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The funding sources had no role in the design or conduct of the study; no role in collection, management, analysis, or interpretation of data; no role in preparation, review, or approval of the manuscript; and no role in the decision to submit the manuscript for publication.

Disclosures: Abbott
Northwestern Department of
Medical Education; Abbott
Northwestern Hospital
Foundation – Medical Education
Innovation Fund.

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Application and Effects of Ambulatory Blood Pressure Monitoring in Primary Care

ABSTRACT

Ambulatory blood pressure monitoring is well-recognized as a valuable tool in diagnosing and managing hypertension and is more predictive of cardiovascular events than office or home blood pressure readings. Yet concerns remain, particularly in the United States, about whether ambulatory blood pressure monitoring can be implemented in a primary care practice, be delivered in an efficient manner, and yield influential information. Ambulatory blood pressure monitoring was made available within a 17-physician internal medicine primary care clinic and was utilized for routine blood pressure management. Patients wore the ambulatory blood pressure monitoring device for 24 hours, with readings taken every 20 to 30 minutes. Data were collected on 3,217 patients who underwent ambulatory blood pressure monitoring between January 2013 and October 2016. Of the 3,217 patients who underwent ambulatory blood pressure monitoring, 43% of patients had their blood pressure control status reclassified. Reclassification was not limited to near-normal office blood pressure readings. Among those with systolic blood pressure >160 mm Hg, 38% were reclassified as normotensive. Among those with systolic blood pressure, <130 mmHg, 44% were reclassified as hypertensive. In those with discordant office and ambulatory blood pressure monitoring measurements, 48% had antihypertensive treatment altered. Ambulatory blood pressure monitoring was efficiently implemented in a primary care clinic and was utilized by internal medicine physicians for routine management of blood pressure. Discordance between office blood pressure and ambulatory blood pressure monitoring was common, and nearly equally divided between underdiagnosis and overdiagnosis. Routine use of ambulatory blood pressure monitoring is feasible and has considerable potential to alter the diagnosis of hypertension and impact individual treatment.

KEY WORDS

blood pressure monitoring, ambulatory; hypertension; masked hypertension; white coat hypertension; primary health care

INTRODUCTION

The treatment of hypertension has contributed significantly to the 70% to 80% reduction in strokes and heart attacks seen in the United States since 1972¹. However, antihypertensive therapy as currently practiced in the United States does not completely eliminate the cardiovascular (CV) risk associated with hypertension. Despite antihypertensive treatment, treated hypertensives, compared to normotensive individuals, have a residual CV risk ratio of 1.5.²

While the benefits of treating hypertension directed primarily by office blood pressure (OBP) has been demonstrated in numerous studies, the current treatment paradigm does not account for the hemodynamic burden posed by diurnal variation of blood pressure. Additionally, there is wide interindividual diurnal variability and sleep-time blood pressure change may be normal, increased, decreased, or reversed.³ Prospective studies have shown that mean 24-hour blood pressure is more predictive of subclinical organ damage^{4,5} and CV events^{6,7} than OBP. Furthermore, mean BP during sleep is superior to 24-hour blood pressure mean in this regard.^{8,9}

However, antihypertensive therapy as currently practiced in the United States does not completely eliminate the CV risk associated with hypertension. Despite antihypertensive treatment, compared to normotensive individuals, treated hypertensives have a residual CV risk ratio of 1.5.²

During sleep, blood pressure levels are typically 10% to 20% lower than awake blood pressure levels.

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Reliance on OBP results in overdiagnosis and underdiagnosis of hypertension.¹⁰ In 2011, the National Institute for Health and Clinical Excellence in the United Kingdom recommended that all adults with an elevated OBP be offered ambulatory blood pressure monitoring (ABPM) to reduce unnecessary antihypertensive drug therapy.¹¹ More recently, in 2015, the US Preventive Services Task Force “found convincing evidence that ABPM is the best method for diagnosing hypertension” and recommended ABPM as the reference standard for diagnosing hypertension.¹² In addition to improving the accuracy of the diagnosis of hypertension, ABPM more reliably assesses the response to antihypertensive therapy.¹³ Despite the above, current primary care management continues to rely on OBP.¹⁷

Notwithstanding widespread evidence and recommendations, perceived barriers to ABPM remain in the United States, including apparent cost and logistical issues.¹⁸ What follows is a description of the development, institution, and impact of an ABPM program within a medium-sized primary care internal medicine practice.

■ METHODS

In January 2013, a 24-hour ambulatory blood pressure monitoring program was implemented in a 17-physician primary care internal medicine practice located in suburban Minneapolis, MN. The practice is affiliated with the Abbott Northwestern Internal Medicine Residency Program. Access to ABPM was made available to all physicians in the group and each individual physician could utilize the test as he or she saw fit. Funding for the startup of the ABPM program was made available through a hospital nonprofit foundation. There was no financial charge to the patients presented in this report. The project was undertaken as a quality improvement project within the clinic, and institutional review board approval was waived.

Office Blood Pressure Measurement

Office blood pressure measurements were obtained on patients as part of routine vital signs during each office visit. A certified medical assistant (CMA) obtained a single OBP using an aneroid sphygmomanometer (Tycos; Welch Allyn, Skaneateles Falls, NY) after the patient was seated with feet flat on the floor for approximately 3 to 5 minutes. This OBP was intended to represent “real-world” OBP and no special procedures beyond the clinic’s standard protocol were followed. Repeat measurements were at the discretion of the CMA or physician. If more than one reading was obtained, the last reading recorded was entered in this data set. The office blood pressure reading was defined

as elevated if systolic blood pressure (SBP) was ≥ 140 mm Hg or diastolic blood pressure (DBP) was ≥ 90 mm Hg.

Ambulatory Blood Pressure Measurement

Ambulatory blood pressure monitoring was performed using an ambulatory blood pressure monitor (Ambulo 2400; Mortara Instrument, Milwaukee, WI) with organization and interpretation of data utilizing hypertension diagnostics suite software (Mortara Instrument). This ABPM device has been independently validated by the American Academy of Measurement Instrumentation and the British Hypertension Society. For ABPM testing, a CMA configured the device on a dedicated laptop computer. Patients with atrial fibrillation were included in this study. Test duration was 24 hours. Blood pressure was obtained every 20 minutes from 7:30 am to 10:30 pm and every 30 minutes from 10:30 pm to 7:30 am. The device was configured so that the measurement was not immediately displayed to the patient.

Physicians placed an order for ABPM in the electronic medical record and patients scheduled their test with the clinic front desk staff. Patients returned at their scheduled time and met with a CMA for device placement. Circumference of the patient’s upper arm was measured by the CMA and an appropriate cuff size selected. Cuff sizes accommodated arm circumferences ranging from 13.8 to 46 cm; patients were excluded if their arm circumference was outside this range. The patient chose 1 of 3 options for holding the device, including a belt clip, neck lanyard, or a self-contained cuff holder; most patients selected the self-contained cuff and device holder. Following device placement, and with the patient seated in the exam room, the CMA manually triggered the device to obtain a blood pressure reading to confirm proper device function. An informational card was given to each patient that included instructions, basic rationale for the test, and a phone number to call if they had problems with the device. Patients logged sleep times and whether they paused or removed the device. Patients were instructed to perform their usual daily activities, but were asked to remove the device during vigorous physical exercise. Actigraphy was measured throughout the 24-hour period by a movement counter housed within the ABPM device. At the end of the 24-hour period, patients either removed the device themselves and dropped it off at the clinic front desk or they were brought into an exam room and a nursing assistant removed the device. A CMA then uploaded data into the computer and prepared data for physician review. See Appendix A for additional methodologic details related to maintenance and management of the ABPM devices.

TABLE 1 Baseline characteristics prior to undergoing ABPM (n = 3,217).

| Characteristic | |
|-----------------------------------|--------------|
| Average age, y (range) | 64.8 (20–98) |
| Women, n (%) | 1734 (53.9) |
| BMI, kg/m ² (range) | 28.7 (15–59) |
| BMI ≥30, % | 37.0 |
| DM, n (%) | 328 (10.2) |
| Current smoker, n (%) | 84 (2.6) |
| Coronary artery disease, n (%) | 445 (13.8) |
| Antihypertensive treatment, n (%) | 1972 (61.3) |

Elevated ABPM was defined based on existing literature: mean sleep time SBP of ≥120 mm Hg, mean sleep time DBP ≥75 mm Hg, mean awake SBP ≥135 mm Hg, or mean awake DBP ≥85 mm Hg.¹⁹ An ABPM test was considered valid for blood pressure management if there were at least 7 sleep-time readings or at least 13 awake readings.²⁰ An interpreting physician (MKC or DPI) evaluated the quality of the data to confirm a valid study and also summarized relevant data into a report for the ordering physician.

Establishing the Sleep-Time Window

To determine the sleep-time window, an integrated diary and actigraphy method was used. The reviewing physician utilized a patient diary, computer algorithm–

derived information, as well as visual inspection of actigraphy data. The diary guided the general timeframe for the patient’s sleep-time window and the interpreting physician then integrated the actigraphy data by reviewing algorithm-derived recommendations (from the ABPM software) and through visual inspection of the data.

RESULTS

A total of 3,386 patients underwent ABPM testing between January 2013 and October 2016. Of those, 3,256 had an adequate number of readings for a valid ABPM study and from those, 3,217 had sufficient clinical and demographic information in their medical record for inclusion in the data analysis. Baseline characteristics are presented in **Table 1**. The age range was broad and an equivalent number of men and women were tested; 61% were on antihypertensive therapy.

Hypertension diagnosis reclassification data are presented in Figure 1. Reclassification occurred in 43%, and this number was nearly equally divided among those who were reclassified from normotensive to hypertensive and from hypertensive to normotensive. Medication treatment status did not alter these numbers.

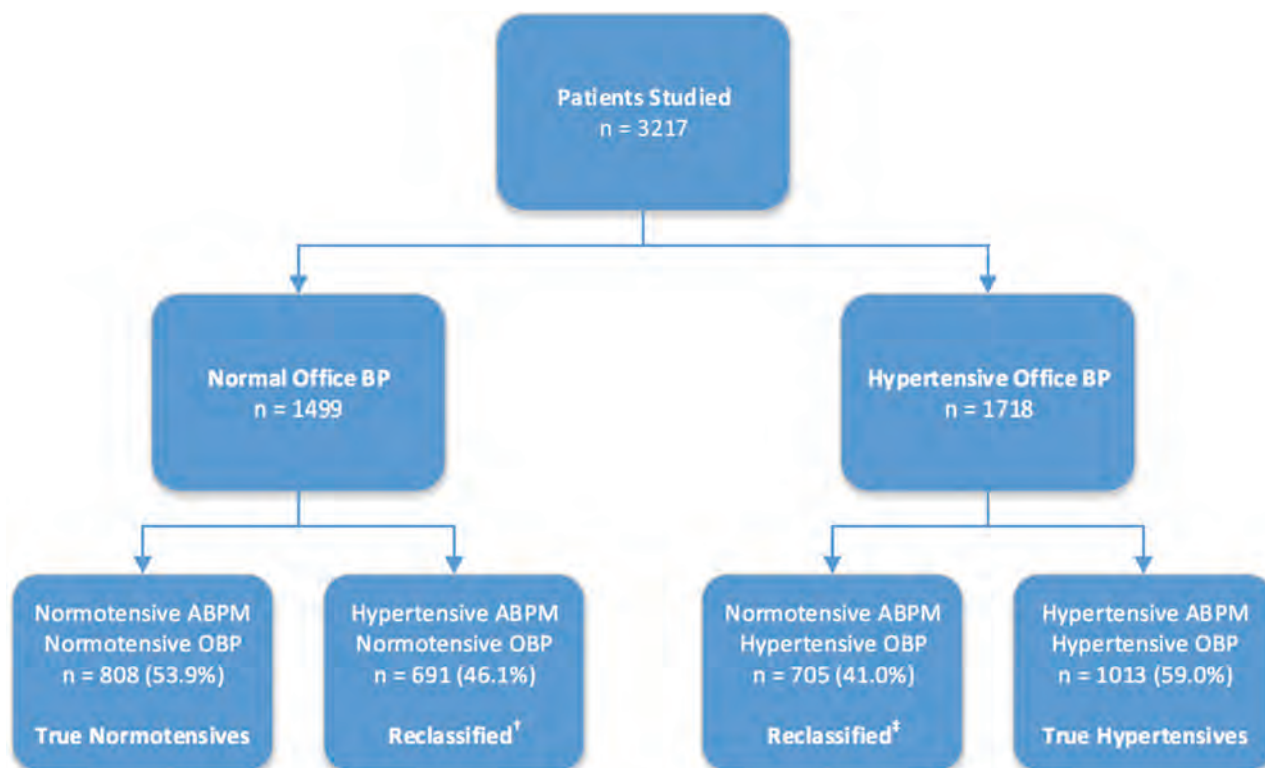


FIGURE 1 Blood pressure control status following ABPM.

† Reclassified to hypertensive following ABPM (masked effect).

‡ Reclassified to normotensive following ABPM (white-coat effect).

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TABLE 2 Reclassified to hypertensive.

| | Office Systolic Blood Pressure | |
|---|--------------------------------|--------------------------|
| | <130 mm Hg n = 869 | 130–139 mm Hg n = 783 |
| On BP therapy hypertensive ABPM, n (%) | 263 (41.8) | 223 (48.7) |
| Not on BP therapy hypertensive ABPM, n (%) | 121 (50.4) | 186 (57.2) |

Results from the ABPM were discordant with OBP readings across a wide range of OBP readings (Tables 2, 3). For example, of individuals not on antihypertensive medication with systolic OBP readings of 150 to 159 mm Hg, 36% were reclassified as normotensive after ABPM. Conversely, among individuals not on antihypertensive medication with a systolic OBP of <130 mm Hg, 42% were reclassified as hypertensive after ABPM. Similar discordance was seen among individuals on antihypertensive medication.

A total of 48% of patients with discordance between their OBP and ABPM had their antihypertensive treatment altered following reclassification. Table 4 summarizes the impact of reclassification on treatment.

In this dataset, 5% of patients did not tolerate wearing the ABPM device and either declined to wear it after the initial clinic measurement or removed the device within 3 hours. Excessive cuff tightness was reported in 20% of patients and was the most common reason a patient removed the device. Uncommon adverse effects included contact dermatitis (0.5%) and arm bruising (0.1%). Moderate sleep disturbance (waking 3–6 times) was reported in 30% of patients, but only 5% experienced sleep disruption severe enough to remove the device until morning.

Total initial costs, including 2 devices and a dedicated laptop computer, were around \$6,000. This allowed performance of 1 or more ABPM studies daily. The 2 main expenses associated with performing an individual ABPM study are setup time for the CMA and the physician's time to read and interpret the test. These ongoing costs for ABPM were approximately \$50 per study in our setting.

Over the 2-year period, 85% of patients returned their devices within 1.5 hours of their scheduled dropoff time, 95% within 2.5 hours, and 99% within 6 hours. No devices were lost, stolen, or destroyed.

■ DISCUSSION

Ambulatory blood pressure monitoring has not been routinely incorporated into primary care in the United States¹⁷; consequently, the disease of hypertension continues to be defined and managed by OBP. Yet,

TABLE 3 Reclassified to normotensive.

| | Office Systolic Blood Pressure | | |
|---|--------------------------------|-----------------------------|--------------------------|
| | 140–149 mm Hg n = 764 | 150–159 mm Hg n = 445 | >160 mm Hg n = 356 |
| On BP therapy normotensive ABPM, n (%) | 193 (46.0) | 94 (40.0) | 85 (37.0) |
| Not on BP therapy normotensive ABPM, n (%) | 157 (45.6) | 76 (36.2) | 49 (38.9) |

OBP has a sensitivity and specificity of 75% compared to the gold-standard ABPM.¹⁰ Our study demonstrates that a medium-size internal medicine practice can successfully implement ABPM and that internists' use of ABPM impacts blood pressure management.

Office and Ambulatory Blood Pressure Discordance

Considerable discordance was demonstrated between casual OBP and 24-hour ABPM. A total of 43% of patients had their blood pressure control status reclassified following ABPM, potentially avoiding overtreatment or undertreatment of hypertension.

Importantly, discordance between OBP and ABPM was not limited to patients with “borderline” systolic OBP readings of 135 to 145 mm Hg. On the contrary, of those with office SBP <130 mm Hg or >149 mm Hg, 44% and 38%, respectively, were reclassified following ABPM. These findings suggest that decisions based on a single OBP will lead to overtreatment or undertreatment of a very large number of patients. Utilization of ABPM is essential to mitigate this potential, even when OBP readings are significantly higher or lower than 140/90 mm Hg.

Overtreatment

The prevalence of white-coat hypertension (elevated OBP, normal ABPM) among presumed hypertensive patients is typically between 15% to 30% in large, population-based studies.²⁴ In our study, among patients not on hypertension treatment, 20% were reclassified as normotensive following ABPM. Of these patients, 90% were not started on a medication and thus avoided unnecessary treatment.²⁵

Undertreatment

Untreated masked hypertensives (normal OBP, elevated ABPM) are at increased risk for CV disease.²⁶ Within our dataset, 25% of patients not on antihypertensive medication were reclassified as hypertensive following ABPM. Among these masked hypertensive patients, 57% were started on a medication, potentially lowering their CV risk.

TABLE 4 Impact of reclassification on treatment.

| | | Medication Started/ Changed, n (%) | Medication Decreased*, n (%) | Medication Increased**, n (%) |
|--------------------------|-------------------------------------|---------------------------------------|---------------------------------|----------------------------------|
| Not on BP Therapy | Hypertensive OBP, normotensive ABPM | 276 (89.6) | N/A | 32 (10.4) |
| On BP Therapy | Hypertensive OBP, normotensive ABPM | 313 (81.7) | 31 (8.1) | 39 (10.2) |
| Not on BP Therapy | Normotensive OBP, hypertensive ABPM | 105 (43.0) | N/A | 139 (57.0) |
| On BP Therapy | Normotensive OBP, hypertensive ABPM | 124 (26.9) | 21 (4.6) | 316 (68.5) |

*Medication discontinued or dose decreased.
**Medication added, dose increased, or dose timing altered.

Residual Risk

Hypertension treatment in the United States does not completely eliminate CV risk and leaves treated hypertensive patients with an elevated residual risk ratio of 1.5 from hypertension.² Undertreatment of hypertension due to reliance on OBP could explain some portion of this residual risk. Specifically among our patients, 20% of treated hypertensives with normal OBP were reclassified as hypertensive, of whom 69% had a medication added, medication dose increased, or dosage timing changed, potentially reducing their CV risk. In addition to improving the accuracy of the diagnosis of hypertension, ABPM more reliably assesses the response to antihypertensive therapy.¹³ While there have been no head-to-head trials comparing antihypertensive treatment directed by OBP to antihypertensive therapy directed by ABPM, the large 2010 Ambulatory Blood Pressure Monitoring for Prediction of Cardiovascular Events (MAPEC) MAPEC trial demonstrated that antihypertensive treatment based on ABPM and directed toward decreasing sleep-time blood pressures resulted in a 4% absolute risk reduction of CV events and a 1.5% absolute risk reduction in all-cause mortality.^{14,15} Importantly, among our patients, 20% of treated hypertensives with normal OBP were reclassified as hypertensive, of whom 69% had a medication added, medication dose increased, or dosage timing changed, further reducing their residual CV risk.

Costs and Reimbursement

Cost has been cited as a barrier to implementation of ABPM in primary care.^{18,27} In our study, startup and maintenance costs were modest. While ABPM reimbursement was not addressed in our study, in a recent review, it was reported that Medicare reimbursed 68% of ABPM claims. In addition, nongovernment insurers have recently expanded indications.^{23,24}

Limitations

Patients who underwent ABPM in this study were predominantly from the southwestern suburbs of the Minneapolis/St. Paul metropolitan area and may not be representative of all cross-sections of the population. Although the measurement protocol for casual OBP used in this study was not as stringent as is used in many

clinical trials,^{8,10} this is likely reflective of “real-world” primary care practices.

Some electronic blood pressure measuring devices list atrial fibrillation as a “contraindication” for use and most 24-hour ABPM studies exclude patients with atrial fibrillation.²⁵ Patients with atrial fibrillation were included in this study, which could raise concerns about the validity of ABPM readings in a small subset of patients. However, when studied, oscillometric blood pressure measurement has been shown to have similar reliability whether a patient is in sinus rhythm or chronic atrial fibrillation. Pagonas et al.²² compared oscillometric measurement of upper arm blood pressure to invasive measurement of blood pressure under controlled settings and found intraindividual variability to be at an acceptable level. Similar reliability of ABPM readings was seen by Giantin et al.²³ comparing ABPM use in patients with atrial fibrillation to those in sinus rhythm. Given the prevalence of atrial fibrillation, inclusion of these patients may actually bolster the generalizability of this study.

Lastly, patients in this study were not randomly selected; rather, an internal medicine physician, for whatever reason they deemed appropriate, ordered ABPM for their patient. Inherent limitations exist in a non-randomized longitudinal study such as this, contributing imprecision to the generalizability. Yet, despite these limitations, this study is large, novel, and relevant to primary care because, contrary to substantial medical evidence, OBP alone continues to direct blood pressure management.¹⁷

CONCLUSION

This study demonstrates that an ABPM program can be implemented and utilized for routine blood pressure management within a medium-sized internal medicine primary care clinic. Discordance between casual OBP and ABPM is common and leads to frequent reclassification in the status of patients’ blood pressure control. This in turn reduces the potential for both overtreatment and undertreatment of hypertension. Though reimbursement remains inconsistent, startup and maintenance costs for ABPM are reasonable and, considering the observed diagnostic and treatment

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benefits of ABPM, compelling reasons exist to utilize ABPM in primary care clinics.

■ ACKNOWLEDGMENTS

The authors would like to thank Brad Zellar, writer and editor at Nocturnal Dynamo, Inc., and Tracy L. Ingham, NP-C, Department of Internal Medicine, Lakeview Clinic, for their critical appraisal of the manuscript; and Shelley Shephard, PharmD, lead pharmacist for Abbott Northwestern General Medicine Associates, for her assistance with data collection and entry. None of these individuals were compensated for their assistance.

Author Contributions: Drs. Ingham, Cummings, and Rosborough had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest: None.

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■ APPENDIX A

Scheduling

ABPM duration was 24 hours, but uploading data, cleaning cuffs, and possible late-return of a device limited how often a device could be used. Therefore, a 32-hour turnaround time was used for scheduling devices in order to minimize risk of a device not being available for a scheduled patient.

Point Person

A physician (DPI) filled the role of point person to maintain the ABPM devices, the ABPM computer, and to troubleshoot various problems that arose. The point person also coordinated logistics with front desk staff, clinical staff, and the office manager.

Cuff Cleanliness

The cuffs and devices were cleaned following each patient with germicidal disposable wipes (Sani-Cloth AF3; PDI Healthcare, Hamilton, NJ). A hypoallergenic detergent (Dreft; Procter & Gamble, Cincinnati, OH) was used approximately every 4 weeks on the fabric cuff to remove odor. To accomplish this, the tube of the blood pressure bladder was clamped with a hemostat and the cuff was soaked in a solution of detergent for 15 to 20 minutes and then air-dried.

Device Calibration

Device calibration was performed at 6-month intervals using a “Y” tube adapter to simultaneously connect the ABPM device to a mercury sphygmomanometer and to a single-tube blood pressure cuff. The cuff was

then placed over a person’s arm and the ABPM device was activated. Calibration was confirmed if the ABPM device and the mercury sphygmomanometer gave the same measurements, ± 3 mm Hg.

Device Energy Source

The ambulatory blood pressure monitoring devices were powered with AA rechargeable batteries. These batteries were charged with commercial chargers (V-6988; Tenergy Corp., Fremont, CA, or a SL00056; SunLabz, New York, NY). Following charging, batteries were tested using a digital readout battery tester (BT-168D; HK Manufacturing, Hong Kong, China) to confirm a charge >1.30 mV, which was adequate to provide more than 24 hours of readings.

Patients with Sensitive Skin

For patients with a history of skin sensitivity or dermatitis, a cotton stockinette was placed beneath the cuff to decrease the chance of developing a reaction. Available literature suggests that this thin barrier should have little to no impact on the accuracy of blood pressure readings.²⁹

Queries for mhij-01-02-04

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