The Accuracy Of The Marshall 85™ Oscillometric Sphygmomanometer In The Ambulatory Care Setting

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***Abstract*: The purpose of this study was to evaluate a partially automated sphygmomanometer for accuracy in the ambulatory care setting. Patients seen in 80 consecutive office visits served as subjects. Blood pressures were measured simultaneously under standard conditions. The oscillometric test instrument and a standard mercury manometer were connected with a Y tube. Paired t-tests were used to determine statistical differences between values obtained from the two instruments. Analyses were done by age, sex, and blood pressure range. While mean differences in blood pressure values were statistically significant in almost every instance, the quantitative differences were 5 mmHg or less with one exception. The differences, although statistically significant, were not great enough to be clinically important. We conclude that the Marshall 85™ oscillometric sphygmomanometer is sufficiently accurate for limited use in the ambulatory care setting. (J Am Bd Fam Pract 1989; 2:247-51.)**

Physicians regularly base their clinical decisions about blood pressure diagnosis and management on indirect measurements. While there are discrepancies between intra-arterial and indirectly measured pressures,[1-2] in practice, indirect measurements are safer, easier, noninvasive, and in routine clinical use.

Recently, home blood pressure measurement devices have been marketed by several companies and are generally available to the public. Evaluations of some automated (e.g., oscillometric) instruments are available,[3-5] but in general, these devices have not been adequately evaluated or found to be sufficiently accurate in the ambulatory care setting.[3] Therefore, their usefulness has not been established.

Advantages of measuring blood pressure in locations other than the physician's office include detecting effects caused by the physician's presence or practice setting, enhancing safety in therapy, obtaining blood pressure measurements easily, and observing circadian variation in blood pressure.[6-10] Moreover, blood pressures measured away from the physician's office might correlate better with severity of complications from essential hypertension.[11]

The purpose of this investigation was to evaluate the accuracy of the Marshall 85™ oscillometric sphygmomanometer. The Marshall 85™ is a relatively inexpensive (less than $80 in Wichita, Kansas), portable, easily used, automated blood pressure measurement instrument. Physicians could recommend this device to their patients if it were shown to be accurate. Blood pressure measurements obtained from the Marshall 85™ were compared with those from a calibrated, wall-type mercury manometer, which served as the reference instrument because it is often used by physicians in making clinical decisions about blood pressure management. We hypothesized that there would be no significant differences between the blood pressure measurements obtained by the two instruments.

Methods

Subjects

Patients, aged 16 years or older, presenting consecutively in 80 visits to the St. Joseph Family Practice Center, Wichita, Kansas, served as subjects. Eighteen visits were by men; 62 were by women. Seven patients were seen twice, but on different days, and both visits were included in

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the overall analysis, because differences between the two blood pressure devices were being investigated, not differences among the patients. Only the first visit of these 7 patients was included in the subanalyses by sex and age.

Instruments

A clean, calibrated, standardized wall-type mercury manometer (Baumanometer™) served as the reference device, and a Marshall 85™ oscillometric sphygmomanometer was used as the test instrument. They were connected by a Y tube (Figure 1) to allow simultaneous blood pressure measurements. This setup eliminated possible discrepancies from moment-to-moment blood pressure variation, patient position, and other such factors.

Procedures

Patients were seated with the left arm positioned at the heart level and supported by the examination table (Figure 2). All patients were measured at midarm, and only those with arm circumferences ranging from 9–12 inches were included for analysis.

The cuff provided with the Marshall 85™ was placed on the patient by the physician. This cuff satisfied the guidelines of the American Heart Association,[12] which state that the maximum arm circumference for this cuff should be 12 inches, even though the manufacturer recommends it for arm circumferences up to 14 inches.

All blood pressure measurements were obtained by the physician investigators who followed the guidelines of the American Heart Association. Phase V Korotkoff sounds were used for determination of diastolic blood pressure obtained from the mercury manometer.

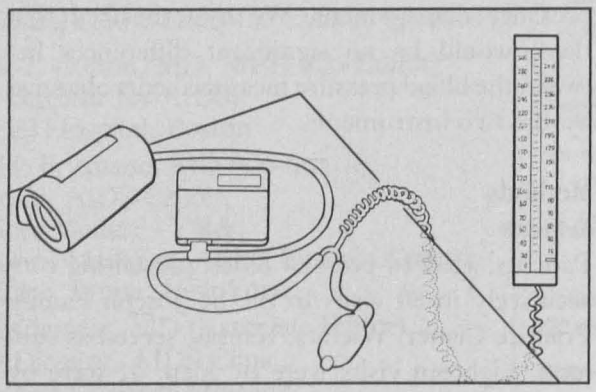

Figure 1. Illustration of Y-tube connections.

Figure 2. Illustration of technique used for simultaneous blood pressure measurement.

Measurements obtained from the Marshall 85™ followed manufacturer's instructions. To prevent bias, the Marshall 85™ was placed on the examination table to prevent the investigators from observing the digital readout while obtaining measurements from the mercury manometer.

Results

Table 1 lists mean values, ranges, and standard deviations for systolic and diastolic blood pressure measurements obtained from both devices. Results of the paired t-tests show statistically significant differences between the instruments for systolic and diastolic measurements.

Table 1 also shows the mean values, ranges, standard deviations, and significance levels for data obtained from patients with systolic blood pressures less than 140 mmHg or greater than 140 mmHg and for patients with diastolic blood pressures values less than 90 mmHg or greater than 90 mmHg. Paired t-tests were calculated for each.* The difference between the means for each analysis was less than 5 mmHg, except for the systolic measurements of patients with blood pressures 140 mmHg or greater.

Table 2 shows the mean values, ranges, standard deviations, and significance levels for analyses on data by sex and by age. In the analyses by sex, only the systolic measurements in women were significantly different. In the age analyses,

*For readers concerned with analytical errors, the Bonferroni t-test[13] was used to determine significance level. This calculation divides the alpha level (0.05) by the number of separate analyses.

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Table 1. Mean Values, Ranges, Standard Deviations, and Significance Levels of Blood Pressure Values.

Type	n	Manometer			Marshall 85™			*P* Level
		Mean	Range	SD	Mean	Range	SD	
All Patients								
Systolic	80	122	86–200	24	119	84–182	22	$P < 0.0001$
Diastolic	80	70	50–92	10	69	44–95	11	$P < 0.01$
Patients with manometric systolic values < 140 mmHg								
Systolic	62	111	86–138	13	109	84–142	13	$P < 0.005$
Diastolic	62	68	50–90	9	65	44–95	10	$P < 0.0001$
Patients with manometric diastolic values < 90 mmHg								
Systolic	75	121	86–200	24	117	84–182	22	$P < 0.0001$
Diastolic	75	69	50–86	8	67	44–95	10	$P < 0.001$
Patients with manometric systolic values ≥ 140 mmHG								
Systolic	18	158	140–200	18	152	127–182	16	$P < 0.01$
Diastolic	18	79	65–92	8	80	65–95	9	$P > 0.05$
Patients with manometric systolic values ≥ 90 mmHG								
Systolic	5	144	138–150	6	144	134–152	7	$P > 0.05$
Diastolic	5	90	90–92	1	93	90–94	2	$P > 0.05$

only the systolic measurements in the 16–25 age category reached statistical significance. In each analysis, the difference between the means was 5 mmHg or less.

Discussion

The Association for the Advancement of Medical Instrumentation (AAMI) has proposed standards for the evaluation of automated blood pressure monitors in comparison with standard sphygmomanometers.[14] The proposed standard recommends that the mean differences in blood pressure between instruments be less than 5 mmHg. Only one mean difference in the present data exceeded 5 mmHg. That difference was for the systolic blood pressure measurements of patients with manometric systolic pressures greater than or equal to 140 mmHg.

One might conclude from our data that the Marshall 85™ is not sufficiently accurate to be clinically useful. We believe, however, that the differences in our data are statistically but not clinically significant. The mean differences between the blood pressure values of the two instruments were very small. We analyzed the raw data to determine which patients would have been managed differently and whether clinical decisions would have been altered based upon the blood pressure measurements obtained from the Marshall 85™. The *Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure* was used as a guide.[15] Our conclusion was that no patient would have been managed differently, and no clinical decisions would have been altered.

The largest mean difference between instruments was noted for patients whose systolic manometric blood pressure values were equal to or greater than 140 mmHg. The mean difference between instruments was small (6 mmHg), as was the number of patients in this category (n = 18).

Conclusion

We believe that the Marshall 85™ is sufficiently accurate to recommend to patients for home blood pressure monitoring. Brief instructions should be sufficient for patients to obtain accurate and easy blood pressure measurements away from the physician's office. To ensure accuracy, the Marshall 85™ should be used on patients with arm circumferences of 9–12 inches.

The Marshall 85™ should not replace the standard mercury manometer in the office. Further, it should be tested in the office for any discrepancies before being used in the home. This procedure would reinforce the quality control procedures of the manufacturer. If the Marshall

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Table 2. Mean Values, Ranges, Standard Deviations, and Significance Levels of Blood Pressure Values by Sex and Age.

Type	n	Manometer			Marshall 85™			*P* Level
		Mean	Range	SD	Mean	Range	SD	
Women								
Systolic	57	119	86–200	25	117	84–182	24	$P < 0.005$
Diastolic	57	70	50–92	10	68	44–94	12	$P < 0.05$*
Men								
Systolic	16	125	102–156	15	122	100–153	15	$P > 0.05$
Diastolic	16	72	58–90	9	71	55–95	11	$P > 0.05$
Patients aged 16–25 years								
Systolic	24	108	94–136	11	105	91–127	9	$P < 0.005$
Diastolic	24	64	50–80	8	61	44–81	8	$P < 0.01$*
Patients aged 26–35 years								
Systolic	15	112	90–140	15	112	89–142	15	$P > 0.05$
Diastolic	15	71	52–90	9	71	51–94	10	$P > 0.05$
Patients aged 36–45 years								
Systolic	5	114	96–138	17	112	87–134	19	$P > 0.05$
Diastolic	5	71	50–90	16	69	50–90	15	$P > 0.05$
Patients aged 46–55 years								
Systolic	8	120	92–154	21	119	99–151	19	$P > 0.05$
Diastolic	8	76	68–92	8	72	59–94	11	$P > 0.05$
Patients aged 56–65 years								
Systolic	8	129	86–150	23	125	84–152	24	$P > 0.05$
Diastolic	8	76	62–90	11	73	52–94	15	$P > 0.05$
Patients aged 66–75 years								
Systolic	6	153	122–170	16	150	104–167	23	$P > 0.05$
Diastolic	6	75	64–86	9	78	61–95	12	$P > 0.05$
Patients aged ≥ 76 years								
Systolic	7	147	120–200	31	142	107–182	29	$P > 0.05$
Diastolic	7	73	66–84	7	71	57–79	7	$P > 0.05$

*These differences were nonsignificant using the Bonferroni t-test.

85™ cannot be tested simultaneously with a mercury manometer by means of a Y tube, sequential measurements under the same conditions a few minutes apart should suffice. Periodic retesting for accuracy is good practice.

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ANNOUNCEMENT

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