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EDITORIAL

Cuff-less measurements of blood pressure: are we ready for a change?

The first non-invasive measurements of arterial blood pressure (BP) became possible in the middle of the nineteenth century when Vierodt had the idea to quantify arterial BP by measuring the pressure required to obliterate an artery [1,2]. Later, the same approach was used by Riva-Rocci and by von Recklingshausen who further improved the method by adding an inflatable arm cuff to compress the artery. In 1905, Korotkoff reported that oscillations induced by the cuff deflation make a sound that could be heard with a stethoscope to determine systolic and diastolic BP. These fundamental findings defined the clinical assessment of BP as physicians are measuring today, using either the auscultatory or the oscillometric method. Since then, devices have been ameliorated substantially enabling to measure BP reliably out of the office, using either wearable devices for ambulatory BP monitoring or easy to use home BP monitoring devices [3].

Today, physicians diagnose hypertension and manage their patients essentially based on BP values obtained in their office with almost the same technique than that used during the last 100 years. This is because all fundamental clinical trials and surveys, which assessed the impact of an elevated BP on clinical outcomes and mortality, have been conducted with conventional office BP. For the same reasons, hypertension guidelines still use office BP values obtained with a standard cuff device to classify hypertensive stages and define the thresholds and targets for antihypertensive treatment [4,5]. Interestingly, this happens despite the well-recognized limitations of office BP, which is known for its imprecision due to several individual and environmental factors (position, stress, ambient temperature …). These latter affect office BP measurements leading sometimes to an overestimation of true BP, for example when the white-coat effect is pronounced, or to an underestimation of BP in the case of masked hypertension. In addition, office BP does not provide any information on night-time BP and largely ignores BP variability, two important parameters associated with the cardiovascular risk.

With the development of 24 h ambulatory BP monitoring, which includes night-time values, and home BP monitoring, it became evident that BP readings obtained in the office have a lower predictive value for cardiovascular events than BP values obtained out of the office, the best predictive BP values being those recorded during the night [6]. Therefore, recent guidelines recommend a wider use of 24 h ambulatory as well as home BP monitoring [4]. In addition, out-of-office BP measurements are more accurate to diagnose white coat and masked hypertension and to confirm resistant hypertension [3].

Office, ambulatory and home BP devices share a common feature: all of them need to position a cuff around the arm (or eventually the wrist) to measure BP. In the vast majority of cases, this does not really create any problem. Yet, in some patients and circumstances, the inflation/deflation process may be annoying and induce falsely elevated BP values. This is the case, for example, in hypertensive patients with obesity when BP is very high. In these patients, arm cuff inflation may be painful and it may be more comfortable for them to measure BP at the wrist. Another common situation is the 24 h measurement of BP. Cuff inflations may interfere with patients' activities during the day and interfere with the quality of sleep during the night. Thus, the ideal BP measuring device should be cuff-less, small, wearable and able to provide continuous BP data over days or even longer without interference. Of course, they should also be accurate and reliable when compared to conventional methods of measuring BP and validated according to most recent standards.

Several cuff-less devices have been developed to measure arterial BP non-invasively, the first one being tested in the early 1980s [7] such as the first prototypes of the Finapress system. More recently, the characteristics of several new devices have been published. Many of them extrapolate BP from photoplethysmography signals measured at the finger [7,8] or at the wrist [9] and/or a pulse wave analysis algorithm applied to photoplethysmography signals [10]. Among other methods, BP could be estimated indirectly from pulse transition time, pulse arrival time [11], pulse wave velocity or their combinations and extrapolation of the pressure values from the electrocardiogram signals [12].

Today, more than 500 wearable wristband devices are available on the online Australian market for home BP monitoring. However, before 2020, none of them had been correctly validated using a strict international reference protocol, or approved as medical devices by the US Food and Drug Administration [13]. Thus, one could consider them as gadgets rather than true accurate and reliable home BP measuring devices. Meanwhile, however, several new devices were developed in a more professional way with the intention to provide physicians with valuable new tools that they can use and share with their patients. Hence, adequate validation studies have beed performed with these devices according to actual

recommendations, although established validation standards are not yet available to specifically assess the accuracy of cuffless devices. These devices were compared to intra-arterial BP, conventional auscultatory or oscillometric office BP and sometimes to 24 h ambulatory BP monitoring [8–10,12–18]. Results of these studies generally demonstrated a good agreement between BP readings obtained with the cuff-less devices and those measured with conventional techniques, suggesting that some of these devices could actually replace traditional methods of BP estimation. Yet, one of the limitation is the need to calibrate periodically the new device using the cuff-based method. However, even those cuff-less devices in advanced clinical development will need additional studies, for example to investigate the quality of the signal in larger groups of patients with or without specific medical conditions such as low BP, arrhythmias, peripheral arterial disease, connective tissue or skin diseases in the case of optic-based finger measurements.

Interestingly, the clinical objectives leading to the development of new cuff-less devices sometimes differ substantially. Thus, smartphone-based devices, such as the OptiBP mobile application [17], which provide intermittent BP measurements, have been developed with the initial intention to increase the awareness and diagnosis of hypertension and consequently improve the management of hypertensive patients, particularly in low-income countries, where BP devices are scarce, but smartphones are widely available. Of course, the same application can be used in the follow-up of treated hypertensive patients for example to support adherence in the context of mobile-health technologies. In contrast, the Aktiia bracelet medical device intended to monitor BP intermittently for 24 h or for several consecutive days or weeks, thus combining the advantages of ambulatory and home BP monitoring but without sleep interference [16]. In that case, the device may compete directly with ambulatory BP monitors. However, once again, the device could also be used to measure only night-time BP or to monitor the effect of changes in drug treatments as illustrated in a recent case-report showing a 4-month monitoring of BP during changes in antihypertensive medications [19].

There is definitely a growing interest for the development of cuff-less BP measuring devices and new technologies are promising. Some of the devices are already available on the market and can be bought by patients as well as by physicians. Today's main issue is the acceptability and the implementation of these new technologies in physicians' offices. Are physicians ready to change their everyday medical practice to include the analysis and discussion of data recorded by patients with their devices and available on their smartphone? The basic concept is that patients acquire these devices themselves and use them in collaboration with their physicians and/or healthcare providers in a shared-decision process. This is now a process highly recommended by recent guidelines [4]. The question is how to integrate this new information in the patients' management? Where should data be recorded and stored? How can physicians deal with data coming from hundreds of patients simultaneously? This is actually a general problem of digital health and mobile health developments. Nevertheless, despite the existing barriers, the development of cuff-less systems to measure BP should be considered as a real opportunity to improve our ability to diagnose and follow our hypertensive patients in the future. Time will tell us how successful these developments will be, but let give them a chance!

Disclosure statement

The authors are the editors of Blood Pressure. M.B. has participated in the clinical validation of some of the devices presented in the text, without financial engagement. The others report no conflicts of interest.

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