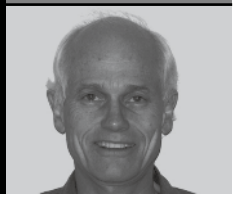
CLINICAL PRACTICE

Practice tip



Sphygmomanometer calibration

Why, how and how often?

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BACKGROUND

Hypertension is the most commonly managed problem in general practice. Systematic errors in blood pressure measurements caused by inadequate sphygmomanometer calibration are a common cause of over- and under-identification of hypertension.

OBJECTIVE

This article reviews sphygmomanometer error and makes recommendations regarding in service maintenance and calibration of sphygmomanometers.

DISCUSSION

Most sphygmomanometer surveys report high rates of inadequate calibration and other faults, particularly in aneroid sphygmomanometers. Automatic electronic sphygmomanometers produce systematic errors in some patients. All sphygmomanometers should be checked and calibrated by an accredited laboratory at least annually. Aneroid sphygmomanometers should be calibrated every 6 months. Only properly validated automatic sphygmomanometers should be used. Practices should perform regular in house checks of sphygmomanometers. Good sphygmomanometer maintenance and traceable sphygmomanometer calibration will contribute to reducing the burden of cardiovascular disease and the number of patients overtreated for hypertension in Australia.

Hypertension is the most commonly managed problem in general practice, accounting for 8.6% of encounters and 7.9% of prescriptions.[1] However, just under half the cases in Australia are untreated.[1] Frequent consequences of hypertension are stroke and cardiovascular disease, which caused 38% of all deaths in Australia in 2002.[2] Hypertension in its early stages can be diagnosed only by measurement of blood pressure (BP).

All measurements are contaminated by errors that may be divided into two types:

- random errors are different on every occasion and can be reduced by averaging a number of measurements (random variation caused by biological variability is usually indistinguishable from random measurement error and is also reduced by averaging), and
- systematic errors, which have approximately the same value on every occasion and are not reduced by averaging.

Inadequate sphygmomanometer maintenance and calibration is a common cause of systematic error in BP measurements. Systematic errors are difficult to detect and correct. The only way to reduce systematic errors is to use the correct measurement technique and well maintained and calibrated instruments.

Hypertension detection and systematic errors

The detection of hypertension is extremely sensitive to systematic errors in BP measurements. *Figure 1* shows that a consistent 5 mmHg error can more than double or halve the number of patients diagnosed with diastolic hypertension. Further analysis of data from the same survey[3] allows the effects of any systematic error on the detection of diastolic and systolic hypertension to be estimated.[4] A consistent 5 mmHg error in systolic pressure can result in systolic hypertension being underdiagnosed by 30% or overdiagnosed by 43%.[4] The current Australian Sphygmomanometer Standard allows systematic errors up to approximately ±4 mmHg in new sphygmomanometers.[5]

Sphygmomanometers

Mercury and aneroid sphygmomanometers

Studies of calibration errors of mercury and aneroid sphygmomanometers in Australia[6–8] have been limited and lacking in quality, but do suggest that all is not well. Several studies indicate that substantial proportions of

sphygmomanometers in general practices and hospitals exhibit clinically significant (>3 mmHg) systematic pressure errors and other faults.[9–12] Some guidelines implicitly assume that mercury sphygmomanometers never require calibration.[13] While aneroid sphygmomanometers fare worse than mercury instruments, many studies have found significant errors in mercury sphygmomanometers.[9,10,12] Rouse and Marshall[14] found that nearly 100 of 1462 sphygmomanometers were in such poor condition that their tester suggested they be withdrawn from service, and Knight et al[10] found that none of the 472 sphygmomanometers they tested complied fully with the British Sphygmomanometer Standard current in 2001. Aneroid sphygmomanometers provided as promotional gifts by pharmaceutical companies have been shown to be less accurate than others[12] and should be avoided.

Automatic oscillometric sphygmomanometers

Most automatic oscillometric sphygmomanometers measure cuff pressure electronically and use proprietary algorithms to estimate systolic and diastolic pressures by analysing the pulsations in cuff pressure as the cuff deflates or inflates. Systematic errors can be caused by both lack of calibration of the electronic pressure sensing system and by the algorithm that estimates diastolic and systolic pressures. Because the algorithms are confidential and differ between instruments, protocols have been developed to validate oscillometric sphygmomanometers against manual auscultatory measurements.[15,16] The dabl Educational Trust (www.dableducational.com) assesses each validation report and makes recommendations according to the results and quality of the validations.[16] Sphygmomanometers can pass validation tests despite producing clinically significant errors that can be greater than 15 mmHg in some individuals.[17] Oscillometric sphygmomanometers perform poorly in pregnant women,[18] diabetics[19] and in patients with stiff arteries,[20] but the causes of systematic errors are not well understood. For these reasons the American Heart Association recommends that each oscillometric sphygmomanometer should be validated for use with every patient before readings are used to diagnose or manage hypertension.[21]

Nonautomatic electronic sphygmomanometers

The anticipated demise of the mercury sphygmomanometer has prompted the development of electronic pressure indicators that can be used with manual auscultation of the Korotkov sounds. These 'hybrid' sphygmomanometers are available with segmented displays that mimic the linear and circular scales of mercury and aneroid manometers. Some versions, which have buttons that the operator presses at the systolic and diastolic pressure points, should reduce some operator dependent errors such as terminal digit preference.[21]

Maintenance and calibration of sphygmomanometers

All sphygmomanometers sold in Australia are required to comply with the Australian Standard AS EN 1060 2002 Noninvasive Sphygmomanometers Parts 1, 2 and 3[5] at the time of sale. Although these standards are primarily intended for assessing and licensing new instruments, they do contain limited performance and quality clauses against which sphygmomanometers in service can be assessed and calibrated.

How often should sphygmomanometers be checked and calibrated?

There are three criteria to consider when selecting a calibration interval:

- the probability that the sphygmomanometer will go out of calibration to a clinically significant extent between calibrations
- the consequences of discovering that a sphygmomanometer has a clinically significant calibration error
- the cost of calibration.

If a clinician is notified by a medical testing laboratory of systematic errors in cholesterol test results, he/she would advise patients to have the measurement repeated. Similarly, if a clinically significant BP error is discovered, the clinician is ethically bound to recall all patients whose BP was measured since the previous calibration when the sphygmomanometer was known to be accurate. A BP determination involves several consultations and the potential costs of the additional visits and the adverse effects of incorrect treatment of a number of patients have to be weighed up against the cost of calibration. There may also be medicolegal consequences of not calibrating sphygmomanometers at appropriate intervals.[22] The calibration interval also depends on the robustness of the instrument and the conditions under which it is used. If an instrument proves to be stable after several calibration cycles it is possible to increase the calibration interval with caution and due consideration of the risks of erroneous measurements. Conversely, if large calibration errors are found, the interval should be reduced or the instrument replaced.

Recommended test and calibration methods

Formal calibration of the pressure indicator

- The pressure indicators of all sphygmomanometers should be calibrated by a laboratory accredited by the National Association of Testing Authorities (NATA) to calibrate pressure gauges or transducers over the range 0–40 kPa (0–300 mmHg). NATA publishes searchable lists of calibration laboratories on its website (www.nata.com.au). Use the keyword 'pressure' to search the measurement science and technology field of testing for a laboratory. The least uncertainty of measurement included in the scope of each laboratory is the best accuracy that laboratory can offer. Look for a least uncertainty of measurement of 0.05 kPa (0.4 mmHg) or less.
- The laboratory should be requested to calibrate the indicator from zero to the maximum pressure on the sphygmomanometer scale at pressure increments not greater than 6 kPa (50 mmHg).
- Calibration intervals should not be greater than those indicated in *Table 1*.

Performance and condition

The general condition of sphygmomanometers and compliance with the other in service clauses of the current sphygmomanometer standard should be checked annually by an experienced technician. Formal records of the

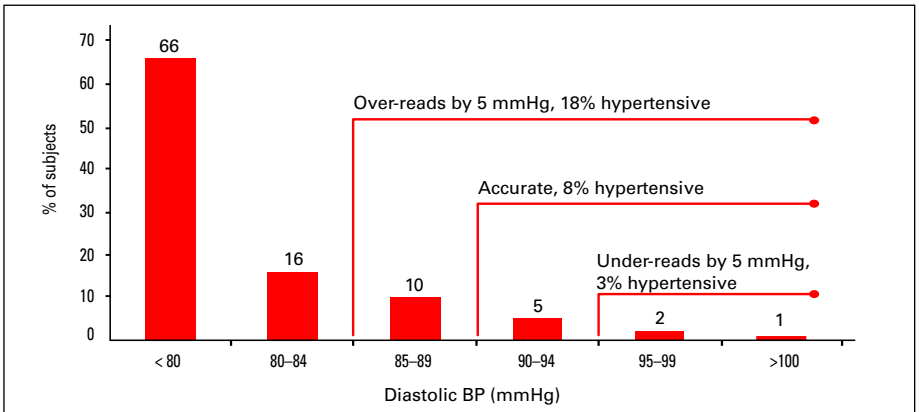

Figure 1. The distribution of diastolic BP in the Canadian population in 1986–1990[3] demonstrates how systematic errors can affect the detection of hypertension. A clinician whose sphygmomanometer is accurate would find that 8% of the population has DBP >90 mmHg. If the sphygmomanometer consistently over-reads by 5 mmHg then patients whose DBP is 85 mmHg would appear to have a DBP of 90 mmHg, so the clinician would find that 18% of the population has DBP >90 mmHg. If the sphygmomanometer under-reads by 5 mmHg then patients whose DBP is 95 mmHg would appear to have a DBP of 90 mmHg, so the clinician would find that only 3% of the population has DBP >90 mmHg

outcomes of these assessments should be kept. At the time of writing we are not aware of any facilities that offer these tests commercially in Australia, but they should become more readily available as demand increases. Aspects that should be tested include:

- air leakage
- rapid exhaust time
- the condition of cuff, tubes, bulb and fittings
- scale visibility
- contamination of the glass tube or mercury
- cuff inflation and deflation control
- security of mercury containment.

In house checks of the pressure indicator

To detect clinically significant calibration errors between formal calibrations and minimise the consequences of erroneous measurements, it is useful to carry out regular in house checks of the pressure indicator.

Practices should maintain a reference manometer (preferably a good quality electronic instrument) that is not used for daily measurements but against which all in service sphygmomanometers are checked at two pressures (eg. 0 and 100 mmHg) regularly in the practice:

- if the sphygmomanometer is electronic set it to a mode in which pressure is continuously displayed
- using Y-connectors and leak free tubing connect the reference manometer to the sphygmomanometer pressure inlet and a sphygmomanometer bulb
- with the valve open check that the reference manometer displays zero and record the pressure indicated by the sphygmomanometer
- increase the pressure to approximately 200 mmHg and deflate slowly, stopping when the reference manometer indicates approximately 100 mmHg
- record and compare the pressures indicated on the reference manometer and on the sphygmomanometer
- open the valve so the pressure decreases to zero over 2–3 seconds and check that the reference manometer displays zero pressure
- record the pressure indicated by the sphygmomanometer

Formal records should be kept of these checks (eg. in a notebook). The reference manometer should be locked away when not used for internal comparisons and formally calibrated by a NATA accredited laboratory annually.

Results of a pressure indicator calibration

A calibration certificate endorsed with the NATA logo should be obtained from the calibration laboratory. If the pressure indicator of the sphygmomanometer is not adjustable (eg. most mercury and aneroid sphygmomanometers) then the calibration certificate should include a table containing corrections that should be added to indicated values to obtain the correct measurement, for both rising and falling pressures. In a busy practice where it may not be practicable to add corrections to every BP measurement, nonadjustable sphygmomanometers that have corrections larger than 3 mmHg should be repaired or replaced.

If the instrument is adjustable (eg. some electronic sphygmomanometers) then the laboratory can be requested to adjust the instrument to minimise the errors over a particular pressure range. In this case it is common to request both before and after calibration correction tables.

Recent evidence suggests that systematic errors of 3 mmHg probably result in clinically significant over- and under-detection of hypertension.[4] Therefore, we recommend that where possible the error of the pressure indicator should be 1 mmHg or less. Good quality mercury and electronic pressure indicators should be capable of achieving this performance.

Oscillometric sphygmomanometers

Some validations of oscillometric sphygmomanometers are poorly performed

Table 1. Recommended calibration and check intervals for mercury, aneroid and electronic sphygmomanometers

Type of instrument	Calibration interval (months)	Check interval (months)
Mercury sphygmomanometers that are permanently fixed to an immovable object	36	6
Portable mercury sphygmomanometers	12	6
Aneroid sphygmomanometers used in a consulting room	6	1
Aneroid sphygmomanometers carried around daily	6	0.5
Electronic oscillometric sphygmomanometers	12	6
Electronic manual sphygmomanometers	12	6

and systematic errors of oscillometric sphygmomanometers are poorly understood and can be clinically significant in some people. Therefore, only oscillometric sphygmomanometers recommended by the dabl Educational Trust should be used. If possible, it is desirable that instruments are rated A/A according to the British Hypertension Society (BHS) protocol.[23]

Following American Heart Association recommendations, oscillometric sphygmomanometers should be validated once in each patient to exclude the possibility of clinically significant systematic measurement error before being used to detect or manage hypertension in that patient. To exclude systematic error, compare several interspersed oscillometric and manual measurements made not less than 1 minute apart on the same arm of the patient, preferably over more than one visit.

Discussion

Stroke and cardiovascular disease are devastating for the patient and contribute substantially to the burden of disease in Australia.[2] Inappropriate antihypertensive treatment increases the cost of health care, decreases the quality of life of patients, and exposes patients to potential adverse effects of treatment. Inadequate sphygmomanometer calibration results in untreated hypertension in some patients, and in some patients, receiving antihypertensive treatment they would not otherwise receive. Traceable calibration of sphygmomanometers will increase the direct costs of running a clinical practice but the resulting reduction in over- and under-detection of hypertension has been shown to be equivalent to the reduction that would be obtained from two additional visits of every patient to their clinician.[24]

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