Accuracy of Blood Pressure Monitoring Devices: A Critical Need for Improvement that could resolve Discrepancy in Hypertension Guidelines

[1]James E Sharman, [2]Thomas H Marwick.

[1]Menzies Institute for Medical Research, University of Tasmania, Hobart, 7000, Australia

[2]Baker Heart and Diabetes Institute, Melbourne, 3004, Australia.

Correspondence to:

James E. Sharman

Menzies Institute for Medical Research, University of Tasmania

Private Bag 23, Hobart, 7000, Australia.

Phone: +61 3 6226 4709 Fax: +61 3 6226 7704

Email: James.Sharman@utas.edu.au

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Abstract

Hypertension is the most significant modifiable risk factor for cardiovascular disease and contributes to the highest global burden of disease. Blood pressure (BP) measurement is among the most important of all medical tests, and it is critical for BP monitoring devices to be accurate. Comprehensive new evidence from meta-analyses clearly shows that many BP monitoring devices (including oscillometric machines and 'gold standard' mercury auscultation) do not accurately represent the BP within the arteries at the upper arm (brachial) or central aorta. Particular variability in the accuracy of BP devices compared with intra-arterial BP has been demonstrated in the cuff BP range from prehypertension to grade I hypertension (systolic BP 120 – 159 to diastolic BP 80 – 99 mmHg). This is within the BP range that is most common among people worldwide and, thus almost certainly, feeding confusion around optimal hypertension guideline thresholds. At the individual level, inaccurate BP devices have major potential consequences for best practice patient management, where underestimation of true BP is a missed opportunity to lower cardiovascular risk (with therapeutics or lifestyle) and overestimation of true BP could lead to overmedication. Each problem leads to increased cost from preventable cardiovascular events and unnecessary medications. Altogether, there is a critical need to improve the accuracy standards of BP monitoring devices. In the meantime, out-of-office BP (24 hour ambulatory BP and/or home BP monitoring) or automated, unobserved in-office BP monitoring that take the average of multiple readings using validated devices are the best available options to determine BP control.

Keywords: Diagnostic equipment; sphygmomanometer; blood pressure monitors.

Hypertension is the single largest risk factor contributing to global burden of cardiovascular disease,[1, 2] and is a problem affecting all countries irrespective of income status.[3] About 1 in 3 adults have hypertension, which is often asymptomatic, but once identified is eminently treatable with lifestyle (exercise and diet)[4, 5] or blood pressure (BP)-lowering medication.[6] There is incontrovertible evidence that these interventions reduce risk for future disability and death from cardiovascular disease,[7, 8] which underlies reasons why the accurate measurement of BP has been touted among the most important tests in all of clinical medicine.[7] Yet somehow inexplicably there still remains controversial discordance between hypertension guideline recommendations.[9] There are a multitude of potential sources of error that can contribute to inaccurate BP measurement from physiological anomalies (e.g. arrhythmias such as atrial fibrillation or large interarm BP differences) or technical issues such as subject preparation, cuff size and body position, to name but a few. Less well known is the source of error related to inaccuracy of the BP monitoring device itself, that is when a device does not accurately record the true level of BP within the large arteries. This problem, which could contribute to guideline discrepancies and threatens the opportunity to reduce disease burden from hypertension, is the focus of this review.

Problems can arise when BP results are viewed from an individual rather than a group perspective. Figure 1 illustrates how a useful test from a population perspective may not deliver the results that are needed for individual decision-making. Cuff BP, despite its place as the clinical standard used daily around the world, may have these shortcomings. The mercury sphygmomanometer method was invented by Riva Rocci in 1896 and refined by Korotkoff in 1905.[10] The fundamental measuring principles of cuff BP devices remain largely unchanged. While cuff BP is time-honored, it is also time to ask whether this antique method is the best tool to deliver optimal care to 21st century patients. Here, we bring to light several lines of evidence that raise serious accuracy concerns around BP monitoring devices even when used under optimal conditions (e.g. correct cuff size, body position and in the absence of issues such as arrhythmias), and suggest that cuff BP may not be a good representation of the true intra-arterial BP values. This knowledge provides an opportunity to improve accuracy, but at the same time, warrants consideration of the potential impact of changing practice on patient diagnosis and management.

What is cuff BP actually measuring?

Of course, it is not the BP within the arm (brachial) artery that causes strokes and heart attacks, rather it is the BP within the central arteries directly interacting with the brain and heart. Thus, while cuff BP is measured at a peripheral (brachial) artery, the goal is to estimate the pressure load experienced by the central organs (supplied by the aorta) as the best marker of risk from high BP.[11, 12] The Riva Rocci method was believed to represent central pressure as the cuff was applied at a large artery branch of the aorta, and therefore a minimal BP difference was expected.[10] We now know that differences in systolic BP can occur such that among individuals with similar brachial systolic BP (e.g. 150 mmHg) the central aortic systolic BP could vary substantially under resting conditions – e.g. from 120 to 150 mmHg (but generally always lower).[13] Thus, even if an accurate measure of cuff (brachial) systolic BP could be derived, the true risk related to BP at the central aortic level may be markedly overestimated in some people. This discrepancy between central and peripheral systolic BP is exacerbated during exercise even at light intensities[14] similar to that experienced during normal daily life when ambulatory BP monitoring may be undertaken.

Adding further complexity to accurate assessment of BP is the knowledge that BP-lowering drugs can differentially affect central aortic BP compared with arm BP. Indeed, modern anti-hypertensives typically lower central systolic BP more than that at the arm,[15] but even more critically, it is possible for drugs to elicit large central systolic BP drops in the absence of any appreciable change to arm systolic BP.[16] These central to peripheral BP discrepancies create the intriguing possibility that clinicians could be ‘chasing’ the wrong BP targets when clinical decisions are guided by cuff BP. These underlying factors could help explain discrepant results from large clinical trials of optimal cuff BP targeting among different patient populations.

The above information provides the basic rationale for development of non-invasive devices aiming to provide a more accurate measure of central aortic BP, which should theoretically lead to better clinical outcomes. Many such devices are now commercially available,[17] but there is minimal clinical trial data[18, 19] and have not been widely adopted in clinical practice. Key criticisms relate to accuracy concerns for determining the true central BP (e.g. compared with an invasive reference standard) - ironically, because conventional cuff BP is still needed for calibration purposes and this induces unacceptable error.[20] Currently, there is a general sentiment in favor of keeping with time-honored cuff BP in preference to any other method, until a strong case for change is provided.[21]

What is the evidence around accuracy concerns with cuff BP?

It is widely appreciated that auscultation and oscillometric cuff BP methods have a tendency towards underestimating true brachial systolic BP on the one hand, but overestimating diastolic BP on the other.[22] This could have the unintended beneficial outcome of cuff BP providing a good estimate of central aortic BP, since systolic BP is usually lower and diastolic BP usually higher at the aorta compared with the brachial artery. Yet, the first study to definitively address the issue on the accuracy of cuff BP was only recently published.[23] In this work, cuff BP was compared with intra-arterial brachial BP or aortic BP recorded at the same (or similar) time under resting conditions, mostly among people having coronary angiographic procedures. These were individual participant data meta-analyses from the 1950’s to the current day that provided the most comprehensive analysis of cuff BP accuracy to date. Comparisons of ambulatory BP with intra-arterial measurements[24] were not undertaken because of scarce availability of studies and protocols that were highly divergent from investigations in which monitoring was conducted at rest. Similarly, the meta analysis avoided studies among patients in hyperacute conditions such as stroke,[25] critical illness or those undergoing surgery, or during maneuvers such as Valsalva or exercise, because of large hemodynamic shifts that may have influenced cuff BP accuracy, and thus potentially introduced bias into the analysis.

In the meta-analyses, when people were categorized according to guideline hypertension thresholds, cuff BP had reasonable concordance with either brachial or aortic intra-arterial BP among people with normal cuff BP (<120/80 mmHg; 60% and 79% agreement, respectively) or grade II hypertension (≥160/100 mmHg; 80% and 76% agreement, respectively) – the extreme ends of the BP risk spectrum. But for those in the middle risk spectrum with cuff BP in the range from prehypertension to grade I hypertension (120 – 159 to 80 – 99 mmHg), concordance with either intra-arterial brachial BP or aortic BP was only 50% to 57%. Results were consistent for auscultation ('gold standard') and oscillometric methods. These are crucial observations because the BP zone with the least accuracy is that which comprises most people worldwide,[26] and thus is a problem that would almost certainly be contributing to confusion around optimal hypertension thresholds and discrepancy between guidelines.[21, 27]

On average, cuff BP underestimated intra-arterial brachial systolic BP by 5.7 mmHg and overestimated diastolic BP by 5.5 mmHg, leading to a sizeable 12 mmHg underestimation of pulse pressure. For intra-arterial aortic BP, the cuff BP variably underestimated and overestimated systolic BP between different cuff BP devices and techniques. Only 33% of cuff BP's were within ±5 mmHg from intra-arterial values (see figure 2). Age and body mass index appeared to have a modulating influence on the magnitude of cuff BP inaccuracy but more work is needed to understand key influential factors. Overall, these are sobering data, strongly supporting a need for improved cuff BP accuracy standards.

What are the potential clinical ramifications of inaccurate cuff BP?

As already alluded, the availability of inaccurate BP devices has a variety of potentially serious consequences for clinical practice. For example, the interpretation of results from seminal clinical trials that influence guidelines may be profoundly altered by having regard to the accuracy performance of the BP device/s used in the trial – could there have been systematic or random errors related to underlying BP level or patient characteristics? To our knowledge these questions have not been probed to date. At the population level, a relatively small error in cuff BP measurement can have major consequences for best practice patient management. In the United States, data projections show that cuff BP inaccuracy of as little as 5 mmHg could misclassify BP control among 48 million people each year.[28] The meta-analyses data above indicate that error of this magnitude (and more) is likely to be the norm rather than an exception.[23] For those individuals where BP is underestimated, there is a missed opportunity to lower cardiovascular risk with therapeutics or lifestyle advice. For individuals where BP is overestimated there is potential risk of overmedication and adverse side effects. Irrespective of the direction in cuff BP inaccuracy the public health outcome is the same – increased cost from preventable cardiovascular events and unnecessary medications.

What are the solutions?

Concerns about the accuracy of cuff BP should not detract from current efforts to measure and control BP. In addition to the challenges of approximating central pressure, a multitude of problems may contribute to hypertension misdiagnosis if doctor-measured BP is relied upon as the sole source of information about BP control (e.g. white coat hypertension and lack of time to measure BP according to guideline criteria). The best available options to confirm diagnosis beyond doctor-measured BP are out-of-office measurement of 24 hour ambulatory BP[29, 30] or home BP monitoring,[31, 32] or automated in-clinic (unobserved) BP[33] using validated BP devices. In general, 24 hour ambulatory BP has the highest sensitivity for predicting cardiovascular clinical outcomes[34] (see table 1 summary).

Although, the same (relatively inaccurate) BP methods are used with out-of-office BP, these techniques acquire multiple BP measures over time, which may reduce error margin and seem to offer more clinical information about chronic BP exposure. There is strong evidence that these methods sizably out-perform office BP in terms of association with cardiovascular outcomes.[35] In this regard, the new US guidelines that place greater emphasis on using out-of-office BP is a step forward for better patient management with potentially more accurate assessment of BP.[27] However, the suggested lowering of the hypertension threshold to 130/80 mmHg does little to address BP-related cardiovascular risk if the devices in the hands of doctors are substantially inaccurate. Ultimately, we need more accurate ways to measure BP and this is an urgent research imperative, which must surely lead to greater agreement between international hypertension guidelines, improved diagnostic confidence, improved clinical decisions and better patient outcomes.

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Figure 1. Illustration of how an unacceptable level of diagnostic misclassification at the individual level may provide reasonable diagnostic performance at the population level. In this example, the individual misclassification of 40% of the intermediate risk group could still provide positive predictive value of 78% and negative predictive value of 89% because of high performance in low and high risk groups. Green = correctly classified low risk; red = correctly classified high risk; black = incorrectly classified low risk; blue = incorrectly classified high risk.

Figure 2. Individual brachial cuff and intra-arterial blood pressure (BP) differences. Plots of brachial cuff and intra-arterial brachial (A; n=735), as well as brachial cuff and intra-arterial aortic (B; n=1823) systolic BP. The mean of the brachial cuff systolic BP and intra-arterial systolic BP is on the x-axis, and the mean difference between brachial cuff systolic BP and the intra-arterial systolic BP is on the y-axis. The proportion of brachial cuff SBP values within ±5 mmHg of the intra-arterial systolic BP measures is represented by the green dashed line, and is reported under the ±5 bar. The same presentation is provided for cuff systolic BP values within ±10 mm Hg (orange dotted line) and ±15 mm Hg (red dot-dashed line). The solid blue horizontal line represents the mean systolic BP difference calculated as brachial cuff minus intra-arterial BP. Reprinted from Picone et al J Am Coll Cardiol (2017)[23] with permission from Elsevier.

Table 1. Summary of key take home messages

• Hypertension is an extremely important cardiovascular risk factor that needs to be detected using blood pressure (BP) monitoring devices that are accurate. • Substantial new evidence definitively shows that many BP monitoring devices are not accurate – this includes the 'gold standard' mercury auscultation. This problem is highly likely to contribute to discrepancy among international hypertension guidelines. • There is a critical need to improve the accuracy standards of BP monitoring devices. • In the meantime, out-of-office BP (24 hour ambulatory BP and/or home BP monitoring) or automated, unobserved in-office BP monitoring that take the average of multiple readings are the best available options to determine BP control.

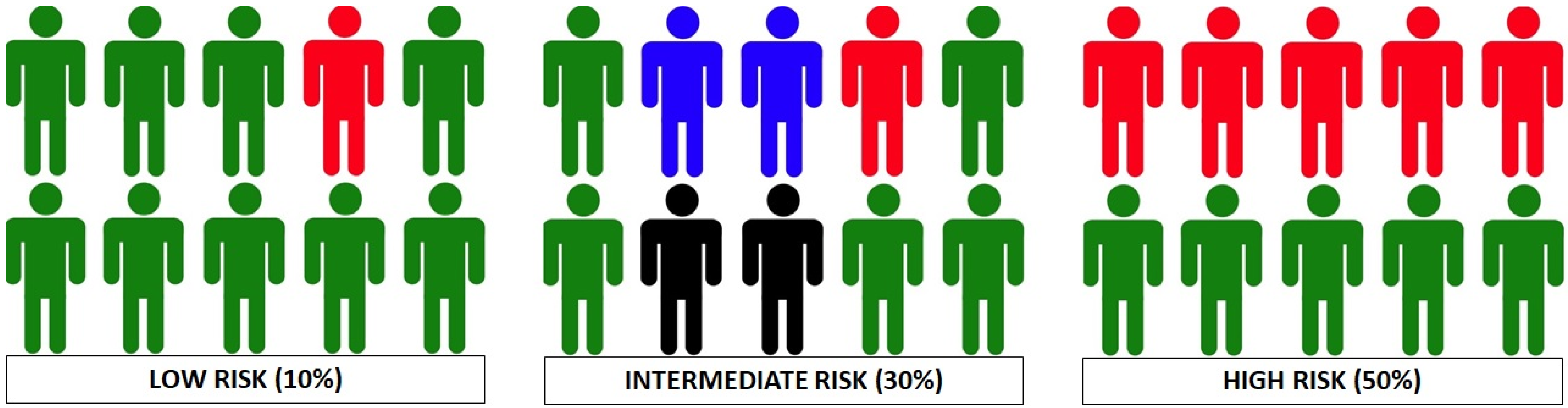

Figure 1

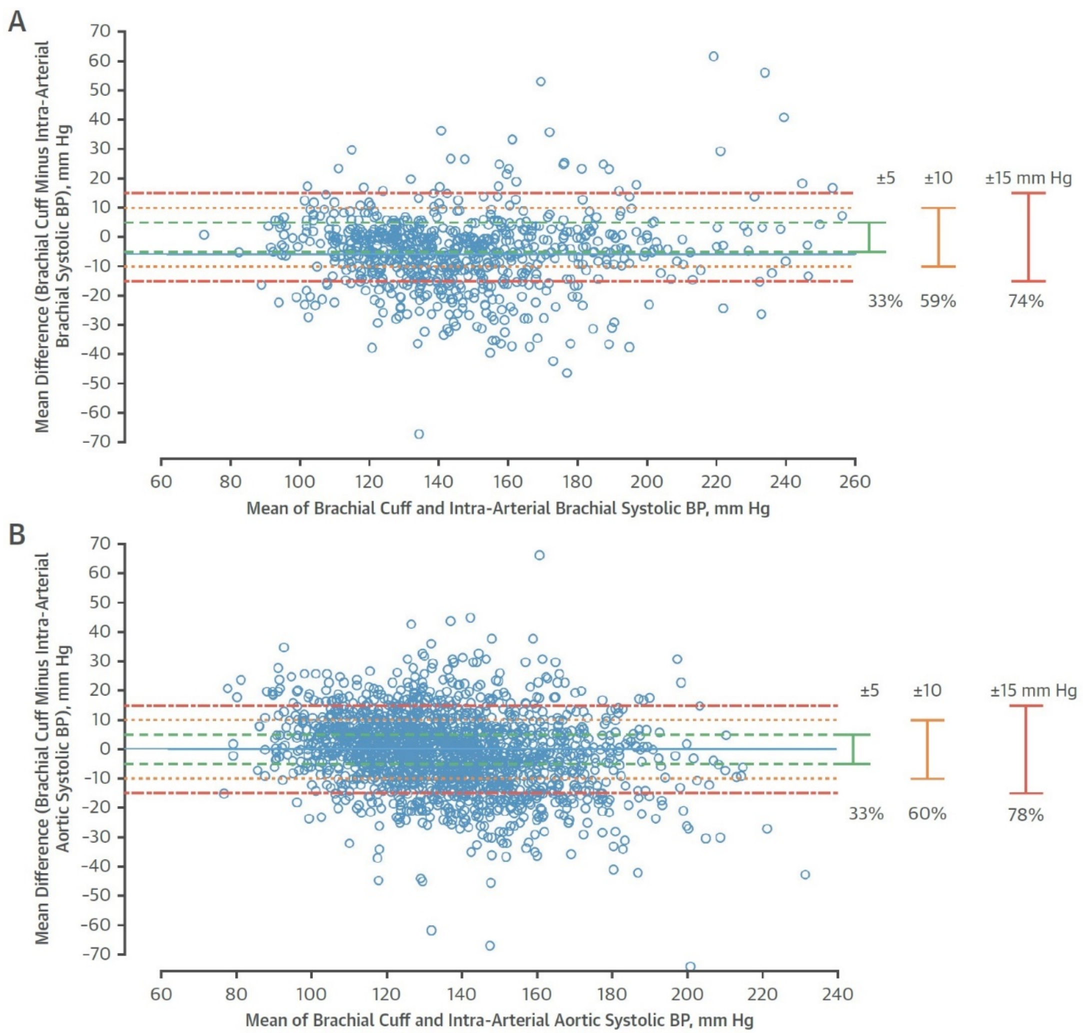
A
Mean Difference (Brachial Cuff Minus Intra-Arterial Brachial Systolic BP), mm Hg
Mean of Brachial Cuff and Intra-Arterial Brachial Systolic BP, mm Hg
±5
±10
±15 mm Hg
33%
59%
74%
B
Mean Difference (Brachial Cuff Minus Intra-Arterial Aortic Systolic BP), mm Hg
Mean of Brachial Cuff and Intra-Arterial Aortic Systolic BP, mm Hg
±5
±10
±15 mm Hg
33%
60%
78%

Figure 2