Cuff Under Pressure for Greater Accuracy

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Abstract

Purpose of Review

To present the evidence that describes what is being measured by upper-arm cuff blood pressure (BP) and the level of accuracy compared with invasive central aortic and brachial BP. Potential causes of inaccuracy and emerging methods are also discussed.

Recent Findings

On average cuff systolic BP systematically underestimates invasive brachial systolic BP, although in a given individual it may substantially under- or over-estimate central aortic systolic BP. Such errors may affect individual health management outcomes and distort population level data on hypertension prevalence and control. Oscillometric cuff BP is particularly susceptible to inaccuracy in people with high arterial stiffness and with pathophysiological BP waveform shapes. Emerging cuffless BP methods will be susceptible to inaccuracy if oscillometric cuff BP is used for calibration.

Summary

The original purpose of cuff BP was to estimate central aortic BP. Recent evidence has shown substantial inaccuracy of oscillometric cuff BP exists for the measurement of invasive central aortic and brachial BP. Thus, development of more accurate BP methods, through better understanding of oscillometric and BP waveform morphology, is needed to improve health outcomes related to high BP.

Keywords: Hypertension, BP, Blood pressure cuff, Brachial blood pressure, Aortic blood pressure, BP management.

Introduction

Raised blood pressure (BP) is the leading cause of disability adjusted life years globally [1]. It is the number one risk factor for cardiovascular disease, which itself is responsible for one in three global deaths [2]. Lowering of BP through lifestyle changes (e.g., exercise and/or diet interventions) or antihypertensive treatment leads to lower risk of adverse events related to BP [3]. Management of BP in clinical practice is guided by measurements taken from upper-arm cuff oscillometric BP devices. However, there remain two major issues regarding the function of oscillometric BP devices: (1) confusion as to what is being measured—do the devices seek to measure central (aortic) BP, that which vital organs are exposed to, or peripheral (brachial) BP, the site of the cuff placement, and (2) significant concerns regarding accuracy. These two highly inter-related issues are important and will be the focus of this review. Potential causes of cuff BP inaccuracy and emerging measurement methods will also be discussed.

Cuff Blood Pressure Measurement Methods

Measurement of BP using an upper-arm cuff was first described by Scipione Riva-Rocci in 1896 [4]. Following the discovery of the Korotkoff sounds in 1905 [5], mercury auscultation was used widely in clinical practice, and to this day, it is the non-invasive reference standard in validation studies testing the accuracy of new BP devices [6]. However, mercury auscultation has been phased out of clinical practice due to environmental concerns. In the 1970s, automated oscillometric BP devices were developed [7] and have since proven extremely popular. Oscillometric devices are now recommended for use in clinic, and for ambulatory and home BP monitoring [8,9,10].

Oscillometric algorithms that estimate systolic and diastolic BP are designed to emulate the values derived from mercury auscultation. The oscillometric method works by recording oscillations in cuff pressure usually during the deflation phase, although some devices make recordings during the inflation phase [11•]. The measured oscillations are used to generate an oscillometric envelope. Proprietary algorithms are then applied to detect mean arterial pressure, systolic BP and diastolic BP. Mean arterial pressure is conventionally assumed to be the peak amplitude of the oscillometric envelope, but because algorithms are proprietary, the precise method of estimation of systolic and diastolic BP is usually undisclosed [12, 13].

What BP Is the Cuff Meant to Measure?

In most people, systolic BP and pulse pressure are higher in the large, peripheral arteries than the central aorta [14,15,16,17,18]. This phenomenon, known as BP amplification, raises questions on whether cuff devices approximate the central aortic BP, as originally intended [4], or peripheral (brachial) BP. The cuff is applied at the upper-arm because this is the closest artery to the central organs where pressure can safely be measured using the sphygmomanometric cuff inflation approach [4]. It has been argued that the purpose of cuff BP devices is to measure central aortic BP because this is the pressure that the vital organs are exposed to and thus is most clinically relevant [4, 19, 20]. Upper-arm cuff systolic BP may be a reasonable proxy for central aortic systolic BP on average [21,22,23,24], which is probably the reason it provides good prognostic information on future cardiovascular events at a population level [3]. Nevertheless, cuff BP is inaccurate in many individuals [25...], and the extent of inaccuracy may be modified by other factors such as age, sex or co-existing disease [26, 27]. Improving our understanding of what cuff BP devices measure is critical because there are potential differences in central aortic BP versus brachial BP for associations with clinical outcomes [28], as well as efficacy of antihypertensive treatment [29, 30], and this has led to the development of cuff BP devices that purport to measure central BP as distinct from brachial BP [31, 32].

Why Does Inaccurate Cuff BP Matter?

Inaccurate cuff BP measurement can have adverse implications for individuals and distort population level data on hypertension prevalence. Inaccuracy may manifest as either under- or over-estimates of true BP, and each type of error has different potentially serious clinical implications. At the individual patient level, if true BP is underestimated, the chance may be missed to initiate or up-titrate anti-hypertensive therapy or embed lifestyle changes to reduce BP and lower cardiovascular risk. Alternatively, if true BP is overestimated, there is risk of overtreatment or unnecessary up-titration of anti-hypertensives, which come with cost to the patient and health systems, as well as potential side effects that would otherwise be avoidable. These errors may have the most impact on individuals at intermediate risk

who have BP on the borderline of hypertension [33] because an inaccurate BP measurement of just a few millimetre Hg could lead to miscategorization of BP and inappropriate clinical decisions [34].

Some individuals may be at greater risk of inaccurate cuff BP, in particular those with a greater level of vascular disease, such as patients with chronic kidney disease. A recent study of 83 patients with chronic kidney disease examined this issue in the setting of coronary angiography [27•]. In the study, cuff systolic BP underestimated central aortic systolic BP to a greater extent with each advancing level of chronic kidney disease (stage 3 (+ 1.8 ± 9.9 mmHg), stage 4 (- 2.1 ± 14.8 mmHg) and stage 5 (- 6.5 ± 9.8 mmHg)). Moreover, in the total study population, which also included 41 controls, greater central artery stiffness, which was estimated by carotid-femoral pulse wave velocity, was associated with greater cuff systolic BP underestimation of central aortic systolic BP.

Because greater arterial stiffness is also more prevalent with increasing age [35], a recent retrospective, multicentre study examined whether there was an influence of age on the accuracy of cuff BP by comparison to invasively measured central aortic BP [26]. In 1674 individuals aged 40 to 89 years of age, cuff systolic BP significantly overestimated central aortic systolic BP among people aged in their forties, but in people aged in their seventies and eighties, cuff systolic BP significantly underestimated central aortic systolic BP. Further, cuff diastolic BP overestimated invasive diastolic BP in all age ranges, albeit to a significantly greater extent in older age, and thus, overall there was a profound influence on the accuracy of cuff pulse pressure, which underestimated central aortic pulse pressure at all ages.

At the population level, inaccurate BP measurement could distort data on hypertension prevalence and control rates. A recent study assessed the theoretical change in perceived prevalence and control of hypertension (defined as \geq 140/90 mmHg) caused by inaccurate BP among 1540 adults from rural China [36]. Small underestimation of BP, by just – 4/– 2 mmHg, reduced the population prevalence of hypertension by 16%, whilst hypertension control dramatically increased (by 36%). Similarly, an overestimation of BP by + 4/+ 2 mmHg markedly increased population prevalence of hypertension by 24% and reduced hypertension control by 30%. These data emphasize that inaccurate cuff BP can theoretically distort statistics on hypertension prevalence and control which are critical for appropriate population health planning. In epidemiological studies, foundational knowledge on how systolic BP and pulse pressure increase and diastolic BP decreases from approximately the 5th decade of life are likely underestimates of the true trends across different age ranges [26].

How Accurate Is Cuff BP for Measuring Intra-arterial BP?

Our recent individual subject level meta-analysis examined the accuracy of cuff BP for measurement of invasive central aortic BP [25]. The analysis was conducted from data among 39 studies and 1823 subjects (mean age 60 years, 62% male). On average, cuff systolic BP was not significantly different to central aortic systolic BP. However, there was considerable under- and over-estimation at the individual level, with an overall mean absolute error of 8 mmHg. Cuff diastolic BP significantly overestimated central aortic diastolic BP (+ 5.5 mmHg), which therefore caused significant underestimation of central aortic pulse pressure (-4.8 mmHg). Using the JNC7 hypertension guideline categories [37], concordance of cuff BP and central aortic BP was also assessed. In pre-hypertension (120-139/80-89 mmHg) and stage 1 hypertension ranges (140–159/90–99 mmHg) concordance was only 50– 57%. This is concerning, because most of the world's population apparently have BP in this range, [38] albeit acknowledging potential accuracy limitations in this population level data itself. The level of agreement was concerning for cuff versus central aortic systolic BP measurements at thresholds ± 5 mmHg (33% agreement), \pm 10 mmHg (60% agreement) and \pm 15 mmHg (78% agreement).

In addition to central aortic BP, the accuracy of cuff BP compared with invasive brachial BP was also examined in the meta-analysis. There is a general expectation that brachial cuff BP represents measures of invasive brachial BP, which appears logical because it is the site of cuff inflation. This assumption may be questionable because inflation of the cuff occludes blood flow, thus altering local brachial haemodynamics. Indeed, contrary to belief, invasive brachial systolic BP and diastolic BP were systematically under- and over-estimated, by an average of -5.7 mmHg and +5.5 mmHg respectively. Overall, on average, this meant that cuff pulse pressure substantially underestimated the true (intra-arterial) brachial pulse pressure (-12.0 mmHg). Altogether, the results from this meta-analysis show that cuff systolic

BP (1) is inaccurate in around 50% of people with systolic BP in the range of prehypertension and stage 1 hypertension (120–160 mmHg), (2) substantially underand over-estimates central aortic systolic BP (random error) and (3) systematically underestimates invasive brachial systolic BP. These data demonstrate the need to understand causes of cuff BP inaccuracy and find appropriate solutions.

Potential Causes of Cuff BP Inaccuracy

As discussed earlier, there is an influence of age on the accuracy of cuff BP. There is a progressive change in the accuracy of cuff systolic BP, from substantial overestimation of invasive aortic systolic BP in children and adolescents [39], through to greater underestimation with increasing age in older adults [26]. On the other hand, cuff diastolic BP is relatively accurate in children and adolescents, but progressively overestimates invasive diastolic BP with increasing age in adults. These errors in the accuracy of systolic BP and diastolic BP lead to marked inaccuracy of cuff pulse pressure for measurement of invasive aortic pulse pressure in both children and adolescents (cuff overestimates) and older adults (cuff underestimates). It is unclear whether these errors are attributable to pathophysiology (e.g., heightened arterial stiffness/disease in older age), some other heretofore undefined issue (e.g., changes in soft tissue characteristics of the upper arm), inadequacies of the oscillometric measurement method, or combinations of the above.

Pathophysiological changes to arterial structure and function, such as arterial stiffening and flow abnormalities [40, 41], are associated with changes to the morphology of arterial BP waveforms and thus could influence the shape of the oscillometric waveform recording [42]. The peak amplitude of the envelope of the oscillometric waveform is regarded as mean arterial pressure. But, envelopes of oscillometric waveforms are often complex and without a clear peak amplitude, unlike classic textbook figures [39, 42]. Oscillometric waveforms that have broader, ill-defined peaks and less smooth features have been shown to produce less accurate estimates of systolic and diastolic BP than waveforms with a clear peak amplitude and smoother curve [39]. In another, albeit small study of 10 people with normal BP (average age 46 years) compared with 10 people with hypertension (average age 57 years), broader oscillometric waveforms were more common in

people with hypertension [42]. Because hypertension is commonly seen in older people and those with greater arterial stiffness, these data provide a potential explanation for the inaccuracy of oscillometric cuff systolic and diastolic BP that has been reported with increasing age [26], and arterial stiffness. [27, 43]

Recent work has also demonstrated how individual differences in invasive arterial waveform characteristics are related to cuff BP accuracy [14]. In 126 patients undergoing coronary angiography, four distinct BP phenotypes were discovered based on variation in aortic-to-brachial and brachial-to-radial systolic BP amplification (Fig. 1). Invasive aortic systolic BP was significantly higher in two of the phenotypes, indicative of elevated cardiovascular risk, but the oscillometric cuff systolic BP measurements did not detect this difference.

Across the systolic BP amplification phenotypes there were also significant differences in arterial waveform morphology, despite no differences in cuff BP. This finding further illustrates that differences in waveform morphology could influence the accuracy of cuff BP. Other recent work has also identified systolic BP amplification as a possible reason for inaccuracy of devices that estimate central aortic BP via pulse wave analysis [17]. Moreover, common 'form factor' equations used to derive mean arterial pressure (e.g., diastolic BP + (systolic – diastolic BP) * 0.33 or diastolic BP + (systolic – diastolic BP) * 0.4) are also susceptible to inaccuracy for the measurement of invasive aortic mean arterial pressure due to systolic BP amplification [44]. This finding is probably due to the dependence of the form factor equations on systolic BP and changes in waveform shape across different levels of BP amplification. Altogether, whilst there has been progress on understanding the potential causes of cuff BP inaccuracy, further mechanistic studies to determine the influence of specific arterial waveform features will be crucial for the development of more accurate BP devices (Table 1).

1. Why are cuff BP measurements inaccurate?	2. How can cuff BP be improved?	3. Testing required for new cuff BP methods.
Requires research on: - Associations with oscillometric waveforms - Associations with invasive/non-invasively recorded BP waveforms - BP amplification - Inclusion of select populations to understand causes of error Elderly Individuals with chronic kidney disease Individuals with high arterial stiffness Children Pregnant women	6	 Validation according to ISO 81060-2:2018 Validation according to the ARTERY statement [45] for pulse wave analysis devices Clinical testing by determining if the new cuff method predicts clinical outcomes above and beyond standard cuff BP

BP blood pressure, ISO International Organization for Standardization, ARTERY Association for Research into Arterial Structure and Physiology

Development of More Accurate BP Devices

The fundamental method of oscillometric cuff BP measurement has changed little since these devices first became commercially available in the 1970s. Some recent efforts to improve the accuracy of oscillometric cuff BP have focused on deeper analysis of arterial waveforms [46, 47]. In one study, [47•] a patient-specific physiological model (which used variables representing brachial artery mechanics) was fitted to the oscillometric waveform with the purpose of improving measurement accuracy across a wide spectrum of BPs. This was a worthwhile objective because oscillometric devices are more inaccurate in people with high pulse pressure and high arterial stiffness [27, 43, 48, 49]. The patient-specific model was trained in 57 subjects and tested among 88 different subjects. In people with high pulse pressure, defined as \geq 50 mmHg, the BP estimated from the patient-specific model was more precise than standard oscillometric cuff devices, as determined by comparison to the reference of invasive brachial BP. In the normal pulse pressure group (< 50 mmHg), there was no difference between the patient-specific model and standard oscillometric devices. These findings support the hypothesis that individualized approaches to oscillometry may be useful to improve the accuracy of cuff BP across a wide range of BPs.

Another novel method performed pulse wave analysis on standard oscillometric pressure waves with the purpose of generating an accurate central aortic BP [46]. This is a unique approach because most brachial cuff-based devices that perform pulse wave analysis use an additional inflation to record the pressure waveform. In 191 subjects undergoing coronary angiography, the authors found excellent agreement between the estimated central BP and invasive aortic values for both

systolic BP (+0.7 \pm 6.0 mmHg) and diastolic BP (+3.0 \pm 5.2 mmHg). Overall, the results from this study place the device as one of the most accurate methods available for the estimation of central BP, albeit noting the importance of replicating the results in other studies. Repeated studies of devices that use mean arterial pressure/diastolic BP for waveform calibration is important because it is well-established that the accuracy of estimated central BP from this method of calibration is highly device specific. [24, 50, 51]

Beyond the standard oscillometric cuff approach, cuff-less BP technologies are rapidly emerging. There are many methods under development including conformal patches, eyewear, ear sensors and wrist-wearable style devices. 'Big tech' companies are also investing in this area, and recently, Samsung had a watch-based cuff-less BP measurement method approved by the South Korean Ministry of Food and Drug Safety [52]. A main limitation of most cuff-less methods, including the Samsung device, is that they require calibration to cuff BP. This means that the inaccuracies from cuff BP are translated to the cuff-less devices. Thus, work to develop cuff calibration-free, accurate cuff-less BP monitoring represents an important ongoing research challenge.

Cuff-less BP measurements from some devices have been compared with cuff BP which implies they are intended to be equivalent [53]. But, cuff-less devices that measure arterial/biometric signals at the wrist may be susceptible to inaccuracy due to brachial-to-radial systolic BP amplification [15, 54]. One recent study examined the issue of brachial-to-radial systolic BP amplification using invasive BP data from 180 individuals undergoing coronary angiography. There was substantial inter-individual variability of amplification, whereby 43% of individuals exhibited little brachial-to-radial systolic BP amplification (≤ 5 mmHg), 46% of individuals had > 5 mmHg amplification, out of which 14% had > 15 mmHg amplification. Because amplification is highly variable between individuals, it may be necessary to predict the level of amplification to allow correction algorithms to be developed. Nevertheless, the primary goal of cuff-less devices should be the accurate measurement of central aortic BP because the vital organs are exposed to this BP and thus it is most clinically relevant.

Another critical step in the development of new BP measurement methods is the validation protocol used to determine accuracy. Each new device must undergo rigorous, standardized validation testing using an internationally accepted protocol that is performed independent of manufacturers [55, 56]. Validation protocols stipulate inclusion of diverse participant characteristics so that different sexes are represented, with a range of BPs and arm sizes so that the findings are broadly generalizable. There are also specific validation protocols for certain populations where accuracy of BP measurement has been proven to be challenging (e.g., atrial fibrillation, pregnancy). The validation process is critical because most BP devices are non-validated and these are less likely to be accurate than those that have undergone rigorous validation testing [57,58,59]. This is also highly relevant to emerging cuff-less methods, and there are specific validation criteria currently under development for these devices. [60]

Key Areas for Future Research

In this review we have presented evidence that oscillometric cuff BP is inaccurate for the measurement of central aortic BP in many people and that BP waveform morphology and arterial stiffness are probably key causes of inaccuracy. Future research should be targeted toward better understanding of the precise mechanisms of inaccuracy. Novel insights may be gained by using modern modelling techniques such as the reservoir-excess pressure paradigm, which is a physiologically plausible approach to pressure waveform separation. Some of the variables derived from the reservoir-excess pressure model are also related to BP amplification [61], which we have shown is related to BP measurement inaccuracy [14, 17, 44]. These studies will need to include people of different ages, levels of vascular disease and a wide range of BPs to ensure generalizability.

Future work on cuff-less BP devices should focus on achieving accurate measurements of central aortic BP without the need for cuff BP calibration. Additional research on arterial physiology and waveform transmission from the aorta through the entire upper limb will also be beneficial to reaching that research objective. Moreover, there needs to be continued education and advocacy on the importance of rigorous validation of new BP devices, whether cuff-based or cuff-less technologies.

Conclusions

The purpose of cuff BP is to approximate central aortic BP, which is the BP that the vital organs are exposed to but which may be quite different from upper arm BP. Oscillometric cuff BP is a reasonable proxy for central aortic BP; however, substantial inaccuracy exists in many individuals and appears to be worse in older age and people with greater arterial stiffness. There is a need for continued research on the relationship between cuff inaccuracy and BP waveform morphology. To date, studies that have leveraged oscillometric cuff BP accuracy. Work in this area should continue with a goal of developing a highly accurate measurement of central aortic BP. This is crucial because inaccurate cuff BP adversely impacts individual health outcomes and population level information on hypertension prevalence and control.

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Conflict of Interest

Dr. Sharman reports his university has received equipment and research funding from manufacturers of blood pressure devices including AtCor Medical, IEM and Pulsecor (Uscom). He has no personal, financial or commercial interests related to blood pressure device companies. The other authors declare no conflicts of interest relevant to this manuscript.

Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

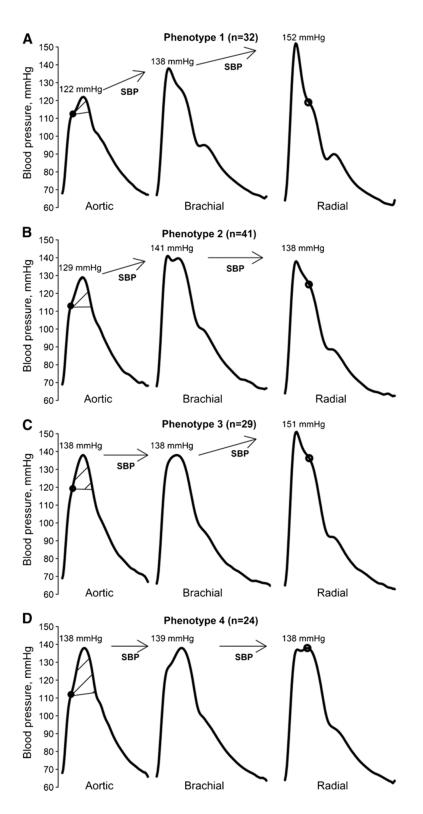


Fig. 1 Systolic BP amplification phenotypes discovered from variability between the aorta-to-brachial-to-radial arteries [14]. Crucially, cuff BP was not different between the four phenotypes despite significant differences in aortic BP. Republished according to the AHA Copyright Transfer Agreement