

Accuracy of an Automated Blood Pressure Device in Stable Inpatients

Optimum vs Routine Use

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Background: Despite widespread use of the automated blood pressure (BP) device (IVAC model 4200, IVAC Corporation, San Diego, Calif), there is little formal validation in the literature on its accuracy.

Objective: To assess the accuracy of the IVAC 4200 device, both under standardized conditions and as routinely used by ward staff, compared with the true indirect BP measured by mercury manometer (MM).

Methods: One hundred forty-five stable inpatients were randomly selected for BP measurements by 3 randomly ordered protocols: (1) MM performed by certified investigators, (2) IVAC 4200 BP performed by trained investigators (research automated [RA]), and (3) IVAC 4200 BP performed by ward personnel (ward automated [WA]).

Results: For RA compared with MM ("true" indirect BP), 59% of systolic and 54% of diastolic readings were within

5 mm Hg and 83% of systolic and 86% of diastolic were within 10 mm Hg for a British Hypertension Society grade C for both. For WA compared with MM, 40% of systolic and 50% of diastolic readings were within 5 mm Hg and 70% of systolic and 80% of diastolic readings were within 10 mm Hg for British Hypertension Society grades D and C, respectively. The presence of arrhythmias and/or low K5 values (fifth phase of Korotkoff sounds <30 mm Hg) significantly increased the inaccuracy for diastolic values. Inappropriate cuff selection significantly increased inaccuracy of systolic BP (WA vs MM).

Conclusions: The IVAC 4200 yields substandard estimates of systolic and diastolic BP even under standardized, thus optimum conditions. The presence of arrhythmias or low K5 values and the selection of inappropriate cuff size by the ward staff also contributed to inaccuracy.

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THE MERCURY sphygmomanometer is currently recognized as the criterion standard for accurate non-invasive blood pressure (BP) measurement and is the method used in the majority of epidemiologic studies examining risk and treatment of hypertension. A variety of automated BP devices have been developed in recent years and are used extensively in many hospitals and clinics. A number of studies¹⁻⁶ have examined the accuracy of these devices with conflicting results. Differing patient populations and equipment, in addition to procedural variations, may contribute to this variability. Previous studies have generally examined the use of automated devices under ideal or standardized conditions, rather than as routinely used by hospital and clinic personnel. In addition, the accuracy of automated devices in such clinical contexts as cardiac arrhythmias and chronic movement disorders is often questioned but remains undefined. The IVAC

model 4200 (hereafter IVAC, IVAC Corporation, San Diego, Calif) is an automated BP-measuring device that is widely used in hospitals and clinics. Despite widespread acceptance of this device, there is little formal validation of the accuracy of this instrument in the literature. This study assesses the accuracy of the IVAC in estimating indirect BP compared with the "true" indirect BP estimated by the mercury manometer (MM). Accuracy of the IVAC was determined, both under rigidly standardized conditions by a trained research team and as routinely used by ward staff, using randomly selected stable medical and surgical inpatients.

RESULTS

PATIENT CHARACTERISTICS

A total of 286 inpatients were assessed for inclusion into the study. Of these patients, 26 were excluded; demographic

PATIENTS AND METHODS

PATIENT SELECTION

Figure 1 shows the process of patient selection. On each study day patients were randomly assessed for inclusion into the study using computer-generated lists of all inpatients within each of 5 wards. Patients were excluded if they were admitted to the hospital within the previous 24 hours, were identified as unable to give informed consent, or were unavailable at the time of the study. Patients not assessed because of time constraints or excluded on a given day were randomized for assessment on subsequent days of their hospital stay. Patients included were assigned to the demographics-only category if they were determined to be clinically unstable, uncooperative, unable to remain semisupine for the duration of the study, or if their arm size was too large for the adult large cuff. In addition, if a procedural variation occurred during BP measurements, the patient was transferred to the demographics-only category. Patients included were studied only once.

EQUIPMENT

The IVAC device measures BP using the auscultatory method with a microphone mounted in the cuff. The cuff initially inflates to a pressure of approximately 15 mm Hg higher than the setting chosen and then deflates at a rate of 4 to 6 mm Hg per second. Systolic BP is measured at the appearance of Korotkoff sounds and diastolic BP at the disappearance of Korotkoff sounds. The machine uses an oscillometric mode as automated backup for failure of the auscultatory mode. A total of 9 IVAC devices were used for the study. Each unit was calibrated for accuracy according to the American Association of Medical Instrumentation (AAMI) standards. The tubing, bladder, and cuffs for the test devices were replaced before the study and the operation of the oscillometric function of the devices was

verified. One device failed to meet calibration standards after the study. Accuracy of measurements generated by this device did not differ statistically from other devices and therefore were included in the final analysis. The MMs used were the standard Baumanometer (Standby Model 0661-0250) on a 4-wheel base with an adult calibrated V-Lok inflation system. Before the study, they were checked to ensure adequate mercury column levels and intact tubing. Stethoscopes with dual sets of earpieces were used for simultaneous MM BP determinations.

PROCEDURE

The study was approved by the subcommittee on human studies at the Medical Center/Portland Division, Department of Veterans Affairs. Patients determined suitable for inclusion were given a brief explanation of the study and informed consent was obtained. Height, weight, and temperature were measured. Arm circumference was measured at the midpoint of the upper arm between the olecranon and acromion processes. A 12-lead electrocardiogram was obtained.

The patient was asked to empty the bladder, and then to remain supine and refrain from eating, drinking, or smoking for the duration of the study. A 10-minute rest preceded BP measurements. Blood pressure measurements were performed for each patient according to 3 different protocols performed serially in randomized order (**Figure 2**): (1) MM BP performed by 2 trained investigators, (2) IVAC BP performed by trained investigators (research automated [RA]), and (3) IVAC BP performed by ward personnel (ward automated [WA]). The duration of each protocol was no more than 10 minutes. The protocol order in each patient was determined with a random number generator such that the frequency of each protocol order was equalized within each study ward.

The MM method was accepted as the criterion standard for measurement of indirect BP. (We chose to use

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data and BP measurements were completed for 145 (the study group) and demographic data only were collected from 115 patients. The characteristics of the study group are summarized in **Table 1**. They were almost exclusively men (99%) and most were white (94% white; 3% black). The mean age was 63 years (range, 23-86 years) and the mean weight was 83 kg (range, 48-182 kg). Hypertension was noted in the medical history of 26% of the patients. Evaluation of the demographics-only group was not statistically different with regard to sex, race, or history of hypertension. The demographics-only group was significantly older (mean age, 66 vs 63 years; $P=.04$).

The MM readings were used to describe the BP characteristics of the study population. The MM BP value for each patient was determined by averaging the 3 paired systolic and diastolic readings. The mean (\pm SD) for systolic and diastolic pressures was 127 ± 20 and 67 ± 11 mm Hg, respectively (range, 79-187 mm Hg for systolic pressures; 44-97 mm Hg for diastolic pressures).

VALIDATION OF STUDY DESIGN

For the MM paired readings, 85% of systolic and 87% of diastolic readings fell within 5 mm Hg and 96% and 97% fell within 10 mm Hg. There were no significant within-patient differences among the 3 serially determined sets of MM BP measurements. Furthermore, when average BPs from MM readings obtained in the first, second, or third positions of the protocol were compared, no significant differences were found. Thus, no time-dependent variation in indirect BP was detected.

ACCURACY OF THE IVAC

For assessing IVAC accuracy under optimal conditions, the RA BP results were compared with the MM results. For all comparisons, the MM reading reflects the mean of the 6 readings taken in each individual patient. The small cuff provided with the IVAC equipment was retrospectively found to be smaller than the standard small

indirect BP rather than direct BP because virtually all clinical trials impacting BP risk and therapeutic management are based on indirect BP by MM.) Thus, the purpose of the MM protocol was not to assess this standard method, but rather to establish an accurate estimate of indirect BP with a high level of confidence and against which the IVAC-based values could be compared. Accordingly, 3 paired dual-observer BP estimates were obtained in the MM protocol, whereas only a single BP value—reflecting routine clinical use—was obtained in the 2 IVAC protocols.

For the MM protocol, 4 of us (N.A., M.H., J.M., and G.R.) were certified in BP measurement technique according to the American Heart Association (AHA) recommendations.⁷⁻⁹ This certification included passing a written examination and a standardized videotape test. In addition, the investigators were required to demonstrate on human subjects accurate measurement techniques using an MM and a stethoscope with multiple earpieces. They were recertified weekly for the duration of the study using a standardized videotape. The 4 investigators worked in 2 teams and were paired with a different partner each study day.

In preparation for the BP determinations by the investigators, the patient was supine, with legs uncrossed, and the right arm slightly flexed and supported at heart level. The right arm was used for the measurement unless a condition precluded this choice. The appropriate cuff size based on the patient's arm circumference was chosen based on AHA guidelines.⁹ Three sets of simultaneous BP readings (phases 1, 2, and 3) were taken at 2-minute intervals using a dual stethoscope. Systolic pressure was recorded at the first of at least 2 regular beats and diastolic pressure was recorded when the last sound was heard (fifth phase of Korotkoff sounds or K5). If sounds were heard to less than 30 mm Hg, the diastolic pressure was recorded at the fourth phase of Korotkoff sounds (K4). Paired investigators recorded their results independently and were blinded to the other's results. A single palpated radial pulse rate was also measured by the investigators.

For the RA protocol, a single BP and pulse rate were measured with the IVAC by a certified investigator. All investigators reviewed the manufacturer's training video before the study. Cuff size was again based on AHA recommendations. The investigators were blinded to the BP and pulse reading of the IVAC by a masking device until all 3 BP protocols on the patient were completed.

For the WA protocol, BP measurement and pulse rate were performed by the ward staff using the same IVAC machine as that used by the investigator. They were instructed to measure the BP using the same arm as that used by the certified investigator. Cuff selection was made by the ward staff. A medium and large cuff (but not small) were made available for their use, reflecting routine ward conditions. (Elimination of the small cuff by nursing personnel reflected the excessively small size of the cuff regularly provided by the IVAC company, corresponding to a pediatric cuff size rather than to a small adult cuff size).

STATISTICAL ANALYSIS

For the MM protocol BPs, repeated measures analysis of variance were performed on the 3 sequential paired MM measurements using within-subjects error variance to assess linear trend over time. The graphs of Δ BP values (difference between the 2 simultaneously measured MM values) vs the average MM determination were performed assuming that the averaged MM determinations were not subject to measurement error and reflected the subject's true BP. The impact of arrhythmias, low K5 sounds, cuff-size mismatch, as well as other possible confounding factors (such as pulse, age, and weight) were analyzed using analysis of covariance, with the difference between RA vs MM and WA vs MM as the outcomes of interest after adjusting for average BP levels. To test the precision of the IVAC relative to MM as a function of level of BP, regressions were done on absolute deviations (Δ BP with respect to MM) vs the average MM values.

adult cuff (19×8.5 cm vs 23×10.3 cm, respectively). Because this introduced an unintended mismatch in cuff size, subjects requiring a small cuff (n=19) were excluded from analysis of optimum-use accuracy. The Δ values between the RA readings and MM for each patient were plotted according to BP level (**Figure 3**). There was no significant variability in the Δ values across the pressure range studied for systolic values, whereas the Δ values were greater for the higher diastolic pressures (ie, IVAC values underestimated mercury readings, $P<.001$ for both slope and intercept). The IVAC would have misclassified 5 of 26 with systolic pressures higher than 140 mm Hg by MM as normotensive (19%) and 9 of 118 with systolic pressures lower than 140 by MM as hypertensive (8%). There were not enough values higher than 90 to be able to assess misclassification based on diastolic readings. To assess IVAC performance under usual ward conditions, similar analyses were performed comparing the WA BP values against the MM readings. All cuff mismatches (excluding small cuffs) were included. The Δ values

(MM BP minus WA BP) plotted against the absolute MM pressure showed no systematic bias with systolic pressures, whereas diastolic pressures by the WA were significantly lower than the MM readings at higher diastolic pressures (**Figure 4**; $P<.001$).

The accuracy of the IVAC, with optimal or usual use, was not found to be affected by patient age, weight, or pulse rate. Accuracy did not vary according to the IVAC machine, ward, or investigator pairs. The effects of movement disorders could not be assessed because of a lack of patients in this category.

INFLUENCE OF ARRHYTHMIAS AND K4,5 SOUNDS ON IVAC PERFORMANCE

Patients with arrhythmias were defined as having an irregular pulse in conjunction with an irregular rhythm on electrocardiogram (sinus arrhythmia, atrial fibrillation, frequent premature atrial contractions, or premature ventricular contractions). Patients with K4,5 notations had very low K5 values measured by the MM (<30

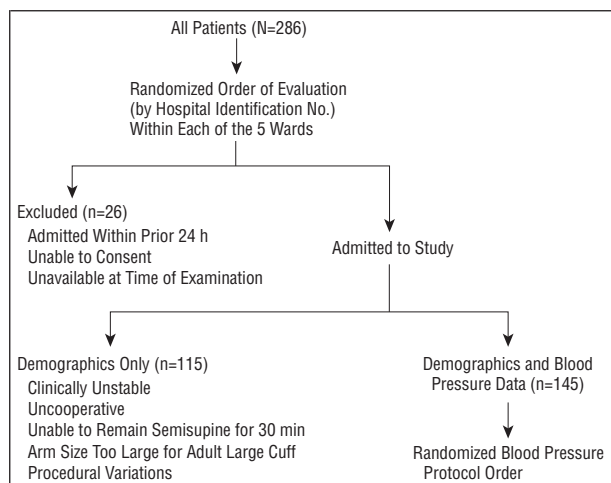


Figure 1. Patient flow diagram.

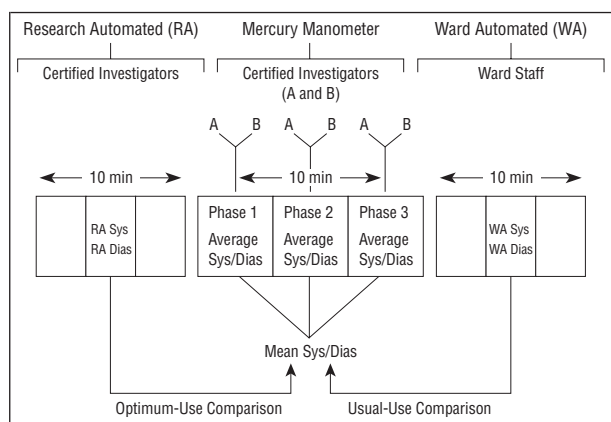


Figure 2. Study design. Blood pressure (BP) protocols performed in each patient serially in randomized order. Sys indicates systolic; Dias, diastolic.

mm Hg). In these cases, the K4 values were recorded as the diastolic pressure for the MM readings. In the pooled group of patients with either arrhythmias or K4,5, a significantly larger number of diastolic readings differed from MM values by more than 10 mm Hg ($P < .05$ for RA and $P < .001$ for WA) or by more than 15 mm Hg ($P < .001$ for RA and $P < .05$ for WA) compared with patients without arrhythmias or K4,5 notations. **Figure 5** demonstrates the average diastolic differences of WA and RA readings compared with the MM for patients with and without arrhythmias and K4,5 notations. The IVAC significantly overestimates diastolic pressure in this subgroup of patients ($P < .001$). Accuracy of the systolic BP was not significantly affected by the presence of arrhythmias and/or low K5 values. (Our general clinical experience supports frequent presence of beat-to-beat variation in systolic BP in atrial fibrillation and thus increased risk of inaccurate BP estimates by all methods.)

ROLE OF CUFF SIZE MISMATCH

Figure 6 demonstrates the influence of cuff size on Δ values between RA readings and MM values. As discussed earlier, the IVAC small cuff as provided by the manufacturer was significantly smaller than the standard adult small cuff

Table 1. Clinical Characteristics of the Study Group*

Characteristic	
Mean \pm SD age, y	63 \pm 13
Sex, male/female	143/2
Race, No.	
White	136
Black	4
Other	2
Information not available	3
Diagnosis of hypertension, %	26
Mean \pm SD	
Weight, kg	83 \pm 21
Systolic BP, mm Hg	127 \pm 20
(range)	(79-187)
Diastolic BP, mm Hg	67 \pm 11
(range)	(44-97)

*BP indicates blood pressure.

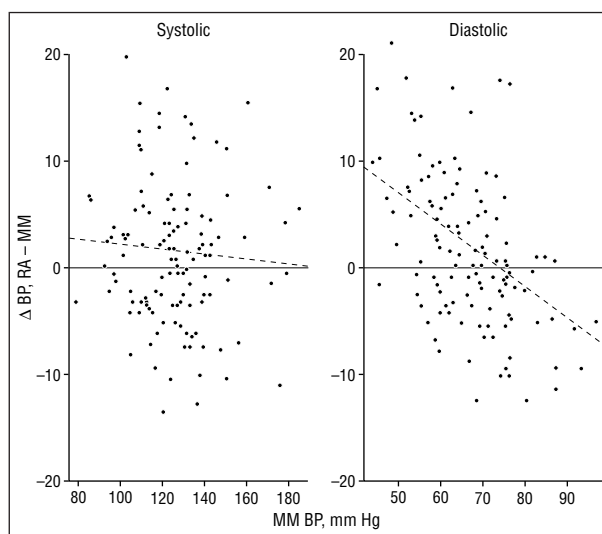


Figure 3. RA (research automated) minus MM (mercury manometer) blood pressure (Δ BP) of individual patients plotted according to absolute BP level as measured by MM. For systolic BP, Δ values not significantly different across the BP range. Diastolic Δ values were more negative in higher BP ranges (ie, RA underestimates diastolic BP) ($P < .001$).

used for the mercury readings. In patients requiring a small cuff size, the excessively small cuff provided by the IVAC led to significantly overestimated systolic BPs ($P < .05$).

Table 2 compares cuff sizes selected by ward staff (columns) and investigators (rows). In 47 (39%) of 118 patients, the ward staff selected the incorrect cuff size according to the AHA guidelines. **Figure 7** plots the Δ values between WA readings and the MM values in the subset of patients with mismatched cuffs (ie, the ward staff selected the incorrect cuff size). The data are plotted against arm circumference. Patients requiring small cuff sizes (thus 100% mismatched) are included in the data. The plus signs indicate instances where the ward staff chose an inappropriately small cuff and the minus signs indicate instances where the ward staff chose an inappropriately large cuff. The most common error by the ward staff was the use of a regular sized cuff for patients requiring a large cuff size despite immediate availability of the larger cuff. Not surprisingly, the ward IVAC readings in these patients were significantly higher for both systolic and diastolic pressures

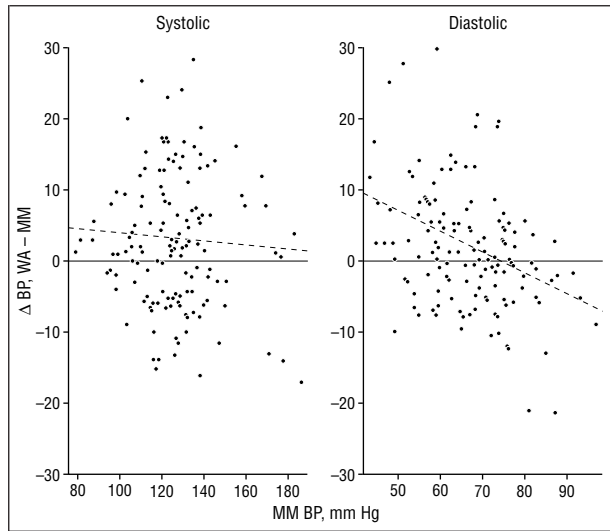


Figure 4. WA (ward automated) minus MM (mercury manometer) blood pressure (BP) for individual patients plotted according to the average absolute BP as measured by MM. For systolic BP, Δ values were not significantly different across the BP range. Diastolic Δ values were more negative in higher BP ranges (ie, WA underestimates diastolic BP) ($P < .001$).

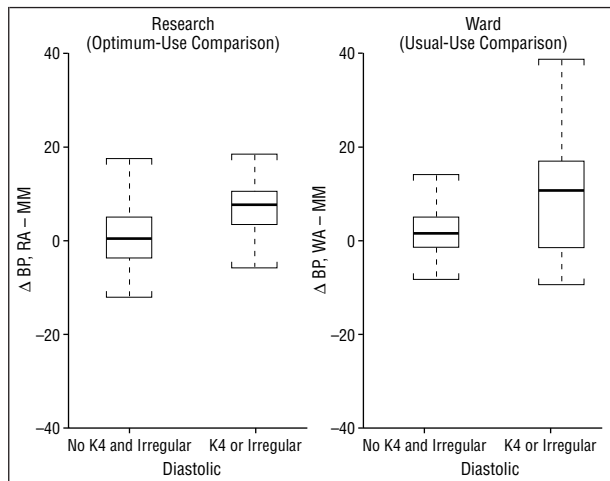


Figure 5. Mean diastolic Δ values for RA (research automated) minus MM (mercury manometer) and WA (ward automated) minus MM for patients with and without K4,5 notations (ie, Korotkoff sound K5 < 30 mm Hg) and/or arrhythmias. The IVAC model 4200 (IVAC Corporation, San Diego, Calif), an automated blood pressure (BP) measuring device, significantly overestimated diastolic BP in patients with K4,5 and/or arrhythmias under optimal conditions ($P < .001$) and with usual use by ward staff ($P = .001$).

compared with mercury readings ($P < .05$). In contrast, the obligate error for patients requiring small cuffs was the use of the regular size (larger) cuff. As expected, the IVAC readings were significantly lower for systolic and diastolic pressures in this group of patients ($P < .001$). In summary, systolic and diastolic readings were significantly overestimated when the ward staff chose an inappropriately small cuff and significantly underestimated when ward staff chose an inappropriately large cuff.

BRITISH HYPERTENSION SOCIETY GRADING SYSTEM AND THE AAMI STANDARDS

The British Hypertension Society has established rigorous guidelines for the evaluation of automated BP mea-

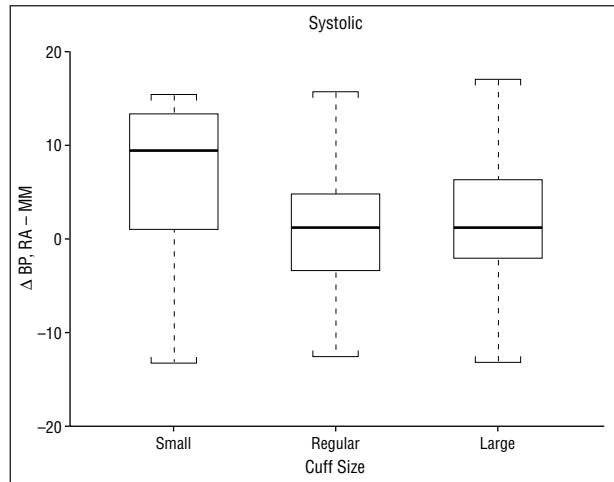


Figure 6. Influence of cuff size on Δ values of RA (research automated) minus MM (mercury manometer) for systolic blood pressure (BP). In those patients requiring small cuff size, the IVAC model 4200 (IVAC Corporation, San Diego, Calif), an automated BP measuring device, significantly overestimated systolic BP compared with the mercury manometer ($P = .005$). The IVAC small bladder size (19×8.5 cm) corresponds to a pediatric cuff rather than to the standard small adult cuff (23×10.3 cm) used in the MM protocol.

Table 2. Comparison of Cuff Selections by Ward Staff and Investigators

Investigators	Ward			Total
	Large	Regular	Small	
Large	8	27	0	35
Regular	3	63	0	66
Small	0	16	1	17
Total	11	106	1	118

suring devices.^{10,11} **Table 3** summarizes the grading system. To achieve the highest grade (A), 80% of the test device's readings must fall within 5 mm Hg of the standard (MM), 90% must fall within 10 mm Hg, and 95% must fall within 15 mm Hg. Only those devices that achieve a grade A or B for both systolic and diastolic readings are recommended for clinical use by the British Hypertension Society.

Table 4 presents the percentage of readings that fall within 5, 10, 15, and 20 mm Hg under ideal use (RA) and usual use (WA) against the MM. The paired mercury readings between the certified researchers achieved grade A for both systolic and diastolic readings. The IVAC achieved grade C for both systolic and diastolic pressures under the RA optimum-use condition and under usual-use ward conditions achieved grade D for systolic pressures and grade C for diastolic pressures. It is through the British Hypertension Society grading system that we were able to compare the accuracy of the IVAC under ideal conditions compared with usual-use ward conditions. Because of the demonstrated inaccuracy of the IVAC BP compared with MM BP, we thought it inappropriate to directly compare the results of the 2 IVAC protocols with each other.

Standards set up by the AAMI have, until recently, been widely used in examining the accuracy of auto-

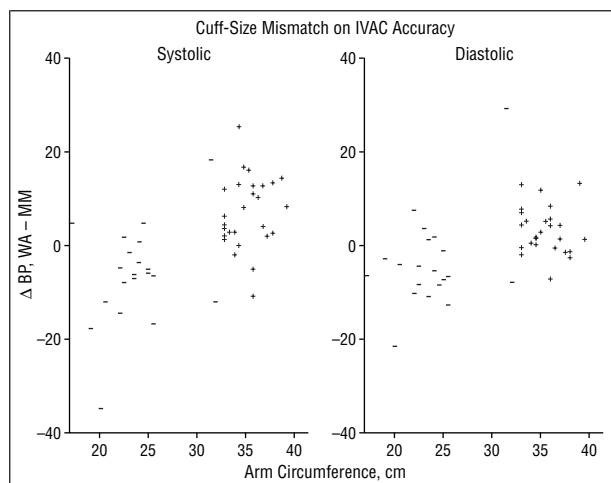


Figure 7. WA (ward automated) minus MM (mercury manometer) Δ values plotted against arm circumference for the subgroup of patients with mismatched cuffs. Systolic and diastolic Δ readings were significantly higher when the ward staff chose a smaller cuff than the investigators compared with when a larger cuff than that of the investigators was chosen ($P < .001$ and $P < .009$, respectively). Data from patients requiring small cuff (ie, 100% obligate cuff mismatch in WA protocol where no small cuff is available) is included. WA cuff smaller than that of the investigators (plus sign); WA cuff larger than that of the investigators (minus sign). BP indicates blood pressure.

mated BP devices.¹² These standards call for averaging Δ values (test instrument vs standard) with the positive or negative sign retained and require that the mean Δ be 5 mm Hg or less and the SD be 8 mm Hg or less. Since positive and negative values cancel out in the summed value, the resulting mean value can be small despite large, clinically unacceptable variability. To emphasize how misleading this can be, note that the IVAC as operated under optimal conditions (RA) was found acceptable by these AAMI standards with a mean (\pm SD) Δ of 1.59 ± 7.4 for systolic and 1.98 ± 7.45 for diastolic, despite the large absolute Δ values shown in Figure 1. Under usual conditions (WA), the IVAC failed even these standards for both systolic and diastolic readings (mean \pm SD Δ , 4.1 ± 11.0 for systolic and 2.65 ± 9.45 for diastolic). In addition, because the AAMI criteria call for pooling Δ values across the entire spectrum of BP, they do not address the possibility of varying performance accuracy at different levels of BP. Because of these important deficiencies, the AAMI criteria are considered insufficiently stringent by most authorities.^{10,11}

COMMENT

We have prospectively examined the accuracy of the IVAC automated BP device for measurement of indirect BP compared with indirect BP estimated by MM readings by certified investigators in clinically stable veteran inpatients. This study is unique in that it assessed both optimum-use accuracy under rigidly standardized conditions and usual-use accuracy as routinely performed by ward personnel. Randomization of patients for inclusion assessment within each of 5 wards permitted a representative sampling of the inpatient population; randomly assigned order of protocol performance obviated bias because of BP change over time during data collec-

Table 3. British Hypertension Society Blood Pressure Grading System (Based on Cumulative Percentage of Readings)

Grade	Difference Between Standard and Test Device, mm Hg		
	≤ 5	≤ 10	≤ 15
A	80	90	95
B	65	85	95
C	45	75	90
D	*	*	*

*Asterisk indicates worse than grade C.

Table 4. British Hypertension Society (BHS) Grading Chart*

	<5	<10	<15	<20	BHS Grade
MM: A vs B					
Systolic	90	98	100	100	A
Diastolic	94	100	100	100	A
RA vs MM					
Systolic	59	83	95	99	C
Diastolic	54	86	94	98	C
WA vs MM					
Systolic	39	69	86	95	D
Diastolic	51	81	92	94	C

*Values are in millimeters of mercury. A, B indicates investigator pairs for mercury manometer readings; MM, mercury manometer; RA, research automated; and WA, ward automated.

tion. Exclusion of patients admitted within the previous 24 hours and allowing an initial rest period before the BP measurements may have diminished the changes in BP over time.

We chose to use the MM BP as measured by trained investigators as our standard rather than intra-arterial pressures as recommended by some investigators because (1) most clinical trials on which BP management is based have used indirect measurements by MM; and (2) intra-arterial measurements are invasive and create risk for study subjects. Simultaneous measurement between the test device and the mercury standard using a Y-tube to connect a common cuff has been used by some investigators. However, the inflation-deflation characteristics and noise of some devices prevent accurate assessment by auscultation for the researcher using the MM. For this reason, the British Hypertension Society recommends sequential measurements of the test device and MM in the same arm as used in our protocol.¹⁰ We used a dual stethoscope allowing simultaneous readings by 2 trained investigators. Our results confirm the validity of this approach as more than 90% of the simultaneous (and blinded) systolic and diastolic BP readings between the researchers differed by only 5 mm Hg or less and more than 95% were within 10 mm Hg.

Based on published standards, the IVAC yields substandard estimates of systolic and diastolic pressures, even under the rigidly standardized optimum conditions of the RA IVAC protocol. Although the IVAC met the requirements of the less stringent AAMI standards, it achieved only a grade C for systolic and

diastolic pressures under the more rigorous requirements of the British Hypertension Society system. A minimum of a grade B is required for an acceptable level of accuracy for clinical practice. In the higher diastolic pressure range, the IVAC underestimates the diastolic pressure. To our knowledge, we have shown for the first time that the presence of an arrhythmia or a low K5 value significantly reduces the accuracy of the IVAC. There was no significant influence of age, weight, or pulse rate on accuracy.

There is only 1 study¹ in the literature that we are aware of examining the accuracy of the IVAC. The study compared the instrument with the manual auscultatory method in 100 healthy adult volunteers. The investigators found that 37% of systolic readings and 26% of the diastolic values differed by more than 9 mm Hg and concluded that clinicians should be cautious when using the instrument to measure BP. The majority of previous studies²⁻⁶ have also raised concerns regarding the accuracy of other auscultatory BP measuring devices. Polk et al² examined the accuracy of the coin-operated Vita-Stat (SpaceLabs Medical Inc, Redmond, Wash) device in 342 adults compared with the random-zero MM. Two of the 4 machines gave significantly higher systolic and diastolic values and resulted in the misclassification of 23% of normotensive individuals as having hypertension. Nystrom et al³ compared direct radial artery pressures with the Infrasond 4000 with 40 male patients under general anesthesia. In contrast to the previous study, they found that the systolic pressures were significantly lower with this automated device, whereas diastolic pressures gave higher values than the direct radial pressures. A larger evaluation of the Vita-Stat (SpaceLabs Medical Inc) device was conducted by Salaita et al⁴ in 518 adult volunteers using a total of 10 machines. In comparison with the random-zero MM, 8 of the 10 machines underestimated systolic BP, whereas 9 of the 10 machines overestimated the diastolic pressure. Pannarale et al⁵ compared the TM 2420 (Bosch & Son, Jungingen, Germany) with simultaneous readings by 2 pairs of trained, blinded observers using random-zero MMs. The TM 2420 (Bosch & Son) overestimated both systolic and diastolic BP. In contrast the Terumo ES-H51 (Terumo Medical Corp, Somerset, NJ) BP monitor was tested against the MM by Imai et al⁶ and found to be accurate. The investigators found that 72% and 93% of systolic and diastolic readings fell within 5 mm Hg of the MM readings. In summary, the majority of studies in the literature on auscultatory BP devices show that the diastolic BP is overestimated compared with the standard. However, the systolic BP error varies with the study, some devices overestimating and others underestimating the systolic BP. Undoubtedly, this is because the studies vary with respect to the method and patient characteristics as well as the specific device tested.

Several possibilities may account for the discrepancies we have obtained between the IVAC and MM readings. The cuff deflation rate for the IVAC (4-6 mm Hg per second) is significantly faster than that recommended by the AHA (2-3 mm Hg per second).⁹ If this was contributing to the inaccuracy, one would expect the IVAC to underestimate systolic pressures and to overes-

timate diastolic pressures. However, our results do not support this pattern of bias. A stress response to the IVAC machine might be expected to increase systolic pressures and could potentially have contributed to the slightly higher systolic pressures measured by the IVAC. Improper machine calibration or machine malfunction could obviously compromise accuracy. One of the machines used in our study was found to fail calibration following the study. However, analysis of the data did not reveal a significant independent effect on accuracy of this particular machine. The inclusion of multiple machines that were calibrated before initiating the study should have decreased the chance of random machine malfunction as the explanation for inaccuracies.

A NUMBER OF factors were examined for their influence on the accuracy of the IVAC, including patient age, weight, pulse rate, BP level, presence of arrhythmias or low K5 values, IVAC machine, investigator, ward, and cuff size mismatch. The presence of an irregular heart rhythm or a low K5 value resulted in a significant decrease in accuracy of diastolic pressure measurement by the IVAC. Diastolic pressures were significantly overestimated by the IVAC in this setting. It is possible that the more rapid cuff deflation rate of the IVAC could play a role in this subset of patients. Our numbers were insufficient to independently assess the effects of arrhythmias and low K5 values; both deserve further study to clarify implications for clinical practice.

Our study is unique in that it examines the accuracy of an automated BP measuring device as it is actually used in the clinical setting. The performance of the IVAC under usual ward conditions is at least partially compromised by incorrect technique by the ward staff. The most obvious error was improper cuff selection, particularly for those patients requiring large cuff sizes. Other potential errors in ward technique, not specifically assessed, included improper cuff placement and allowing the patient to talk or change positions during the procedure. As expected, selection of a regular-sized cuff rather than the appropriate large cuff resulted in significantly higher systolic readings. More disturbing was the inappropriately sized adult small cuff provided with the IVAC equipment. The bladder size of the "small adult cuff" provided with the IVAC is significantly smaller than the dimensions recommended by the AHA and, as would be expected, results in falsely elevated systolic pressures in patients requiring adult small cuff sizes.

It should be emphasized that we studied primarily normotensive elderly men who were considered stable inpatients. Extension of these results to populations with other characteristics or the outpatient population should be performed with caution. Frequent major discrepancies between hypertension clinic nursing check-in BP by IVAC and the medical provider's routine mercury BP (vs the before IVAC period) originally led to our concerns about IVAC accuracy. However, because of the unexpected paucity of patients with hypertension in our study, we are unable to draw valid conclusions about the accuracy of the IVAC in individuals with hypertension. None-

theless, the tendency to underestimate diastolic pressures in the higher BP ranges raises concern that IVAC may yield even greater inaccuracy in the population with hypertension. Further study is needed in this area.

In summary, the IVAC demonstrates substandard accuracy in estimating both systolic and diastolic pressures; the errors were exaggerated in patients with arrhythmias or low K5 values. Identification of this subset of patients would be difficult without a screening MM reading by a trained individual. Accuracy of the IVAC was further compromised by procedural errors by the ward staff, particularly the selection of inappropriate cuff size. The provision by the IVAC manufacturer of an inappropriately sized small adult cuff precludes accurate BPs by the IVAC for adults with small arm sizes. Based on these results, we conclude that the IVAC should not be used for the diagnosis or treatment of hypertension or for routine BP measurement in patients with arrhythmias or low K5 values. We also cannot confidently recommend its use in stable normotensive patients without arrhythmias or low K5 values. Our results provide support for obtaining an initial MM reading to detect diastolic K5,4 variants and/or arrhythmia before relying on even accurate automated BP instruments. Finally, the importance of re-establishing regular training in BP measurement for ward personnel should be emphasized, regardless of the technique of BP measurement.

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