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Challenges in selecting a sphygmomanometer for accurate BP measurement in research settings

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***Abstract*- Blood pressure (BP) measurement, although, one of the standard recordings in research settings, but is often prone to inaccuracies. Auscultatory method of measuring BP using a mercury sphygmomanometer is widely regarded as the "gold standard" for BP measurement, but widespread implementation of the ban in use of mercury sphygmomanometers continues to diminish the role of this technique in research settings. This has led to the proliferation of non-mercury devices and has changed (probably for ever) the preferable modality of BP measurement. Whatever device is used, it must be properly validated, regularly maintained and recalibrated according to the manufacturer's instructions. In this article, the challenges that occur in selecting a sphygmomanometer for measurement of accurate BP in research settings,are discussed.**

Keywords:-Blood pressure, hypertension, sphygmomanometer, mercury sphygmomanometer, aneroid sphygmomanometer, automated sphygmomanometer, validation.

1. Introduction

Hypertension is the leading risk factor for death and disability globally according to the World Health Organization (WHO)[1]. Although much of hypertension is preventable, especially by reducing the amount of salt added to foods, hypertension treatment can also prevent the adverse consequences of stroke, heart attack, and heart and kidney failure [2],[3]. Unfortunately, about half of patients with hypertension remain undiagnosed [4]. Hence, the national, international hypertension societies and research organisationshave made the increase in regular BP assessments and encouragement of widespread BP screening programs linked to accurate diagnosis and management of hypertension to be among the highest of priorities.Decisions made based on these recordings will be for the benefit of the population, depending on the accuracy of their measurement [5].

2. Challenges in selecting a sphygmomanometer for research settings

The selection of a BP monitor or sphygmomanometer is crucial in obtainingaccurate BP measurement. Since the first description of mercury sphygmomanometer, it has been regarded as the "gold standard" for BP measurement, not only in clinical practice but also in research studies. Indeed, the world's primary standard for BP measurement is mercury sphygmomanometer. This is because of its low cost of purchase as well as maintenance (no need for electricity or battery), simple design, lesssusceptibility to loss of accuracy over time, no requirement of regular calibration and validation of mercury BP measurements against direct intra-arterial measurements in many clinical circumstances [6],[7].

However, in recent years, alternatives to replace mercury sphygmomanometers arebeing worked at because concerns rightly exist about the toxicity of mercury for individuals using mercury sphygmomanometers due to accidental spillage of mercury in the workplace and for the environment due to the unsafe disposal of broken mercury sphygmomanometers. Several countries have banned or restricted the import, sale, and/or the use of mercury sphygmomanometers [8]. Therefore, if mercury sphygmomanometers are not banned in the country, city, hospital or research institution, a mercury sphygmomanometer can be used if properly calibrated and free from physical defects. Furthermore, the staff should be trained to ensure safe handling during normal use and storage in the event of a mercury spillage, disposal or when a complete instrument is discarded.

An aneroid sphygmomanometer, can be used as substitute in the unavailability of mercury sphygmomanometer. But in the research settings where large numbers of subjects need to be screened using multiple BP measurements, over a long period of time, moving parts of aneroid sphygmomanometer may be subjected to fatigue, a major source of errors in aneroid sphygmomanometer. Therefore, if these sphygmomanometers are used in such settings, they should be inspected for physical defects and calibrated for accuracy against a standard mercury sphygmomanometer at regular intervals to prevent inaccuracy in measurements.

However, irrespective of the type of sphygmomanometer (mercury or aneroid), the auscultatory sphygmomanometry technique is time consuming due to themanual inflation and deflation of the cuff at specified rates and interpretation of the Korotkoff sounds for recognising SBP and DBP values. In addition, auscultatory sphygmomanometry is prone to observer bias that may add to the possibility of inaccuracy in measurements. Thus, the use of mercury and aneroid sphygmomanometer needs elaborate training of the observer.

Automated sphygmomanometers are very helpful for providing accurate measurements in research settings due to their advantages of reduction in observer fatigue, measurement time, and elimination of observer error as they provide measured BP value on a digital display. Unlike mercury and aneroid sphygmomanometers, automated

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sphygmomanometers require infrequent calibration and maintenance. Moreover, elaborate training is not required, although a period of instruction and an assessment of proficiency will always be necessary. Most importantly, the automatic inflation-deflation and data storage facility of automated sphygmomanometers contributes to reduce the burden of observer and enhance the measurement accuracy.

The accuracy of a sphygmomanometer selected for use should not be based merely on claims from manufacturers; instead, independent validation results at least according to one of the key performance protocols should be demanded. However, purchasers often assume that all the sphygmomanometers available in themarket will measure BP accurately. Aware of this problem, the American Association of Medical Instruments (AAMI) published standards for validation of automated and aneroid sphygmomanometers in 1987, and this was followed in 1990 by the protocol of the British Hypertension Society (BHS). Till the date, validation protocol of BHS was revised only once in 1993, but protocol of AAMI was revised twice, in 1993 and 2002 [10]. Since the two protocols can be reconciled, the joint criterion was applied in most published validation studies. The criteria for fulfilment of the BHS protocol are that the test sphygmomanometer must achieve at least grade B for systolic BP (SBP) and diastolic BP (DBP); whereas AAMI protocol required that the test sphygmomanometer must not differ from the mercury standard by a mean difference of greater than 5mmHg or a standard deviation of 8mmHg. Since the introduction of AAMI and BHS protocols, many sphygmomanometers have been evaluated. However, experience revealed that the conditions necessitated by these protocols are extremely difficult to fulfil because of the large sample size and the ranges of BP required. Furthermore, due to the requirement of long time duration for completion of a validation study it is difficult to recruit trained staff for an investigation. These factors made validation studies difficultto perform and burdensome. One consequence of this has been that there are still many sphygmomanometers in the market that have not been adequately validated by the manufacturers. More recently, in 2002, an international group of experts who were the members of the European Society of Hypertension (ESH) Working Group on BP Monitoring produced an international protocol that was not burdensome and could be performed without sacrificing the integrity of the AAMI and BHS protocols. This international protocol was revised in 2010 [11-13]. A summary of AAMI, BHS and ESH protocol is shown in Table 1.

Table1. **Summary of the AAMI, BHS and ESH protocol used for validation of sphygmomanometers (O'Brien*et al*., 1993; O'Brien*et al*., 2002)**

Validation Protocol	Requirements
AAMI (2002)	**Sample size**: 85 subjects with 3 measurements on each **Selection**: to represent a range of BP from, at least less than 10% <100/60mmHg and 10% >160/100mmHg, and 10% to be subjects in arm sizes less than <25cm and 10% >35cm **Comparison**: simultaneous measurements in the same arm **Criteria**: difference has mean <5mmHg and standard deviation (SD)<8mmHg **Statistical methods**: treated as 255 independent measurements
BHS (1993)	**Sample size**: 85 subjects with 3 measurements on each **Selection**: to represent a range of BP from <90/60mmHg to >180/100mmHg, MUAC **Comparison**: sequential measurements in the same arm **Criteria**: the acceptable differences vary according to the true BP-see full protocol for details **Statistical methods**: treated as 255 independent measurements
ESH (2010)	**Sample size**: 33 subjects with 3 measurements on each **Selection**: 90-180mmHg for SBP and 40-130mmHg for DBP. However, if patients with BPs outside these ranges are available they may be included but only to a maximum of four such pressures **Comparison**: : sequential measurements in the same arm **Criteria**: at least 2/3 of subjects have at least 2/3 of differences <5mmHg; no >3 out of 33 subjects have differences > 5mmHg. Moreover, it requires that the test instrument measures within 5mmHg for 73% of the time, within 10mmHg for 87% of the time, and within 15mmHg for 96% of the time (for any two of the three measurements) or within 5mmHg for 65% of the time, within 10mmHg for 81% of the time, and within 15mmHg for 93% of the time (for any two of the three measurements (for three measurements) **Statistical methods**: account for both subject level and observation level variation (see criteria)

Studies divulged that the introduction of international protocol of ESH has expanded the validation procedure worldwide by three to four-times compared with the period prior to its publication. The grading criteria of BHS are given in Table 2. Grades represent the cumulative percentage of readings falling within 5mmHg, 10mmHg, and 15mmHgof the mercury standard. All three percentages must be greater than or equal to the values shown for a specific grade to be awarded.

Table 2Grading criteria used by BHS

Grade	Absolute difference between standard and test sphygmomanometer (mmHg)

	≤5	≤10	≤15
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

These validation protocols, which differed in detail, had a common objective of standardization of validation procedures to establish minimum standards of accuracy performance to facilitate comparison of one sphygmomanometer with another. Many sphygmomanometers, available in the market, have beenevaluated for accuracy according to the validation protocol of AAMI, BHS and ESH [13], [14].

3. Conclusion

In view of the above discussion, we recommend that if no ban has been imposed on the use of mercury based medical devices, mercury sphygmomanometer can be used for BP measurement, but safety measures should be used to deal effectively with mercury spills. Although, aneroid sphygmomanometers can be used as an alterternative in the unavailability of mercury sphygmomanometer but they should be regularly calibrated to prevent inaccuracy in measurements. In addition, to prevent observer bias associated with the use of auscultatory technique based sphygmomanometers (both mercury and aneroid), observer should be properly trained. The use of automated sphygmomanometerscan be helpful in eliminating observer bias as measurements are provided on a digital display. Specifically, if time constraint is associated with a research study to be performed on large sample size, the use of OMRON HEM-7203 can be beneficial due to reduction in measurement time and observer fatigue.

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