Indian J Physiol Pharmacol 2012; 56(3) : 255–261

CLINICAL VALIDATION OF ANEROID SPHYGMOMANOMETER

YOGESH SAXENA[1]*, VARTIKA SAXENA[2], AND RANI GUPTA[1]

Departments of [1]Physiology and [2]Community Medicine,
Himalayan Institute of Medical Sciences,
Jolly Grant, Dehradun – 248 140, India

(Received on June 27, 2011)

Abstract : Recent concerns about the mercury toxicity and its ill effects on the environment and health has led to widespread use of aneroid manometers. Present study was conducted to analyse whether this change would lead to any systematic shift in measured blood pressure or consistency of blood pressure measurement in clinical setting. The clinical accuracy of the Welch Allyn aneroid sphygmomanometer model 7670-04 was studied against the mercury sphygmomanometer on 83 volunteers from Dehradun. Two blood pressure reading of each study subject was recorded with pre-tested instruments (aneroid and mercury sphygmomanometer). Data analysis showed the difference of means between the reading of two devices against mean of the observer reading for both systolic (-3.62±4.88) and diastolic (-2.36±3.77) blood pressure were not statistically different. The corresponding values of the SBP and DBP from both the instruments showed significant correlation. Regression analysis of mercury versus aneroid showed regression line (Y = 9.52 + 0.95X for SBP, Y = 0.36 + 0.96X for DBP) significantly different from line of equality (P<0.001). The study has demonstrated that the aneroid device (model: 7670-04) achieved grade B performance according to the British Hypertensive Society criteria.

Key words : SBP : systolic blood pressure DBP : diastolic blood pressure aneroid

INTRODUCTION

The mercury manometer still serves as the “gold” standard for measurement of blood pressure (1). Environmental concerns about mercury-contamination and risk of spills from mercury sphygmomanometers, the mercury manometer is being phased out with alternative mercury-free instruments in health care set ups and hospitals across several countries including India (2-4). Aneroid devices are inexpensive, portable and have been proposed as an alternative to mercury sphygmomanometers.

Following studies by Hill and Bernard (5) aneroid are in use as an indirect method of Blood pressure measurement. As they easily lose calibration (6, 7), device accuracy assessment within a clinical setting is recommended before its introduction & routine clinical use. Published studies (8-10)

*Corresponding Author : Dr. Yogesh Saxena, Department of Physiology, HIMS, Jolly Grant, Dehradun, Cell : 9719040008; Email: drysaxena@rediffmail.com

shows that aneroid devices could be accurate, but several issues remained unanswered in relation to clinical trial studies, which may vary with accuracy of aneroid models. The prior studies have validated aneroid by connecting it to a reference unit & comparing the reading to a static pressure measurements at a fixed point. Several sources of variation in blood pressure may be involved in clinical usage, which may range from observers factors to variation in arm circumference participant factors, techniques of measurement or interaction with participants.

To ensure quality and consistency of our blood pressure data across hospital, and to determine whether such a conversion to aneroid manometers would cause a systematic shift in measured blood pressure, the study was designed with selected aneroid sphygmomanometer (model 7670-04).

MATERIAL AND METHODS

A review of our institutional experience with mercury spills and global initiatives for use of non-mercurial alternatives led to the replacement of mercury sphygmomanometers with aneroid devices (Welch Allyn Model 7670-04) throughout our inpatient facilities and several outpatient clinical areas. A regular maintenance program was developed and implemented. The accuracy of the aneroid model being used was the subject of debate. The authors have taken up the study with a focus to assess the accuracy of specific aneroid sphygmomanometers.

Study was conducted after approval from the institutional review board and written informed consent was taken from all the volunteers before their participation in the study. The validation procedure was performed by one observer who was conducting out- clinics for several years & was trained using the British hypertensive society blood pressure measurement protocol. An Aneroid and a Mercury sphygmomanometer were used in the study.

1. Mercury sphygmomanometer model desk model gravity sphygmomanometer (300 mm Hg), manufactured by W.A. Baum, in Copiague, NY.

2. Aneroid sphygmomanometer model: we selected the Welch Allyn Tycos 767-Series Mobile Aneroid Model 7670–04 as its aneroid sphygmomanometer.

The aneroid gauge consists of a metal bellows and a watch-like movement connected to the compression cuff. Variations of pressure within the system cause the bellows to expand and contract. Movement of the bellows rotates a gear that turns a pointer pivoted on bearings, across a calibrated dial.

The Netech DigiMano digital pressure and vacuum meter (rated at ±0.1 mm Hg for accuracy of gauge being tested to be within ±3.1 mm Hg) was used for accurate calibration of the aneroid mode at the pressure difference of 50 mm Hg at the institute. Verification was done immediately before initiation of the comparative study and then at the end of the study to ensure optimal calibration and function of each device. Both before and after study verification at the Himalayan Institute of Medical Sciences for all the seven measurement values (each drop of 50 mm Hg) were within the ±3 mm Hg range both for the mercury and the aneroid and difference of the measurements with Nec-tech meter was within acceptable limits. The aneroid passed the pre- use calibration (Table I).

TABLE I : Before use validation of aneroid & mercury at ground level.

	Nec-tech meter verification pressure (±3 mm Hg)	
	Difference with Aneroid	*Difference with Mercury*
Before study	–2.14±0.57	–2.27±0.38
After study	–2.31±0.63	–2.73±0.45

Study procedure

The examined population consisted of 83 random selected volunteers both males & females who were residents of Dehradun. To determine meaningful differences for analysis a total of 83 differences were recorded, which is more than the recommended 45 differences recommended by the clinical validation protocol of European society of Hypertension (11). Subjects were seated comfortably for 5 min before their Blood pressure was recorded. The ambient room temperature recorded was between 20-22°C. The same appropriate - sized cuffs, the same arm, and the same posture during measurement were used for both devices. Blood pressure was recorded in the same arm with a gap of 5 min between the two recordings. To reduce measurement bias the order of sphygmomanometer type (aneroid and mercury sphygmomanometer) for measurement was randomly assigned.

The study conducted dual, sequential measurements in 83 participants. A resting (5 min) systolic and diastolic arm blood pressure was measured between 9:00 to 11:00 AM in the morning using both the new aneroid and the standard mercury device. The two sequential measurements of each volunteer from both the instrument were recorded within difference of 30 sec. BP measurements by the two devices were separated by 30 s, and measurements were recorded on a data entry form.

British hypertensive Society grading (12) is determined by the percentage of differences between device ≤ 5, ≤ 10 and ≤ 15 mm Hg (Table II). The device need to obtain A or B for both systolic and diastolic measurements to be recommended. Furthermore criteria set by Association for the Advancement of medical instrumentation (AAMI) (13) require the mean of differences of device to be within 5 mm Hg and Standard deviation to be within 8 mm Hg for recommendation.

TABLE II : British Hypertension Society grading criteria (12).

Grade of Absolute difference between Standard and test device			
	≤ 5	≤ 10	≤ 15
Cumulative percentage of reading (%)			
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

Statistical analysis

Each participant had four readings of systolic blood pressure (SBP) (two from each sphygmomanometer) and four reading of diastolic blood pressure (DBP). The average of the two repeated blood pressure readings was used for comparison of the two types of sphygmomanometer. Repeat readings from the mercury sphygmomanometer provided estimates of variation within participants and within technicians. Bland–Altman analysis (14) was used to compare the difference of mean values between the two instruments to mercury apparatus. Paired Student's *t*-test was used to test if the difference between the two types of sphygmomanometers is equal to zero. In addition, correlation analysis (15) was used to compare the two types.

RESULTS

Data collected were analyzed data from 83 volunteers (age group 18–40 years) who participated in this study and had valid data. The average of the two readings from the mercury sphygmomanometer for SBP was 119.5 mm Hg (range 91–149) and for DBP 77.2 mm Hg (ranges 55–91). The comparable aneroid sphygmomanometer means were: 115.9 mm Hg (range 83–158) for SBP and 79.03 mm Hg (50–89) for SBP. The mean difference (±SD) between the two sphygmomanometers (aneroid - mercury) was –3.60±4.88 mm Hg (P=0.060) for the SBP and –2.34±3.61 mm Hg for DBP (P=0.058).

Although the systolic & the diastolic blood pressure showed more variability with aneroid (SBP: 14.5; DBP: 12.8) as compared to mercury (SBP: 13.8; DBP: 11.5) sphygmomanometer but the coefficient of variance was within acceptable limits. Bland - Altman plots (14) shows the difference between the devices reading against the mean of the observer reading for the systolic (Fig. 1) and diastolic (Fig. 2) blood pressure with most of the difference of the means lying within ± 2SD of subjects

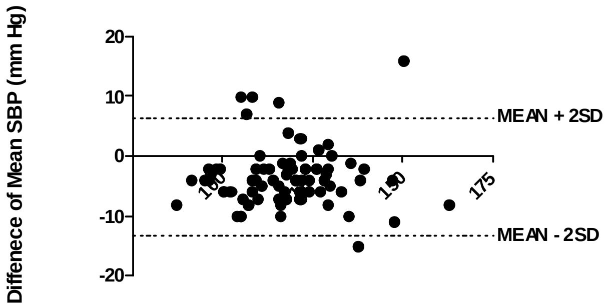

Fig. 1: Bland–Altman plot for difference between the devices reading against the mean of the observer reading of systolic blood pressure for validation of aneroid device in the examined altitude population (83 subjects).

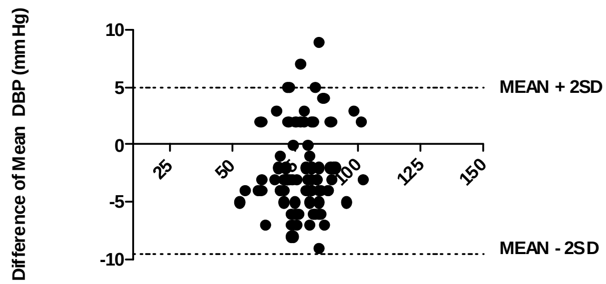

Fig. 2: Bland–Altman plot for difference between the devices reading against the mean of the observer reading of diastolic blood pressure for validation of aneroid device in the examined altitude population (83 subjects).

mean. The values of the SBP and DBP from both the instruments showed a linear correlation with systolic blood pressure (SBPr = 0. 94; DBP r = 0. 92). Corresponding to the 82 degrees of freedom both the mean difference of SBP (Z = –1.60 & P>0.06) and DBP (Z = –1.19 & P>0.06) was not statistically significant.

Linear regression analysis of between-device measurements in mean SBP (Aneroid & that measured from the mercury sphygmomanometer) showed that the measurements were positively associated with level of SBP (coefficient 0.05, 95% confidence interval (0.91, 0.97), P<0.0001 with model R^2 = 0.88). The mean DBP also showed that the sphygmomanometers measurements were positively associated with level of DBP (coefficient 0.05, 95% confidence interval (0.89, 0.95), P<0.0001 and model R^2 = 0.86). (Table III). Quantitative analysis of the SBP and DBP by both the instruments suggests that a higher value of SBP was recorded by mercury while the mean DBP by both the instrument was nearly same. However most of the DBP reading by mercury was on the higher range.

Regression analysis of aneroid BP vs. mercury BP revealed the following relationships

- SBP (mercury) = 9.52 + 0.95 SBP (aneroid)
- DBP (mercury) = 0.36+0.96 DBP (aneroid).

The slopes in both equations are significantly different from the line of equality (P<0.001) and intercepts significantly different from zero (P<0.001).

Validation : (Table IV) aneroid blood pressure measuring device is accurate for measuring blood pressure. It achieved grade of B for systolic and grade A for diastolic blood pressure, according to recommendation of BHS. Furthermore it fulfilled the AAMI recommendation as the mean (Standard deviation) of the differences between the observer and device were –3.60 (4.88) for systolic and –2.36 (3.77) for Diastolic respectively and is less than the 5 mm Hg for the mean and less than 8 mm Hg for the standard deviation.

Quantitative analysis of the SBP and DBP by both the instruments suggests that a higher value of SBP was recorded by mercury while the mean DBP by both the instrument was nearly same. However most of the DBP reading by mercury was on the higher range. (Table IV).

DISCUSSION

Study has been attempted to assess the variability of differences of blood pressure

TABLE III : Correlation and limits of agreement analysis between the Mercury and Aneroid sphygmomanometer in examined population (n= 83).

Parameter	*AneroidPressure (mm Hg)*	*MercuryPressure (mm Hg)*	*Correlation coefficient*	*PressureDifferences* (mm Hg)*	*95% CI*	*P-value*
SBP	115.90 (14.45)	119.50 (14.53)	0. 94***	–3.60 (4.88)	–8.01–0.85	0.056
DBP	77.26 (9.71)	79.03 (9.33)	0. 92***	–2.36 (3.77)	–5.29–0.57	0.058

Data are presented as mean (SD); * mean aneroid reading – mean mercury reading; SBP: systolic blood pressure; DBP: diastolic blood pressure.

TABLE IV : Grading Blood pressure (mm Hg) with BHS grading criteria & pressure difference between mercury & aneroid sphygmomanometer in examined population (n=83).

Difference between mercury and Aneroid device in mm Hg					
Observer	*Grade*	*≤5 mm Hg (%)*	*≤10 mm Hg (%)*	*≤15 mm Hg (%)*	*Mean (SD) of Differences*
SBP	B	56.62	95.18	98.79	–3.60 (4.88)
DBP	A	78.3	97.5	100	–2.36 (3.77)

by aneroid and standard mercury sphygmomanometer. Within-participant variation was explored by comparing back-to-back duplicate readings from the mercury device. There was no significant difference between sequential systolic measurements within participant (mean at 0.38 mm Hg, P=0.45). The second reading of DBP was slightly lower (0.2 mm Hg, P=0.47) vs. the first (as might be expected from an accommodation effect). The variation within participant's pair explains most of the between-device variation. Based on the result no clinically significant differences were observed between the two types of sphygmomanometers.

Aneroid sphygmomanometers have more moving parts as compared to mercury sphygmomanometers and are subject to fatigue. Bailey *et al* (8) reported that the selected aneroid sphygmomanometers (models not specified) were inaccurate in 80% of the units' tested. However study by Canzanella et al (9) established that aneroid can provide accurate measurements of blood pressure with proper maintenance protocol and but the devices measure lower readings than reference (0.05 mm Hg) with almost all of the instruments reading falling within 4 mm Hg of reference. Annual calibration was justified for accurate aneroid devices measurements in the study by Yarrows & Qian (10). All above studies connected the aneroid sphygmomanometer to a reference unit and then compared the aneroid readings to the static pressure measurements set at fixed points. Similar to our study Yong et al (16) also found no statistically significant difference for systolic blood pressure (SBP) (P>0.05) and but a small but significantly (P<0.0001) lower (0.8 mmHg) reading for diastolic blood pressure (DBP) using the aneroid sphygmomanometer of same model across various clinics at America. A significant correlation (P<0.001) was detected between aneroid & mercury sphygmomanometer with a lower reading of aneroid both in SBP and DBP.

Present study, regression analyses indicates that for both SBP and DBP, readings from the aneroid will underestimate however; the differences are very small and clinically not significant. When compared, this device is within the "pass" range set by Association for the Advancement of Medical Instrumentation (a mean ≤ 5 mm Hg and standard deviation ≤ 8 mm Hg) and grade B for systolic & A for diastolic blood pressure recording by British Hypertension Society (60% of the errors be within 5 mm Hg, 90% of the errors within 10 mm Hg, and 95% within 15 mm Hg). Study by Canzanello VJ et al on wall mounted aneroid in hospital & clinic setting also reported lower values of aneroid when compared to reference devices 0.5mm Hg (95% confidence interval, 0.3-0.7), with 100% values lying within ±4 mmHg as recommended by AAMI (9).

This study is consistent with previous publications of aneroid accuracy based on directly connecting aneroid models with a standard calibrator (8-9). It appears that variation within participant could have accounted for most of the variation in the blood pressure. The authors are of the opinion that the selected aneroid device accuracy could be maintained across the clinics with several staff over a wide range of blood pressure measurements. Therefore the Welch Allyn mobile aneroid Model 7670-04 tested in this validation study can be used as a non-mercurial alternative for measurement of blood pressure in our clinical setting.

There is no conflict of interest with the users or with the company, which supplied the equipments.

ACKNOWLEDGEMENTS

Authors are grateful to Himalayan Institute of Medical Sciences, HIHT University for providing support services and infra structures for the study. We are also thankful to biomedical Department of HIHT University for their support and help.

REFERENCES

1. O'Brien E, Fitzgerald D. The history of blood pressure measurement. *J Hum Hypertens* 1994; 8: 73–84.
2. UNEP. Global Mercury Assessment, UNEP Chemicals [Newsletter] Geneva 2002; 6: 1.
3. Messelbeck J, Sutherland L. Applying environmental product designs to biomedical products research. *Environ Health Perspect Suppl* 2000; 108: S6.
4. Ide CW. Demise of the mercury manometer [letter]. *Scott Med J* 1998; 43: 87–88.
5. Naqvi NH, Blaufox MD. In: Blood Pressure Measurement. An Illustrated History. New York: Parthenon Publishing Group Inc. 1998; 71.
6. Waugh JJS, Gupta M, Rushbrook J, Halligan A, Shennan A. Hidden errors of aneroid sphygmomanometers *Blood Press Monit* 2002; 7: 309–312.
7. Beevers G, Lip GHY, O'Brien E. ABC of Hypertension. Part II. Conventional sphygmomanometry: Technique of auscultatory blood pressure measurement. *BMJ* 2001; 322: 1043–1047.
8. Bailey RH, Knaus VL, Bauer JH. Aneroid sphygmomanometers: an assessment of accuracy at a University Hospital and Clinics. *Arch Int Med* 1991; 151: 1409–1412.
9. Canzanello VJ, Jensen PL, Schwartz GL. Are aneroid sphygmomanometers accurate in hospital and clinic settings ? *Arch Intern Med* 2001; 161: 729–731.
10. Yarows SA, Qian K. Accuracy of aneroid sphygmomanometers in clinical usage: University of Michigan experience. *Blood Press Monit* 2001; 6: 101–106.
11. O' Brein E, Pickering T, Asmar R, et al. Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for Validation of Blood pressure measuring device in Adults. *Blood Press Monit* 2002; 7: 3–17.
12. O'Brien E, Petrie J, Littler W et al . The British Hypertension Society protocol for evaluation of Blood pressure measurement devices. *J Hypertens* 1993; 11(S): 43–62.
13. Association for the Advancement of Medical Instrumentation. American National Standard for Manual, Electronic or automated sphygmomanometers. Arlington, Va: AAMI; 2003; 13.
14. Bland JM, Altman DG. Statistical Methods for assessing agreement between two methods of clinical measurements. *Lancet* 1986; 1: 307–310.
15. Latman NS, Lanier R. Expressions of accuracy in the evaluation of biomedical instrumentation. *Biomed Instrum Technol* 1998; 32: 282–288.
16. Yong Ma, Marinella Temprosa, Sarah Fowler, et al. Evaluating the Accuracy of an Aneroid Sphygmomanometer in a Clinical Trial Setting. *Am J Hypertens* 2009; 22: 263–266.