

Accuracy of a New Wrist Cuff Oscillometric Blood Pressure Device

Comparisons With Intraarterial and Mercury Manometer Measurements

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Accurate measurement of arterial blood pressure is of great importance for the diagnosis and treatment of hypertension. Because of the chronic nature of antihypertensive drug therapy, the involvement of the patient in blood pressure control is desirable. Such an involvement, however, is only feasible if simple, user-friendly, and precise blood pressure measurement devices are available.

In this study we tested a new wrist cuff oscillometric blood pressure measurement device in 100 consecutive patients undergoing cardiac catheterization. Blood pressures were simultaneously taken intraarterially (axillary artery) and with a mercury manometer and stethoscope or noninvasive measurement device (OMRON R3). Intraarterial measurements were directly compared with two measurements taken in random order with either an arm cuff mercury manometer or the wrist cuff device.

Systolic and diastolic blood pressure as assessed with the mercury manometer was higher, especially when compared with the intraarterial and the wrist cuff values, which were comparable. Correlations of blood pressure values with intraarterial measurement were 0.86 systolic and

0.75 diastolic ($P < .01$) for the wrist cuff and 0.84 systolic ($P < .01$) and 0.59 diastolic ($P < .05$) for the mercury manometer measurements.

Reproducibility of both measurements was good for the wrist cuff device ([systolic/diastolic]: $r = 0.94/0.92$; $P < .01$) and the mercury manometer ($r = 0.97/0.88$; $P < .01$). Both methods overestimated high diastolic values, whereas only the wrist cuff underestimated high systolic values.

Thus, the new oscillometric wrist cuff blood pressure measurement device measures arterial blood pressure with great accuracy and reproducibility. As compared with intraarterial values, the wrist cuff device overestimated high diastolic and underestimated high systolic blood pressure values. Blood pressure values as measured by the mercury manometer were higher than intraarterial values and those of the wrist cuff. Both noninvasive devices overestimated high diastolic values. *Am J Hypertens* 1998; 11:1469-1474 © 1998 American Journal of Hypertension, Ltd.

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The advantages of blood pressure self-measurement have been well documented.¹⁻³ Indeed, blood pressure self-measurement not only provides valuable information on blood pressure control for the treating physician, but also improves patient's compliance with antihypertensive therapy.^{4,5} Obviously, blood pressure self-measurement is only practicably useful if the devices are accurate, user-friendly, and relatively inexpensive.

As the practice of blood pressure self-measurement has become more accepted and widespread, the electronics industry has found this to be quite a lucrative market for noninvasive blood pressure measurement devices. Because of this, a plethora of devices are now available. Although some use the auscultatory method with the help of electronic filters, other models use oscillometry to assess blood pressure.⁶ The vast majority of these devices measure blood pressure at the upper arm, which requires placement of a cuff at an anatomical site that is not easy to reach, particularly for elderly and handicapped patients. More recent technical developments now allow the use of very small blood pressure devices that can be placed at the wrist. It remains to be shown, however, whether this increased user-friendliness provides the same accuracy of blood pressure measurement. This question is particularly important as such devices are increasingly being advertised by the industry directly to patients. In this study we compared a new automatic oscillometric blood pressure device against a mercury manometer and intraarterial blood pressure measurements in 100 patients during cardiac catheterization.

MATERIALS AND METHODS

Patient Selection One hundred patients undergoing a routine cardiac catheterization were selected for this study. The mean age was 63.5 ± 1 years, and the male:female ratio was 63:37. Patients were included only if the diagnostic part of the procedure necessitated visualization of their internal mammary artery, so no unnecessary catheter placements were performed. The patient's consent was obtained before the measurements were begun, and the project was approved by the hospital's ethics committee before commencement. The patient exclusion criteria were occlusive arterial disease of the innominate or subclavian artery and their branches; atrial flutter; fibrillation or other cardiac arrhythmias; and venous cannulation on both arms.

Arterial Blood Pressure Measurement Intraarterial blood pressure was measured using a water-filled diagnostic Judkins cardiac catheter (Cordis 'infinite' Judkins Right 4, 5F) placed either in the truncus brachiocephalicus or the subclavian/axillary artery. The

catheter was attached to an electronic transducer (Ohmeda TNF-R disposable transducer, Comet AG, Switzerland), which was, in turn, connected to a Hewlett Packard CathStation 900 (Hewlett Packard, Switzerland) with an 18-Hz filter. The system was zeroed before each measurement. A printout of the recorded blood pressure was taken at 5 mm/s and marked to indicate when the other measurement devices were being used. The mean systolic and diastolic values obtained during each noninvasive measurement were calculated from the printout and recorded to provide a basis for comparison with the other measurements.

Riva-Rocci Blood Pressure Measurement A mercury manometer (Erkometer 300, Erka AG, Bad Tolz, Germany) with an inflatable cuff (12-cm width, 22-cm length) was used. For each measurement, the cuff was inflated to a pressure level greater than the systolic blood pressure. Then pressure was slowly released with a speed of about 2 to 5 mm Hg/sec. Systolic blood pressure was obtained at the first occurrence of the Korotkoff sounds (Phase I) and diastolic blood pressure when the pulsatile sounds disappeared (Phase V).⁷ Two investigators (SW and CM) performed data collection including assessment of mercury manometer measurements; the correlation between the two investigators was excellent (see Results). Measurements within each patient were always performed by the same investigator. Start and end of each mercury manometer measurement was marked on the printout of the intraarterial blood pressure and mean intraarterial pressure during mercury manometer measurement calculation.

Oscillometric Wrist Blood Pressure Measurement Device The oscillometric wrist blood pressure measurement device is a novel piece of equipment developed by Omron Tateisi Electronics (Advance AG, Switzerland). Briefly, it is a microprocessor combined with an electric pump and electrostatic capacity-type pressure sensor (3S5Y). This is contained in a small (76 mm \times 78 mm \times 33 mm), durable plastic casing, which also holds the two 1.5-volt batteries. The unit weighs only 140 g including batteries. It is attached to a 78-mm \times 309-mm cuff that has Velcro fasteners. It has an LCD screen that displays the measured blood pressure and pulse rate. The unit measures pressures from 30 mm Hg to 250 mm Hg and has a deflation rate of between 2.9 and 5.6 mm Hg/s.

Measurement Protocol The arm (left or right) on which the measurements were to be carried out was determined by the placement of the venous cannula. As the oscillometric wrist blood pressure measurement device is positioned on the wrist (as are the majority of the cannulas), the cannula-free side was

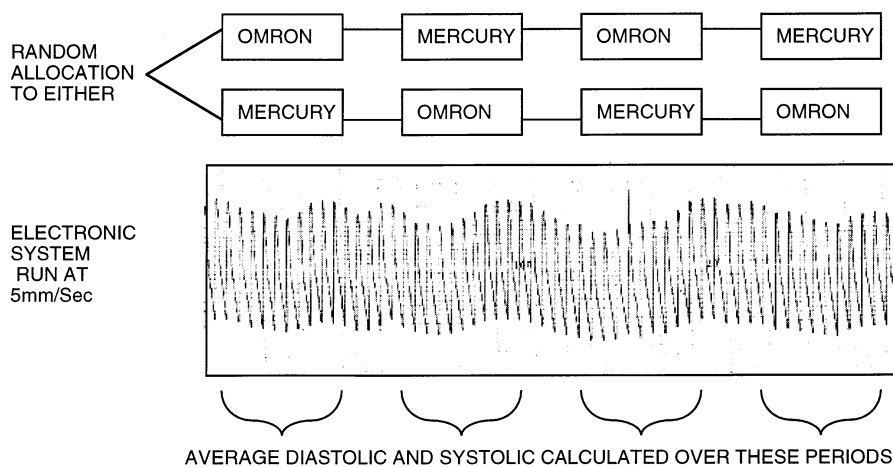


FIGURE 1. Protocol of measurements. For the duration of the experiment, blood pressure was continuously measured with the intraarterial catheter (IABP), whereas the oscillometric wrist blood pressure measurement device (OWBP) and the cuff mercury manometer (MM) were used twice in random order.

taken for measurement with all three systems. In accordance with the manufacturer's instructions, care was taken to ensure that the patient's wrist was comfortably positioned at the level of the heart before the oscillometric wrist blood pressure measurement device was put in place. The mercury manometer cuff was then placed around the patient's upper arm in a fashion that did not restrict blood flow from or to the lower arm. The zero of the mercury column was placed at the level of the patient's heart.

The measurements were performed by two well-trained investigators according to the BHS protocol⁸ and blinded for the results.

With the intraarterial printout running, the noninvasive measurements were carried out according to one of two protocols, to which the patient had been randomly assigned (Figure 1). The randomization code had previously been established and used as patients were recruited. Either a measurement was first taken with the mercury manometer, then the oscillometric wrist blood pressure measurement de-

vice, the mercury manometer again, and then finally with the oscillometric wrist blood pressure measurement device, or the order was reversed, and the oscillometric wrist blood pressure measurement device was used first.

Data Analysis and Statistics Data have been analyzed using Stat View 4.5 (Abacus, California). Analysis of variance (ANOVA) was applied to assess statistical significance. A $P \leq .05$ was accepted as statistically significant. The differences of the means and the limits of agreement have been calculated according to the literature.⁹

RESULTS

Absolute Values Mean values of wrist blood pressure were similar to the values obtained by intraarterial measurement for both systolic and diastolic blood pressure (Figure 2; $P = NS$ v intraarterial). In contrast, blood pressure values assessed with the mercury manometer were higher when compared with the intraar-

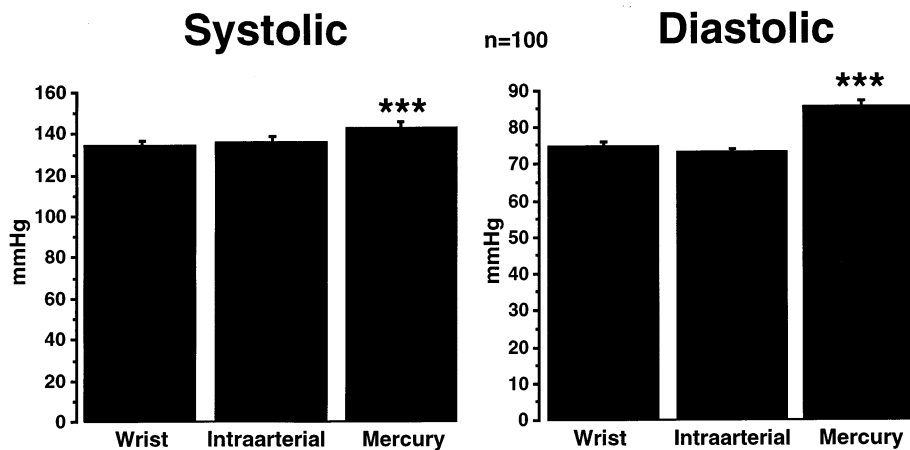


FIGURE 2. Absolute values of blood pressure measurement with the three different methods. *** $P < .001$ v wrist and v intraarterial.

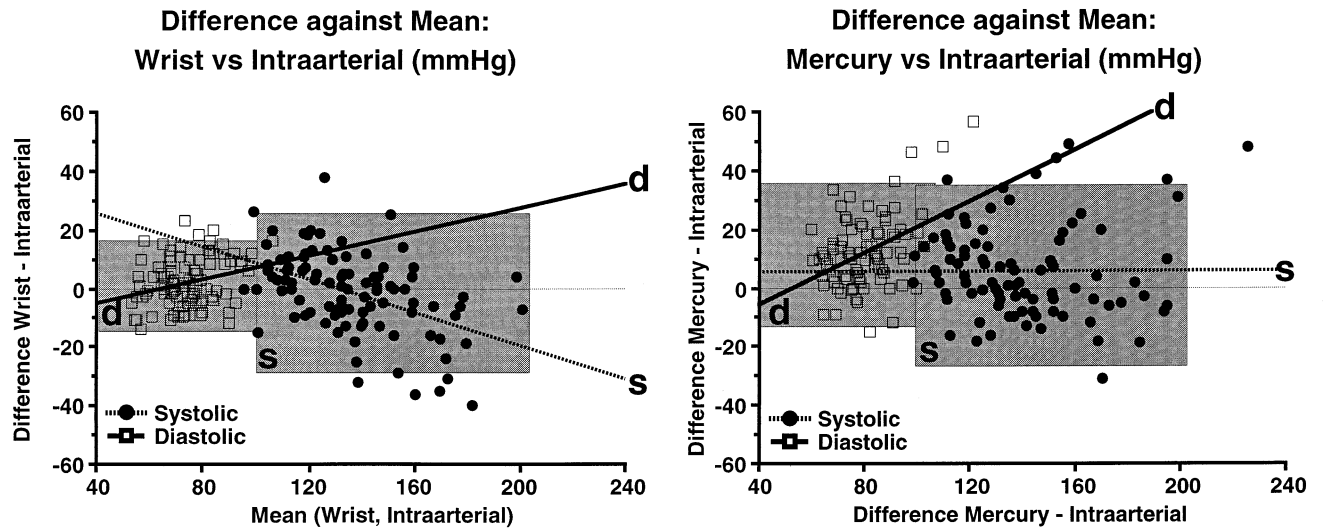


FIGURE 3. Difference-against-mean plot of noninvasive methods *v* intraarterial blood pressure values. Shaded area, limits of agreement for systolic (s) and diastolic (d) blood pressure; black line, regression for diastolic blood pressure; dotted line, regression slope for systolic (s) blood pressure.

terial measurement (Figure 2; $P \leq .01$ *v* intraarterial). However, the correlation between the two investigators (SW and CM) was excellent (systolic: $r = 0.91$, $P \leq .001$; diastolic: $r = 0.92$, $P \leq .001$).

Correlation of Wrist Blood Pressure With Intraarterial Blood Pressure Wrist blood pressure measurement correlated well with intraarterial measurement for both systolic and diastolic blood pressure (systolic: $r = 0.86$, $P \leq .01$; diastolic: $r = 0.75$, $P \leq .01$). The difference-against-mean plot revealed a slight overestimation of higher diastolic and an underestimation of high systolic blood pressure values (Figure 3, left panel). Limits of agreement were -1 ± 13 and $+1 \pm 9$ for systolic and diastolic blood pressure, respectively.

Correlation of Mercury Manometer Blood Pressure With Intraarterial Blood Pressure Systolic blood pressure assessed with the mercury manometer correlated well with intraarterial blood pressure, too, whereas correlation of the diastolic blood pressure measured with the mercury manometer was lower (systolic: $r = 0.84$, $P \leq .01$; diastolic: $r = 0.59$, $P \leq .05$). The difference-against-mean-plot revealed a marked overestimation of high diastolic blood pressure values, whereas systolic blood pressure measurements were assessed linearly (Figure 3, right panel). The limits of agreement were $+6 \pm 15$ and $+12 \pm 12$ for systolic and diastolic blood pressure, respectively.

Reproducibility of Blood Pressure Measurements Both systolic (left panel) and diastolic (right panel) blood pressure were nicely reproducible when assessed within 5 min in the same subject with either of

the methods, ie, with wrist cuff measurement (Figure 4) or with mercury manometer (Figure 5).

DISCUSSION

In this clinical study we directly compared blood pressure values obtained intraarterially with a cuff mercury manometer and a novel oscillometric wrist blood pressure measurement device (Omron R3).

This study clearly demonstrates the accuracy of the oscillometric wrist device in the clinical setting. It should be emphasized, however, that each of the subjects was in a supine position during measurement. Both the American Association for Medical Instrumentation (AAMI)⁷ and the British Hypertension Society (BHS)⁸ protocols stipulate that the measurements should be made on subjects while they are seated, standing, and supine. The results, therefore, do not attempt to validate the chosen device under either of these standards, but to test its accuracy in a limited setting but under exacting conditions.

Three different methods were used to measure blood pressure; intraarterially, through a water-filled system attached to an electronic transducer; auscultatorily, using the Korotkoff method; and oscillometrically with the Omron R3. Intraarterial measurements using the described method are generally accepted as being the gold standard method of recording blood pressure,¹⁰ despite inaccuracies that may be inherent in the system. It is against this that the other two methods have been compared, and both related quite favorably to it, although the Omron R3 returned more accurate results.

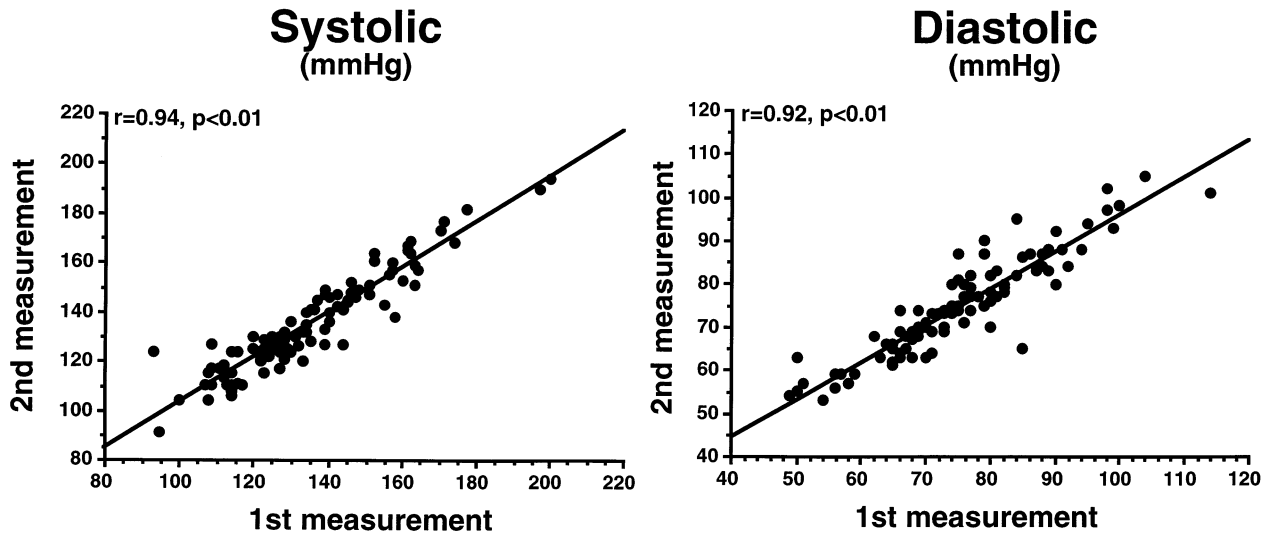


FIGURE 4. Reproducibility of wrist cuff measurements.

The limitations of the Korotkoff auscultatory method have been well documented,¹¹ but it continues to be widely used in the clinical setting. It was the method used to determine the parameters by which hypertension is diagnosed, and as such must be considered a gold standard itself. Both the BHS and AAMI protocols use the auscultatory method to test the accuracy of the devices being examined, using either two or three trained observers to reduce operator bias.^{7,8} This study not only confirmed that intraarterial and auscultated blood pressure measurement systems yield different values, but it has also shown that the device under examination better approxi-

mated the intraarterial pressure than did the auscultatory method. It is known from other studies that the readings with the two methodologies do differ in certain patients.¹²⁻¹⁴ Although intraarterial readings are the gold standard and accurate, the Riva-Rocci method estimates blood pressure derived from the Korotkoff sounds. As these sounds are determined after compressing the artery, structural characteristics of the blood vessel wall as well as local hemodynamics of the blood column in the arm where blood pressure is measured contribute to the final results. Hence, as reported in the literature, there are certain patients in whom the correlation is less good than in others.¹²⁻¹⁴

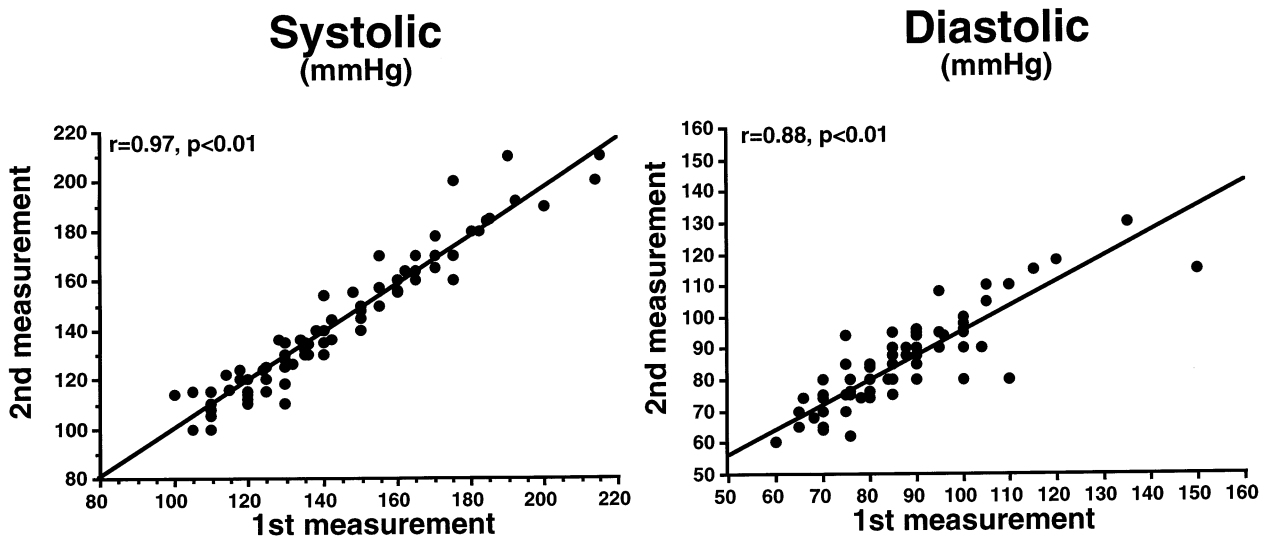


FIGURE 5. Reproducibility of mercury manometer measurements.

This study did not investigate the accuracy of the new wrist cuff method under regular conditions, ie, movement artefacts or handling errors. Of course, such situations definitely influence the device and may lead to wrong results. Furthermore, it is possible that intraarterial blood pressure is different in the radial when compared with the subclavian artery. However, the present study aimed to assess whether the new wrist cuff device accurately reflects intraarterial blood pressure, compared with the gold standard.

With the number of people undergoing cardiac catheterization increasing each year, a readily accessible study population is within easy reach of every hypertension researcher. This study raises the question of whether this objective method of device assessment is superior, in terms of cost-effectiveness and accuracy, to those described in the AAMI and BHS protocols. Such a quick and objective form of device validation eliminates many of the factors that complicate the present methods,¹⁵ and may well develop into a respected validation method in its own right.

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