Self blood pressure monitoring at home by wrist devices: a reliable approach?

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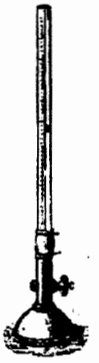
In this issue of the Journal, Kikuya *et al.* [1] describe the results obtained by assessing the accuracy of two wrist and two arm cuff devices for self-blood pressure measurement (self-BPM). Factors affecting the accuracy of wrist devices are also addressed. Their final conclusion is that wrist devices are less reliable than arm devices and therefore their use should be discouraged, a conclusion that is of major clinical relevance given the wide adoption of wrist self-BPM devices in clinical practice. In spite of some methodological problems that deserve to be critically discussed, this paper is of particular interest because it focuses attention on a few specific aspects often disregarded in the validation of wrist blood pressure measuring devices. Before addressing this issue in detail, however, some more general considerations on wrist blood pressure measurement might be useful to set the scene.

Historical aspects

As documented in the history of medicine, the first attempts to assess blood pressure in humans focused on the wrist. During the XVIII century in Europe, and even much earlier in China, feeling the pulse at the wrist level was the only available non-invasive approach to assess the characteristics of arterial circulation and, indirectly, to assess blood pressure in a clinical setting. Indeed, according to antique Chinese medicine, a clever physician should have been able to identify at least 40 different patterns of radial arterial pulse, reflecting different clinical conditions [2]. Over the XIX century, in the pre-Riva Rocci era, thanks to progress in technology, a number of non-invasive devices aimed at more or less quantitatively assessing the radial pulse and thus, indirectly, at measuring blood pressure in humans, were developed. The first of these devices proposed for indirect blood pressure measurement was probably the 'sphygmometer' as manufactured by Hérisson in France (Fig. 1) [3]. This device consisted of a mercury reservoir covered at the bottom by a rubber membrane, and connected on the top with a graduated glass column. The mercury reservoir, through the rubber membrane, was compressed against the radial artery until the oscillations in the mercury column stopped. At this point, the level of mercury in the column indicated systolic blood pressure. A few years previously, Karl Vierordt had invented the first of a series of devices capable of recording the radial pulse on paper. This was carried out via a weight resting on the radial artery, the pulsations of which were transmitted through a series of levers to a pen engraving a sheet of paper, either rotating on a cylinder or sliding through a clock-operated machinery [4]. These devices were known as 'sphygmographs', and two of them, namely the sphygmograph developed by Marey around

Fig. 1



The 'Sphygmometer' by Hérisson (1834). Reproduced with permission [2].

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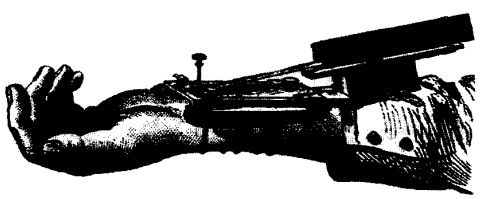
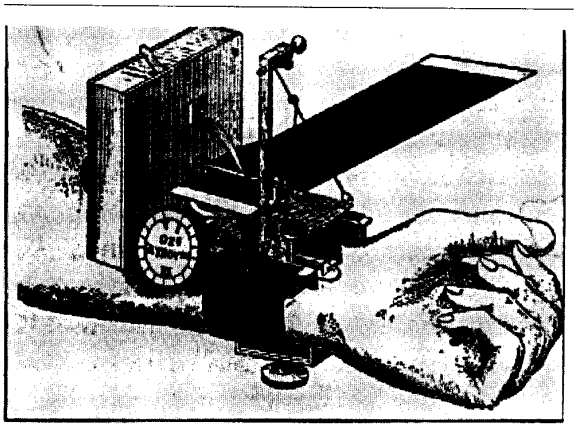
1881 (Fig. 2) and that described by Dudgeon around 1890 (Fig. 3), gained some popularity as they introduced considerable technical improvements compared to the recorder originally described by Vierordt [5,6]. In particular, they were smaller in size, lighter and easier to use and might indeed be considered as the first wrist blood pressure monitoring devices with potential applications in human physiology and pathophysiology. The first quantitative assessment of radial blood pressure that had a clinical application was made possible a few years later, thanks to the description of devices based on the arterial occlusion technique, the most famous ones being the 'sphygmometers' and 'sphygmomanometers' introduced by von Bash [7] and by Potain [8] (Fig. 4). By compressing the radial artery with a water-filled rubber ball, connected through a rubber tube with an aneroid manometer, Potain measured systolic blood pressure as the water pressure necessary to obtain disappearance of the radial pulse manually felt on the wrist distally to the rubber ball position. In spite of its very simple application, however, this approach was abandoned only a few years later, mainly because of the high variability in the blood pressure values obtained, as a function of the more or less precise positioning of the rubber ball above the radial artery and of the variable degree of manual compression exerted on the water ball that was needed to occlude the artery. Notwithstanding their failure to enter regular clinical practice, the introduction of these 'sphygmomanometers' importantly contributed toward the application of the occlusion technique to upper arm blood pressure measurement made in 1896 by Scipione Riva Rocci through the type of mercury sphygmomanometer we are still using in our clinics today [9].

Fig. 2



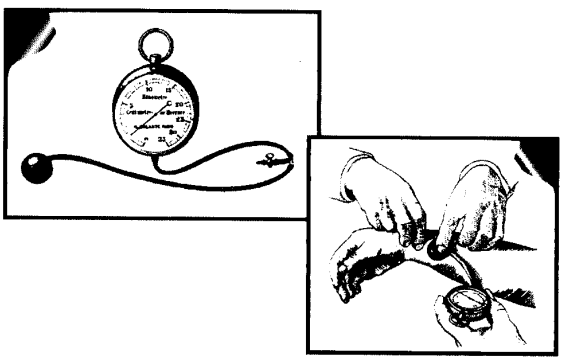
The 'Sphygmograph' by Marey (1860). Reproduced with permission [2].

Fig. 3



The 'Sphygmograph' by Dudgeon (c. 1893). Reproduced with permission [2].

Fig. 4



The 'Sphygmometer' or 'Sphygmomanometer' by Potain (1889). Reproduced with permission [2].

Over the last few decades, technological progress has led physicians to reconsider the possibility of measuring blood pressure at the wrist level, thanks to the introduction of electronic and more or less complex computer-operated devices. One example comprises a sophisticated and expensive device for continuous non-invasive blood pressure monitoring (Colin BP-508 monitor; Colin Co, Komaki City, Japan) [10], which is aimed at providing beat by beat quantitative assessment of the radial pulse through an applanation tonometer periodically calibrated by upper arm automated oscillometric blood pressure measurements. This system is now frequently used in cardiovascular physiology laboratories, but it is obviously not suitable in daily clinical routines because of its high cost. In clinical practice, the use of smaller and cheaper devices, sometimes only slightly bigger than a sports watch, has been proposed in recent years by manufacturers for home self-BPM, based on oscillometric automated wrist blood pressure readings. The dream of having a watch-like device that might improve the art of 'feeling the pulse' (Fig. 5) and might thus measure blood pressure at the wrist site in a simple and inexpensive fashion thus seemed to have become a reality.

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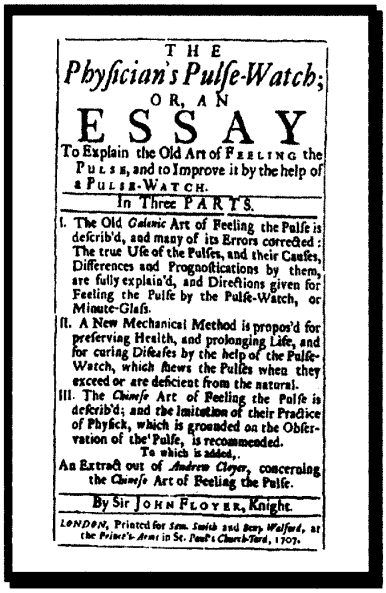
Fig. 5



THE
Physician's Pulse-Watch;
OR, AN
ESSAY
To Explain the Old Art of FEELING the PULSE, and to Improve it by the help of a PULSE-WATCH.
In Three PARTS.

I. The Old *Galenic* Art of Feeling the Pulse is describ'd, and many of its Errors corrected: The true Use of the Pulses, and their Causes, Differences and Prognostications by them, are fully explain'd, and Directions given for Feeling the Pulse by the Pulse-Watch, or Minute-Glass.

II. A New Mechanical Method is propos'd for preserving Health, and prolonging Life, and for curing Diseases by the help of the Pulse-Watch, which shews the Pulses when they exceed or are deficient from the natural.

III. The *Chinese* Art of Feeling the Pulse is describ'd; and the Imitation of their Practice of Physick, which is grounded on the Observation of the Pulse, is recommended.

To which is added,
An Extract out of *Andrew Cleyer*, concerning the *Chinese* Art of Feeling the Pulse.

By Sir JOHN FLOYER, Knight.

LONDON, Printed for *Sam. Smith* and *Benj. Walford*, at the *Prince's Arms* in St. *Paul's Church-Yard*, 1707.

The introduction of the 'Pulse Watch' by Sir John Floyer (1707).

Clinical aspects

Self-BPM at home is now regarded as a useful procedure to complement office blood pressure readings in the management of hypertensive patients, and also offers advantages in clinical trials on antihypertensive therapy. In fact, self-BPM values are more reproducible, are not affected by the 'white-coat effect' and therefore are more likely to be representative of the average daily pressure than clinic blood pressure values [11]. Self-BPM has also been shown (although only by a few studies until now) to be more closely related to hypertension target organ damage and cardiovascular morbidity and mortality than clinic blood pressure [11,12]. Furthermore, self-BPM is of particular interest in assessing the effectiveness and the time distribution of the blood pressure effects of antihypertensive therapy, both in the routine follow-up of hypertensive patients and in drug studies [11,12]. This technique has also the advantage of stimulating patients to become more actively involved in the management of their own blood pressure problem, thus having the potential to improve patient compliance with the prescribed therapeutic regimen. and to provide a more cost-effective management of hypertensive subjects [11].

Manual blood pressure measurement at the upper arm level, using a mercury or, if frequently checked and calibrated, an aneroid sphygmomanometer, was in the past generally regarded as the standard method for home blood pressure monitoring. However, thanks to their easier and more practical application, electronic devices based on the oscillometric blood pressure measurement technique applied at the upper arm, wrist or finger site have now become very popular. Their diffusion has indeed shown a constant increase over the last 10–15 years, as testified by their current high rate of sale, which in Germany has reached the remarkable figure of 1.2 million for all home blood pressure monitoring devices sold annually [12].

In spite of their increasing popularity, however, the first electronic blood pressure monitoring devices undergoing independent validation testing all failed to satisfy the criteria of established protocols [13], such as those proposed by the British Hypertension Society (BHS) [14] and by the American Association for the Advancement of Medical Instrumentation (AAMI) [15]. On the other hand, due to continuous progress in technology, some more recent electronic devices for self-BPM, based on automated arm cuff inflation, have been found to be acceptably accurate according to the above criteria [16–18]. In contrast, all finger devices proposed for home blood pressure monitoring have been proved inaccurate [18]. Besides possible technical failures, this seems to depend on a number of other factors, such as (i) the physiological differences between pulse waveforms at the digital and the brachial artery levels (responsible for a narrower and higher systolic peak in the digital artery because of wave reflection effects); (ii) the effects of vasomotor activity changes in the extremities; and (iii) the impact of changes in the hydrostatic height pressure difference between the instrumented hand and the heart, whenever the hand is not carefully held at the heart level at the time of each blood pressure measurement [19]. Because of all these problems, the clinical use of automated finger blood pressure measuring devices is definitely not recommended at present [11].

Over the very last few years, electronic devices which measure blood pressure from the wrist have become a very popular approach to self-BPM at home, with their sale comprising approximately 50% of all electronic devices for self-BPM sold annually in Germany [12]. In fact, wrist devices have gained as much as 30% of the market share for all automated blood pressure measuring devices worldwide [1]. Interestingly, more than 90% of patients performing self-BPM seem to prefer wrist rather than arm devices [20], the popularity of the former (in particular among elderly subjects) probably depending on their small size and light weight and by the fact that their use is found quite easy and convenient, as the cuff can be more easily wrapped around the wrist than around the arm, and because they allow blood pressure measurements to be obtained without

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undressing. Moreover, some patients also prefer wrist devices because they experience much less discomfort when a cuff is automatically inflated around the wrist rather than around the upper arm. These devices have the potential advantage of being more suitable than arm devices in obese subjects with extremely large or with cone-shape upper arms, although, to the best of our knowledge, the accuracy of wrist devices in obese patients has not been specifically tested according to international protocols.

As in the case of finger devices, one of the major disadvantages of wrist devices is that the wrist must be held at heart level during a blood pressure measurement, and it must be kept at that level at the time of each subsequent measurement. If this is not done, substantial systematic errors may occur due to the influence of the arm–heart hydrostatic pressure difference [19]. Another problem is the possible errors introduced by flexion or extension of the wrist during measurement, which may lead to different degrees of compression of radial and ulnar arteries by the inflated cuff (see below). Therefore, because of these drawbacks and due to the limited data provided from properly conducted validation studies (the majority of which have yielded negative results), most authorities still recommend that devices measuring blood pressure at the arm level should be preferred to wrist devices [11].

In spite of these discouraging recommendations, which are in agreement with the latest Guidelines for Hypertension management issued by the World Health Organization/International Society of Hypertension and by the American Joint National Committee [21,22], whether wrist self-BPM devices should or should not be used is still a matter of debate in the scientific community, and even more so in clinical practice, due to the complex intertwining of the advantages and disadvantages that characterize their use. The need for further investigation in this field was also recently emphasized during the Eighth Consensus Conference on Blood Pressure Monitoring held in Sendai (Japan) in October 2001. The conclusion reached by an ad-hoc Task Force, including members of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension, was that there is urgent need to reassess the possibility of using self-BPM devices on the background not only of their inherent limitations (see above), but also of their potential usefulness in specific populations, as well as regarding recent progress in technology (Proceedings of the Sendai Conference on Blood Pressure Monitoring, *Blood Press Monit* 2002; in press).

These conclusions, and in particular the need for caution in proposing wrist blood pressure devices in routine clinical practice, appear to be even more appropriate after critically considering the results of the study by Kikuya *et al.* [1].

Interest and limitations of the paper by Kikuya *et al.*

In their paper, Kikuya *et al.* [1] compare the values obtained by two wrist and two arm devices for self-BPM with those obtained through auscultatory readings. Although this study has the merit of including a fairly large number of subjects, an important criticism of these data is that none of the established validation protocols (BHS or AAMI) has been used. Therefore, it is difficult to precisely evaluate the accuracy of the tested devices based on the available standards, and to compare the present findings with previous reports. The validation procedure used in the study by Kikuya *et al.* showed that blood pressure values provided by wrist devices differ from auscultation by more than 10 mmHg in systolic and/or more than 5 mmHg in diastolic blood pressure in approximately 30 and 50% of the measurements, respectively. Although all the requirements of the AAMI validation protocol were not fulfilled in the present study, if we were to apply the AAMI validation criterion as a post-hoc procedure (according to which the average difference between tested and reference method should be $\leq$5 mmHg with a SD $\leq$ 8 mmHg) to the total of the data provided by each device [15], both wrist devices and one of the arm devices would be rejected as inaccurate. The large variation in the results observed for the same device when comparing data obtained by different clinical centres participating in the study is also of some concern, as there are differences in systolic/diastolic blood pressure measurement accuracy of 11.5/12.6 mmHg between Centres 6 and 12 for wrist device 1, and of 11.2/9.4 mmHg between Centres 6 and 7 for wrist device 2. These between-centre differences can hardly be explained simply on the basis of device inaccuracy. Patient characteristics do not seem to play a role either as there were no specific differences between centres in terms of the age of the participants or their blood pressure level. Thus, the between-centre differences in the reported findings should most likely be attributed to technical problems with observer performance in some centres. Training of observers to a very high standard is of critical importance in validation studies, as emphasized by the BHS protocol which has paid special attention to this methodological aspect [14]. Between-centre differences with respect to ensuring proper positioning of the wrist compared to heart level at the time of blood pressure measurement may also have contributed to these data [19]. Finally, because the between-centre differences in the reported results were larger for wrist than for arm devices, other problems specifically affecting the wrist measurement technique are likely to have contributed to the reported

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findings. Additional factors resulting from the use of a non-established validation procedure may have further affected the results. First, subjects with a rather narrow range of pressures (fewer than 10% of patients with diastolic blood pressure > 100 mmHg and systolic blood pressure > 180 mmHg) were included, which may have affected proper validation in favour of the devices because the accuracy of automated blood pressure measuring devices has been shown to deteriorate with increasing levels of blood pressure [14]. Second, in the present study, the devices under investigation were not subjected to field use before validation, while the BHS protocol takes this aspect into consideration because the reliability of automated devices may also depend on whether they have or have not been exposed to an in-use assessment phase prior to the validation phase [14]. Third, in this study, device validation was carried out by comparing automated and auscultatory measurements using a cross-over method. Using this method for measurement comparison, instead of sequential same arm measurements as proposed in the BHS protocol, might also have introduced some bias in the validation procedure [14].

Notwithstanding these problems two important observations made by Kikuya *et al.* should be emphasized, as they contribute to making their study quite different compared to most of the available validation studies on wrist monitors, and suggest new perspectives in the assessment of the accuracy of wrist blood pressure measuring devices [1]. First, these authors clearly showed that changing the wrist angle between hand and forearm (i.e. shifting from palmar-flexion to dorsal-flexion (extension) of the hand and vice-versa) is accompanied by significant changes in measured systolic and diastolic wrist blood pressure. Second, also as a function of the hand–forearm angle of flexion, inflation of the wrist cuff above systolic blood pressure levels in some cases failed to completely occlude the radial and/or the ulnar artery, as shown by the persisting presence in this condition of a finger pulse, assessed through finger plethysmography. This phenomenon was particularly common during flexion of the wrist, occurring in six out of 29 subjects included in the study. It should be noted that measurements performed in these conditions were not considered as erroneous by the devices, and always gave higher systolic blood pressure values compared to the simultaneous auscultatory readings [1]. These novel observations are methodologically important, because a complete artery occlusion is an essential prerequisite for accurate measurement of blood pressure according to the classical 'arterial occlusion technique' introduced by von Bash, Potain and Riva Rocci, even when performed by the oscillometric approach. Moreover, the dependence of wrist blood pressure measurements on the wrist–forearm angle as well as on the wrist-heart hydrostatic height difference also emphasizes the need for very careful training of patients before the proper use of wrist blood pressure monitors might be guaranteed. Although these conclusions may not be necessarily valid for all wrist devices, the findings by Kikuya *et al.* should focus greater attention on these issues, which were largely neglected in previous validation papers.

Validation of wrist blood pressure measuring devices has indeed been performed by a number of other studies in the last few years, either using established validation protocols [12,23–26] or by means of non-established validation procedures [27–30]. While, in some of these studies, an acceptable correspondence was reported between wrist blood pressure measurements and the reference blood pressure measuring technique, most of them came to the conclusion that wrist devices fail to meet the required validation criteria. Taken together, in addition to the results and the methodological problems raised in the study by Kikuya *et al.*, these conflicting data support the view that the available evidence is not enough to allow a final conclusion to be reached on the actual accuracy and suitability of wrist devices in hypertension management. Given the widespread use of wrist blood pressure monitors, which makes solving this issue considerably important from a clinical perspective, there is thus an urgent need for additional validation studies to be carefully carried out according to established protocols.

Conclusions

In spite of the time-honoured interest in wrist blood pressure measurement, the above observations strongly emphasize the need for great caution when dealing with wrist blood pressure measuring devices, and in agreement with recent Hypertension Management Guidelines, they support the view their general use in clinical practice should not at present be recommended.

In particular, this cautious approach is based on the following: (i) the evidence that blood pressure measuring devices based on arm-cuff inflation provide more reliable measurements in most cases, and that in virtually all the outcome studies that demonstrated the higher risk associated with elevated blood pressure and the benefits of antihypertensive treatment, arm-cuff and not wrist-cuff devices were used; (ii) the conflicting data provided by available validation studies on wrist blood pressure monitors, (iii) the methodological problems that have affected most of these studies, allowing them to fulfil the requirements of established validation protocol only in a minority of cases; and (iv) the additional technical difficulties associated with the wrist approach, related to wrist anatomy, which have emerged from the study by Kikuya *et al.* [1].

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In practice, this means that measurement of blood pressure at the upper arm level should still be regarded as the standard method in the diagnostic and therapeutic management of hypertensive patients, both in the doctor's office and at the patients' home.

However, given the potential advantages of the wrist approach in specific populations, such as the obese or the elderly patients in whom arm-cuff devices are sometimes not applicable, the possibility of recommending wrist blood pressure monitoring by modern devices, at least in selected clinical conditions, needs to be further addressed. This should be performed through properly conducted validation studies carried out by expert groups, taking into account the methodological issues raised by Kikuya *et al.* [1].

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