure; blood pressure determination; sphygmomanometer.

I. INTRODUCTION

Since the first description of mercury sphygmomanometer in 1896, it has been served as the “gold” standard for BP measurement, not only in clinical practice, but also in research conditions. Due to the environmental concerns about the disposal of mercury contaminated medical waste and the risk of spills from them, many institutions began switching from mercury to non-mercury sphygmomanometers [2-5]. Its usual replacement, the aneroid sphygmomanometer, has been found to be a satisfactory replacement if properly maintained, mainly in regard of calibration [6]. Some studies have shown unsatisfactory calibration conditions of the aneroid devices error that may lead to misdiagnosis or mistreatment of the subjects under study [7, 8]. Considering the possibility of the change in the use of sphygmomanometry in the new century, automated devices may play an important role. These devices may help to improve subject’s involvement in their care and they may allay physician’s concerns about a possible “white-coat syndrome”. The international entities, the British

Hypertension Society (BHS) [9] and the Association for the Advancement of Medical Instrumentation (AAMI) [10], have established criteria for allowing the validation of automated devices. Many devices available in the market have failed to fulfill the requirements of the two international entities [11-17].

The objective of this study is to test whether the validated automated sphygmomanometers OMRON HEM-7203 could provide the same high-quality BP measurements as a calibrated aneroid sphygmomanometer.

II. MATERIAL AND METHODS

A. Subject Population

This study involved 50 normal and 24 hypertensive subjects of SLIET campus. The subjects were randomly selected for enrollment in the study and were contacted by personal meeting. All gave consent to the study.

B. Devices Used

- HEINE GAMMA G5:-The Heine Gamma G5 sphygmomanometer is an aneroid type device that works on the principle of auscultation with a BP measurement range 0-300 mm Hg. Systolic and diastolic BP measurements are displayed on an analogue display (circular scale with a pointer). Accuracy of measurements is ± 3 mm Hg. Standard adult small cuff for an arm circumference ranging from 290-410mm is provided.
- OMRON HEM-7203:-The OMRON HEM-7203 is a fully-automated BP measurement device that records brachial BP oscillometrically with a BP measurement range 0-299 mmHg and heart rate range of 40-180 beats/min. Systolic, diastolic BP and heart rate are displayed on a liquid crystal display (LCD) read-out. Accuracy of measurements is: pressure: ± 3 mm Hg, pulse: $\pm 5\%$ of display reading. Both inflation and deflation are automatic. Measurement starts

automatically after having pressed and released the power button. Deflation is made by pressing the air release button to release the air in the cuff. Standard adult cuff for an arm circumference ranging from 220-320mm is provided.

C. BP Measurement

The study was conducted over a period of two months. A specially separated room was organized to conduct the study. This ensured minimal interference within the room while the tests were being carried out. The observers involved in the study were trained using the BHS BP measurement training materials [18]. BP was measured on the same arm of each subject using the test and standard devices sequentially. Subjects remain seated with the back supported and left arm at heart level. The left arm circumference was measured and appropriate cuff size was used accordingly. The subjects were allowed to rest for 5 minutes before the first reading was taken; this was then discarded. Three more readings were taken, each 1 minute apart and the mean value was recorded for each individual. There was a 2-minute break between the BP readings. All measurements were obtained under similar conditions except for the different BP recording devices [19, 20].

III. DATA ANALYSIS

Data were expressed as mean±SD. A paired t-test was used to assess the differences between the manual and automated BP readings. Data values were calculated as manual systolic BP-automated systolic BP and manual diastolic BP-automated diastolic BP. Multivariable regression analysis was used to determine the effect of age, height, weight, BMI and arm circumference on 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 BP values. All data was analyzed using MedCalc version 12.1.3.0.

IV. RESULTS

Socio-demographic characteristics of the participants are presented in Table I.

TABLE I. CHARACTERISTICS OF PARTICIPANTS

Characteristics / Subjects	^a Normal (Number, N = 50)	^a Hypertensive (Number, N = 24)
Age (years)	23.1±1.2 (21-28)	50.5±11.3 (28-80)
Height (m)	1.6±0.04(1.43-1.67)	1.6±0.1 (1.51-1.83)
Weight (kgs)	55.2±7 (39-70.9)	73.6±9.5 (50.3-92)
BMI (kg/m ²)	21.5±2.4 (15.1-26.3)	27.07±2.2(21.530.4)
Arm Circumference (cm)	27.5±0.5 (22-31)	29.1±1.8 (24.5-31)

a. Data were expressed as mean±SD (Range)

Mean value of BP (systolic/diastolic) taken with the HEINE GAMMA G5 aneroid device was 106.49/66.33 compared to 106.4/66.09 for the OMRON HEM-7203 device for normal and 109.66/68.02 compared to 109.59/67.92 for hypertensive

subjects. The results of paired t-test are demonstrated in Table II. Parameters such as age, height, weight, BMI and arm circumference did not predict the differences in systolic and diastolic BP between the aneroid and automated measurements.

TABLE II. COMPARATIVE PERFORMANCE OF TWO DEVICES USING PAIRED T-TEST

Subjects	^b Mean difference±SD	^b p
Normal	0.09±0.68/0.24±0.92	0.3/0.07
Hypertensive	0.07 ± 0.6/0.1±1.05	0.5/0.6

b. All readings (systolic/diastolic) expressed in mm Hg

Linear regression analysis showed that automated BP is significant predictor of manual BP readings for normal and hypertensive subjects as shown in Table III. Fig. 1 and Fig. 2 showed the relationship between manual BP readings and those measured with automated sphygmomanometer tested of normal and hypertensive subjects.

TABLE III. COMPARATIVE PERFORMANCE OF TWO DEVICES USING LINEAR REGRESSION ANALYSIS

Subjects	Regression Equation	^c R ²	^c R	^c p
Normal	y=3.2976+0.9682x/ y=0.4062+0.9902x	0.97/0.97	0.98/0.98	<0.001
Hypertensive	y=27.1277+0.752x/ y=13.6645+0.8003x	0.84/0.84	0.7/0.7	<0.001

c. All readings were expressed as systolic/diastolic

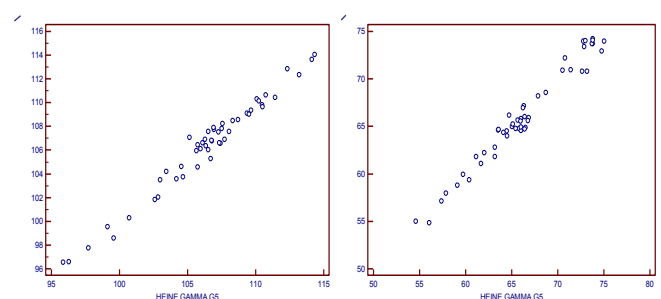


Figure 1. Fitted regression line for SBP and DBP measurements for the linear regression analyses of HEINE GAMMA G5 versus OMRON HEM-7203 sphygmomanometer (Normal subjects).

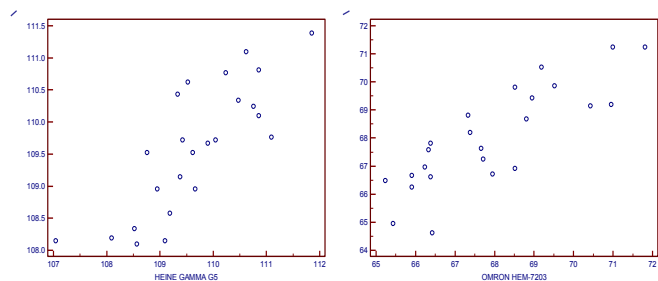


Figure 2. Fitted regression line for SBP and DBP measurements for the linear regression analyses of HEINE GAMMA G5 versus OMRON HEM-7203 sphygmomanometer (Hypertensive subjects).

V. DISCUSSION

The automated OMRON HEM-7203 sphygmomanometer minimized the impact of observer-subject interaction on the measurement of BP in the research setting [21]. This approach removes several aspects of bias associated with BP measurement using aneroid sphygmomanometer. The role of the observer in recording the BP is eliminated and replaced with a validated, accurate, digital device. 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 [22]. 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 [23].

If the manual and automated BP measurements were performed under standardized conditions, the mean values were quite similar. In a formal validation study reported by Wright *et al.*, [24] mean BpTRU values for systolic and diastolic BP differed from reference readings taken with a mercury device by only $-0.2 \pm 4.3/-1.4 \pm 4.2$ mm Hg, respectively. In a study in clinical practice, [23] the mean \pm SD of two readings taken using a mercury sphygmomanometer ($163 \pm 23/86 \pm 12$) was similar to the first BpTRU reading taken in the presence of the observer ($162 \pm 27/85 \pm 12$).

Linear regression analysis of the automated and manual 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. The results of this survey have demonstrated that manual BP readings taken using aneroid sphygmomanometer can be replaced by a validated, automated recorder. Instead of underestimating hypertension, the automated readings may actually reflect the true hypertension status in the population when one takes into effect the close relationship between automated BP readings and mean waking ambulatory BP, the current gold standard for assessing cardiovascular risk.

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