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Influence of Patient Characteristics on Success of Ambulatory Blood Pressure Monitoring

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Abstract

Study Objective—To examine the influence of specific patient characteristics on the success of ambulatory blood pressure monitoring (ABPM).

Design—Retrospective analysis.

Setting—University-affiliated family care center.

Patients—Five hundred thirty patients (mean age 52.7 yrs, range 14–90 yrs) who were undergoing ABPM between January 1, 2001, and July 1, 2007.

Measurement and Main Results—Specific patient characteristics were identified through an electronic medical record review and then examined for association with ABPM session success rate. These patient characteristics included age, sex, weight, height, body mass index (BMI), occupation, clinic blood pressure, travel distance to clinic, and presence of diabetes mellitus or renal disease. The percentage of valid readings obtained during an ABPM session was analyzed continuously (0–100%), whereas overall session success was analyzed dichotomously (0–79% or 80–100%). Univariate and multivariate regression analyses were performed to examine the influence of patient characteristics on the percentage of valid readings and the overall likelihood of achieving a successful session. In the 530 patients, the average percentage of valid readings was 90%, and a successful ABPM session (≥80% valid readings) was obtained in 84.7% (449 patients). A diagnosis of diabetes was found to negatively predict ABPM session success (continuous variable analysis, $p=0.019$; dichotomous variable analysis, odds ratio [OR] 0.45, 95% confidence interval [CI] 0.23–0.87, $p=0.019$), as did renal disease (continuous variable analysis, $p=0.006$; dichotomous variable analysis, OR 0.39, 95% CI 0.17–0.90, $p=0.027$) and increasing BMI (continuous variable analysis, $p<0.001$; dichotomous variable analysis, OR 0.78, 95% CI 0.65–0.93, $p=0.005$). Renal disease and BMI remained significant predictors in adjusted analyses.

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Conclusion—For most patients, ABPM was successful; however, elevated BMI and renal disease were associated with less complete ABPM session results. Adaptation and individualization of the ABPM process may be necessary to improve results in these patients.

Keywords

ambulatory blood pressure monitoring; ABPM; kidney diseases; diabetes mellitus; body mass index; BMI

The role of ambulatory blood pressure monitoring (ABPM) is well defined. It is recommended in several clinical situations, such as evaluation of “white coat” hypertension, treatment resistance, hypotension, episodic hypertension, and autonomic dysfunction.¹ It has also proved helpful as a guide in the titration of antihypertensive therapy.² Provision of ABPM to patients requires an organizational structure to complete several functions, including patient scheduling, patient education, cuff fitting and monitor setup, report analysis, and recommendation for treatment based on the information obtained from the session. Management of an ABPM service is a role well suited for clinical pharmacists involved in the management of hypertension. An ABPM referral service, codirected by a board-certified family physician and board-certified pharmacotherapist, has been in place at the University of Iowa Family Care Center (Iowa City, IA) since January 1, 2001.^{3–6} This pharmacist-physician collaboration has resulted in successful operation with approximately 600 referrals to the service since its inception.

Although most insurance carriers in the United States do not reimburse for the recommended ABPM indications, ABPM has been approved for reimbursement by the Centers for Medicare and Medicaid Services for patients with suspected white coat hypertension. Automated monitoring with use of ABPM offers several advantages over traditional office-based and home blood pressure monitoring, such as providing a more accurate estimate of a 24-hour blood pressure interval by eliminating observer bias and incorrect technique, allowing for examination of the diurnal blood pressure pattern, and stronger prognostic ability in predicting target organ damage.^{6, 7}

There is potential for the use of ABPM to become even more widespread. However, with routine use of ABPM in all hypertensive patients, a substantial increase in health care costs could occur. It has been estimated that ABPM performed on 3–5 million patients would add \$600 million to the cost of hypertension treatment.⁸ Other cost-effectiveness analyses have proposed that this estimate does not take into consideration the cost savings that ABPM may provide through prevention of unnecessary antihypertensive drug use and reduction in the number of follow-up visits required.⁹

Not all patients with hypertension are candidates for ABPM, and not all candidates for ABPM are able to achieve a large number of valid readings during a 24-hour session. Thus, the potential cost savings afforded by ABPM depends on the ability to identify appropriate patients not only by indication, but also by the individual characteristics that will lead to a high success rate for the session. Although guidelines exist to help clinicians decide which indications may be appropriate for ABPM, we found no information describing specific

patient characteristics that may influence the likelihood of achieving a high percentage of valid readings and, therefore, what would be considered a clinically useful ABPM session.

Since ABPM requires patients to wear a cuff and monitor for 24 hours, encompassing both awake and sleep times, problems may occur that lead to incomplete readings. Proposed standards for ABPM suggest that the number of valid blood pressure readings obtained during a session should be at least 80% of the total number attempted.¹⁰ Furthermore, this threshold is used in clinical trials in which patients are excluded if they obtained fewer than 80% of valid readings during an ABPM session.¹¹ Clinical experience suggests that certain patient characteristics may lead to missed readings and, therefore, unsuccessful ABPM sessions. A priori identification of these patients may assist in controlling health care costs associated with ABPM, as more cost-effective alternatives to ABPM may be used for these individuals. Alternatively, the current processes used for ABPM may be individualized to produce better results for these specific patients. The purpose of this study was to examine the influence of specific patient characteristics on the success of ABPM.

Methods

This study was approved by the University of Iowa institutional review board. All patients who underwent an ABPM session through the University of Iowa Family Care Center ABPM referral service since its inception (January 1, 2001) through July 1, 2007, were included in the analysis. The service processes referrals from both the family medicine and internal medicine outpatient clinics of the Family Care Center. Any patient can be considered for referral by their primary care physician if he or she deems the session clinically indicated. Referrals received for patients with known cardiac arrhythmias (e.g., atrial fibrillation) or dementia are not performed. The 90217 Ultralite ABP monitors (SpaceLabs, Issaquah, WA) were used for each session. Standardized education about the ABPM session is provided to each patient when they meet with the pharmacotherapist to receive the ABP monitor, and the patient is fitted with an appropriate-sized cuff based on arm circumference. After cuff placement, patients rest in a seated position for 10–20 minutes before the monitor is activated to assess the blood pressure reading in the clinic. Most patients are fitted during morning hours between 8:00 and 10:00 A.M., to be worn, ideally, during the patient's routine workday. The monitors are programmed to record a blood pressure reading every 20 minutes during the daytime hours (6:00 A.M.–10:00 P.M.) and every 30 minutes during the nighttime hours (10:00 P.M.–6:00 A.M.).

Patient Characteristics Evaluated

Specific patient characteristics were identified through an electronic medical record review and then examined for association with ABPM session success rate. These characteristics included age, sex, weight, height, body mass index (BMI), occupation, clinic blood pressure, travel distance to clinic, and presence of diabetes mellitus or renal disease. Occupation was divided into four categories: administrative or professional, labor or trade, health care, and other. The group deemed "other" was largely composed of patients who were unemployed, retired, or students. Renal disease was defined as having a documented serum creatinine concentration above 1.4 mg/dl or microalbuminuria of 30 µg/mg of creatinine or greater at

anytime within 12 months before the ABPM session. Diabetes mellitus was defined as having a documented hemoglobin A_{1c} of 7% or greater or two fasting blood glucose levels of 126 mg/dl or greater at anytime before the ABPM session.

Selection of patient characteristics used for the analysis was based on hypotheses and clinical experience of the investigators, as, to our knowledge, no published literature exists discussing this specific topic. Common demographic features, such as age and sex, were selected to provide general information about the study population. Diabetes mellitus and renal disease were examined because they are disease states commonly associated with hypertension. Travel distance and occupation were selected because of their potential association with arm motion, as it is known that excessive arm movement may interfere with the ability of oscillometric ABP devices to accurately record blood pressures.

Data Analysis

Two separate analyses were completed, each using a different definition of ABPM success as the dependent variable. In the dichotomous variable analysis, ABPM success was defined as having at least 80% valid readings in a session. A valid reading occurred when an attempted blood pressure measurement resulted in a recorded blood pressure reading. In the continuous variable analysis, there was no differentiation between successful and unsuccessful ABPM sessions. Instead, the overall percentage of valid readings obtained during an ABPM session was used as the dependent variable, with a higher percentage indicating a more successful session. Univariate regression was used to evaluate the patient characteristics and their potential associations with ABPM success. Significant variables identified in the univariate analysis were then examined in a multivariate approach. A p value of 0.05 or less was considered to indicate a statistically significant association.

Results

The analysis included 530 patients. Table 1 provides the details of the patient characteristics. The average age of the population was 53 years (range 14–90 yrs), and 50% were male. The average BMI was 29.5 kg/m². A diagnosis of diabetes mellitus and renal disease was present in 10.6% and 6.1% of patients, respectively (data for these comorbidities were only available for 490 patients, as 40 of the 530 patients were referred from satellite Family Care Center clinics, and their medical records were not available for review). On average, patients lived 85.8 km (53 miles) from the clinic. Most patients were referred for evaluation of blood pressure while receiving their current regimen, with suspected white coat hypertension as the next most common indication. Occupations varied, with most patients being classified in the group deemed other, which was primarily composed of retirees and students. The mean clinic blood pressure reading before undergoing the ABPM session was 150/83 mm Hg. The average ABPM session duration was 22.4 hours. Successful ABPM sessions (capturing 80% valid readings) were obtained in 449 (84.7%) of the 530 patients, and the average percentage of valid readings obtained was 90% (range 10–100%).

In the dichotomous variable analysis, significantly fewer patients with diabetes experienced a successful ABPM session compared with those without diabetes mellitus (73.1% vs 85.8%, odds ratio [OR] 0.45, p=0.019). Similarly, patients with renal disease experienced

significantly fewer successful sessions compared with patients without renal disease (70.0% vs 85.6%, OR 0.39, $p=0.027$). An increase in BMI of 5 units was also associated with significantly fewer successful sessions (OR 0.78, $p=0.005$). Clinically, this means that a patient with a BMI of 30 kg/m² would have been 22% more likely to experience an unsuccessful session compared with a patient with a BMI of 25 kg/m². No other characteristics were found to have significant associations with ABPM success (Table 2).

In the continuous variable analysis, the same associations were observed, as patients with diabetes obtained significantly fewer valid readings during an ABPM session compared with patients without diabetes mellitus (86.2% vs 90.2%, $p=0.019$). Similarly, those with renal disease obtained only 84.2% valid readings, whereas those without renal disease obtained 90.2% valid readings ($p=0.006$). An increase in BMI of 5 units was also associated with 1.6% fewer valid readings ($p<0.001$). No other associations approached significance (Table 2).

Because of the relationship with BMI, renal disease, and diabetes, a multivariate analysis was performed to assess for confounding associations with these patient characteristics. In the multivariate analyses, the inverse relationship between BMI and ABPM success consistently maintained significance; however, the relationship between renal disease and ABPM success remained significant only in the continuous variable adjusted analysis and not the dichotomous variable adjusted analysis. The association seen with diabetes mellitus and ABPM success lost significance in both adjusted analyses (Table 3).

Discussion

Most patients who underwent ABPM achieved the proposed standard for what is considered to be a clinically valid or successful session. Diabetes mellitus, renal disease, and BMI were associated with less complete ABPM sessions; however, the significance of the association between diabetes and ABPM success was lost after controlling for renal disease and BMI. The association between diabetes and ABPM success demonstrated in the unadjusted analyses is likely due to a confounding association between diabetes and renal disease or diabetes and elevated BMI.

Why a significant association between renal disease and ABPM success was observed is not clear. One plausible explanation may have to do with renal vasculature changes in kidney disease and the effect this has on blood pressure and blood pressure measurement. It has been demonstrated that systemic inflammation in kidney disease affects vascular smooth muscle cells and results in vascular contraction and resistant artery tone.¹² These arterial and vascular changes could interfere with the oscillometric method of blood pressure measurement. To our knowledge, ABP devices are not routinely validated in this population with use of the standards set forth by the British Hypertension Society¹³ or Association for the Advancement of Medical Instrumentation.¹⁴ Our findings suggest manufacturers of the devices should consider subjecting their monitors to further validation studies in this population.

The most important finding of our study was the clear demonstration of an inverse relationship between BMI and ABPM success. This association could be partially explained by the discomfort caused by the cuff. Despite the availability of different cuff sizes, certain body types are not suited for any of the cuffs because of variable arm length and girth dimensions. The most difficult arm to fit properly has a short distance between elbow and shoulder but a wide girth, appearing “cone shaped.” The bladder of the largest cuff will correctly encompass at least 80% of the arm circumference in these circum-stances, but due to the short distance between elbow and shoulder, it will be excessively long. This creates a pinching effect when the cuff is inflated. An ill-fitted cuff may interfere with proper recording of blood pressure measure-ments, and may cause additional blood pressure elevation due to discomfort. Another probable explanation is that the blood vessels of obese patients lie deeper and are surrounded by greater amounts of adipose tissue, thus obscuring the ability of the oscillometric monitor to detect the pressure response in the brachial artery as blood resumes its flow when the cuff bladder is deflated.

We believe our study is the first to examine patient characteristics and their association with ABPM success. Based on our findings, we should not exclude the use of ABPM in patients with renal disease or increased BMI. Instead, as a different approach, ABPM could be adapted for these specific patients. For example, it is possible that the limitations could be overcome by simply having more readings, such as by increasing the frequency of readings or prolonging the session duration beyond 24 hours. Another possibility is whether a shortened session, perhaps as a subset of intermittent periods throughout a 24-hour period, can provide an accurate representation of the patient’s blood pressure.⁵ An advantage in this case may be in reducing patient fatigue and discomfort. Research should be performed to identify the optimum number of blood pressure recordings that will have the greatest sensitivity and specificity in characterizing these patients as having elevated, or normal or controlled, blood pressure. Finally, the production of additional cuff sizes or modification of current design could help improve accuracy.

This study provides interesting and clinically useful results, but there are limitations that should be acknowledged. Among these is the fact that this is a retrospective study, allowing for demonstration of association but not cause. Although multivariate analyses with selected patient characteristics were performed to adjust for confounding relationships, it is possible that other unidentified factors that may influence ABPM success were not examined. One example of an unmeasured factor is the possibility that patients may have purposefully removed the cuff during the 24-hour session for convenience or comfort reasons, leading to missed readings that would not be explained by the factors analyzed in the study. Although possible, our experience is that this behavior is not common, and it is discussed during the education session before beginning an ABPM session.⁴

An additional consideration is the difference in accuracy among ABP monitors. SpaceLabs Ultralite ABP monitors were used in this study; therefore, the conclusions from this study may not be generalizable to devices from other manufacturers. Several individual devices of the same model were used in our study, and it is possible that the individual monitors could have varying levels of internal accuracy. However, the overall effect of these differences is probably limited because of regular testing of each monitor for accuracy and random

rotation in the use of each individual monitor. Finally, given the programming frequency of the monitor readings, the differences in overall percentage of successful readings noted for diabetes and renal disease would be based on a difference of only a few actual readings. With the exception of renal disease in the continuous variable adjusted analysis, these differences did not persist in multivariate analysis, which suggests they may be of minimal clinical importance.

Despite these limitations, the association found between elevated BMI and reduced ABPM success was consistent and persisted throughout several analyses even after varying the definition of ABPM success and controlling of confounding factors. The consistency of the results in each analysis lends support to the robustness of this finding. The large number of subjects in the study also provides strength to the overall results.

Conclusion

We found that although most patients will have successful ABPM sessions, those with elevated BMI or renal disease are likely to have less complete ABPM session results. These findings are important because current guidelines suggest only the indications for which ABPM is useful and do not provide guidance in helping identify which patients may have difficulty achieving the proposed standard for number of valid readings. This has important resource implications for use of ABPM in clinical practice. Additional research is needed to clarify these associations, particularly with renal disease. Specifically, we recommend that future studies pursue validation of ABP monitors in populations with renal disease and obesity, as well as examination of the optimal number of blood pressure recordings or session duration that will best characterize the blood pressure profile in these patients.

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Table 1**Clinical and Demographic Data of the 530 Study Patients**

Characteristic	Value
Valid readings/session, mean (range)	90% (10–100%)
	Mean $\pm$ SD
Age (yrs)	52.7 $\pm$ 15.9
Body mass index (kg/m ²)	29.5 $\pm$ 6.6
Session duration (hrs)	22.4 $\pm$ 3.3
Clinic blood pressure (mm Hg)	150/83 $\pm$ 20/11
Distance to clinic (km)	85.8 $\pm$ 338.4
	No. (%) of Patients
Male	265 (50)
Successful sessions	449 (84.7)
Indication for test	
Suspected white coat hypertension	137 (25.8)
Borderline hypertension	126 (23.8)
Evaluation of blood pressure during therapy	148 (27.9)
Resistant hypertension	64 (12.1)
Other	55 (10.4)
Diabetes mellitus ^a	52 (10.6)
Renal disease ^a	30 (6.1)
Occupation	
Administrative or professional	189 (35.7)
Labor or trade	54 (10.2)
Health care	48 (9.1)
Other	239 (45.1)

^aData were only available for 490 patients (40 of the 530 patients were referred from satellite Family Care Center clinics, and their medical records were not available for review).

Table 2

Association Between Patient Characteristics and Ambulatory Blood Pressure Monitoring Success as a Dichotomous Variable and as a Continuous Variable

Characteristic	Dichotomous Variable: Successful Sessions ^a			Continuous Variable: Overall Percentage of Valid Readings	
	No. (%) of Patients	Odds Ratio (95% CI)	p Value	Mean (%)	p Value
Diabetes mellitus					
Yes (n=52)	38 (73.1)	0.45 (0.23–0.87)	0.019	86.2	0.019
No (n=438)	376 (85.8)	1.0		90.2	
Renal disease					
Yes (n=30)	21 (70.0)	0.39 (0.17–0.90)	0.027	84.2	0.006
No (n=460)	394 (85.6)	1.0		90.2	
Occupation					
Administrative (n=189)	166 (87.8)	1.45 (0.83–2.52)	0.128	91.3	0.125
Labor or trade (n=54)	41 (75.9)	0.63 (0.31–1.29)		87.3	
Health care (n=48)	43 (89.6)	1.73 (0.64–4.64)		89.5	
Other (n=239)	199 (83.3)	1.0		89.7	
Sex					
Male (n=265)	228 (86.0)	1.25 (0.78–2.01)	0.359	90.6	0.234
Female (n=265)	221 (83.4)	1.0		89.4	
		Odds Ratio (95% CI)	p Value	Percent Change	p Value
5-unit increase					
In body mass index		0.78 (0.65–0.93)	0.005	–1.63	<0.001
In systolic blood pressure		0.96 (0.88–1.05)	0.283	–0.27	0.128
In diastolic blood pressure		0.94 (0.83–1.05)	0.352	–0.02	0.945
5-year increase in age		0.98 (0.91–1.05)	0.623	–0.20	0.199
8-km increase in distance		1.00 (0.98–1.05)	0.686	< 0.01	0.947

CI = confidence interval.

^aDefined as having 80% valid readings in an ambulatory blood pressure monitoring session.

Table 3

Results of the Multivariate Analysis: Association Between Patient Characteristics and Ambulatory Blood Pressure Monitoring Success as a Dichotomous Variable and as a Continuous Variable

Characteristic	<u>Dichotomous Variable: Successful Sessions^a</u>		<u>Continuous Variable: Overall Percentage of Valid Readings</u>	
	Odds Ratio (95% CI)	p Value	Mean (%)	p Value
Diabetes mellitus	0.59 (0.27–1.27)	0.177	98.3	0.336
Renal disease	0.44 (0.18–1.10)	0.079	94.6	0.016
5-unit increase in body mass index	0.27 (0.10–0.70)	0.007	–8.24 (percent change)	<0.001

CI = confidence interval.

^aDefined as having 80% valid readings in an ambulatory blood pressure monitoring session.