Why Is It That We Continue to Deny Patients Ambulatory Blood Pressure Monitoring?

Eoin O’Brien

Why have we become the slaves of evidence-based medicine at the cost of abandoning deductive reasoning? Aristotle would have been happy to accept the deductive proposition that multiple measurements of a physiological phenomenon, which is subject to marked variability, are likely to be superior to a single measurement. And yet we, as clinical scientists in hypertension, have supported the latter concept in favor of the former for the best part of a half-century! Our scientific successors may judge us leniently, at least in part, by virtue of the fact that we were victims of an age in which scientific fashion (for want of a better word) was besotted with the need for evidence. But we will not be forgiven for allowing the prejudices that thrived during the latent period of gathering evidence to render us impotent when that evidence arrived in overwhelming abundance.

I am referring, of course, to what will be seen in hindsight as the debacle of blood pressure (BP) measurement. Our failure to act decisively on the fundamental principle of measurement will be to the detriment of countless thousands who might have been saved from the ravages of hypertension, now dubbed the largest epidemic ever known to mankind. Indeed, it was deductive rather than evidence-based reasoning that motivated the following statement from my department nearly 30 years ago: “Faced with a patient with borderline hypertension, the doctor should be slow to diagnose hypertension until some attempt has been made to categorize the behavior of BP over time: ambulatory BP measurement is the best way to do this.”

One of our greatest shortcomings as scientists is undoubtedly our failure to insist that all diagnostic and treatment decisions should be dependent on 24-hour ambulatory blood pressure monitoring (ABPM). I will support this contention by examining the recommendations from the US Preventive Services Task Force (USPSTF), which have been published recently. These publications have carefully examined the evidence as to which method of BP measurement will be to the detriment of countless thousands who might have been saved from the ravages of hypertension, now dubbed the largest epidemic ever known to mankind. Indeed, it was deductive rather than evidence-based reasoning that motivated the following statement from my department nearly 30 years ago: “Faced with a patient with borderline hypertension, the doctor should be slow to diagnose hypertension until some attempt has been made to categorize the behavior of BP over time: ambulatory BP measurement is the best way to do this.”

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USPSTF Recommendations

The USPSTF was created in 1984 as an independent, volunteer panel of national experts in prevention and evidence-based medicine. Since 1988, the Agency for Healthcare Research and Quality has been authorized by the US Congress to convene the Task Force and to provide ongoing scientific, administrative, and dissemination support to the Task Force to enable it to fulfill its mission to improve the health of all Americans by making evidence-based recommendations about clinical preventive services, such as screenings, counseling services, and preventive medications. Recommendations are based on a rigorous review of existing peer-reviewed evidence, and they are intended to help primary-care clinicians and patients decide together whether a preventive service is right for a patient’s needs. Each year, the Task Force makes a report to Congress that identifies critical evidence gaps in research related to clinical preventive services and recommends priority areas that deserve further examination. In an effort to make the USPSTF recommendations clearer and its processes more transparent, the Task Force posts and invites public comment on its draft Recommendation Statements before publication in a peer-reviewed journal. Given this provenance, the recent recommendation of the USPSTF on the best methodology for BP measurement is likely to be a major influence on clinical practice in the United States.

There have been 3 phases in the USPSTF process.

Phase I. Review of the Literature

When the USPSTF last made recommendations on BP measurement in 2003, it did not address either ABPM or HBPM, as these topics were identified as evidence gaps to be addressed in future systematic reviews. So just over a decade later the USPSTF has diligently reviewed 19309 abstracts and 1171 full-text articles addressing BP measurement. The review was conducted by the Kaiser Permanente Research Affiliates Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality. The detail of the review process, which was published early in 2015, concludes in the Abstract to the article that “evidence supports ABPM as the reference standard for confirming elevated office BP screening results to avoid misdiagnosis and overtreatment of persons with isolated clinic hypertension.”

Phase II. Posting of Recommendation

The second phase in the USPSTF process was posting the recommendation on the USPSTF website inviting public

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comment, and this was done during 2014 to 2015 with the following grade A (highest category) statement: “The USPSTF recommends screening for high BP in adults aged ≥18 years. Ambulatory BP monitoring is recommended to confirm high BP before the diagnosis of hypertension, except in cases for which immediate initiation of therapy is necessary.”

Phase III. Publication of Recommendation
The final phase in the process was publication of the USPSTF recommendations in late 2015. Screening for High BP in Adults: USPSTF Recommendation Statement was published in the Annals of Internal Medicine, with the full project strategy being available on the USPSTF website. Because of the comprehensive review process conducted by the Kaiser Permanente Research Affiliates Evidence-based Practice Center and the influential weight of the USPSTF on clinical practice in the United States (and much further afield), it is important to examine carefully the substance of this publication. The article justifies the need to examine the issue of BP measurement by enumerating the dismal consequences of hypertension for US citizens and for the government that has to support the cost of what is largely a preventable disease, or at least, one that can be treated to prevent its enormous cardiovascular and fiscal impact on society. High BP is a prevalent condition in the United States, affecting ≈30% of the adult population. Of these, nearly 20% are unaware that they have hypertension, and 76% are on BP-lowering medication with only 53% achieving BP control as defined by a BP of <140/90 mm Hg (by an undeclared measurement technique!). The consequences of hypertension are of such a magnitude that, as is so often the case with major international calamities, the repetitive impact of the horrendous statistics dulls their meaning. Elevated BP is the largest contributing risk factor to all-cause and cardiovascular mortality, and it is a major contributor to heart attack, stroke, and congestive heart failure. In 2010, high BP was listed as a primary or contributing cause of death for >362,000 Americans. In 2009, the estimated direct medical cost of treating hypertension in the United States was $47.5 billion, with prescription medications accounting for 45% of the costs ($21.4 billion). In 2010, there were 280,000 hospitalizations with a first-listed diagnosis of essential hypertension and >55 million physician office, emergency department, and outpatient visits with hypertension as the primary diagnosis code.

Turning to the important issue of determining the best methodology to measure BP in adults in primary care, the USPSTF acknowledges at the outset, that OBPM is a flawed and inaccurate method of measuring BP: “The disadvantages of diagnosing hypertension solely in the office setting include measurement errors, the limited number of measurements that can be made conveniently, and the confounding risk for isolated clinic hypertension.” However, the review also acknowledges that automated office blood pressure, which is an average of multiple automated measurements taken while the patient is alone in a room, may yield results similar to those of daytime ABPM. The introduction of automated office blood pressure as a technique to remove the inaccuracy of conventional BP measurement is a welcome innovation and the recent use of automated office blood pressure in the Systolic Blood Pressure Intervention Trial (SPRINT) study has added greatly to the robustness of the results of the study. The technique, cannot, of course provide night-time BP as with ABPM. Moreover, the cost effectiveness and practicality of applying automated office blood pressure in primary care and in other healthcare settings, such as hospital clinics, awaits further evaluation.

The question remaining to be answered by the USPSTF was straightforward—is ABPM superior or inferior to HBPM? This question has been answered emphatically, first in the published review, and second in the unequivocal statement for public comment cited earlier. Moreover, in the published recommendation there are repeated statements attesting to the superiority of ABPM over HBPM.

How is it then, one must ask, that in the face of the overwhelming evidence for ABPM to be the method of BP measurement in primary care, this recommendation is not even mentioned in the abstract of the final article, which is the first and probably only piece that will be read by busy general practitioners, and media reporters. Instead, the abstract states: “The USPSTF recommends obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment.” One has, therefore, to express concern as to how this came about. A possible explanation may be found in the statement relating to the public comments received on the draft version: “The USPSTF acknowledges the current barriers to implementation of its recommendation, including the availability and affordability of ABPM. In response, it revised the final recommendation to include HBPM as an alternative method for confirmation of a diagnosis of hypertension when ABPM is not feasible. The USPSTF also provided more information on the implementation of diagnostic confirmation and industry standards for home BP monitors.” This statement is difficult to reconcile with the fact that there was no need to revise the final recommendation to include HBPM as this methodology is included as an a priori feature of the project. Could other influences have prompted the omission of ABPM from the summary recommendation? Whatever the answer to this question, it is, I think, important, albeit belatedly, to suggest that a more appropriate recommendation should read: “The USPSTF recommends obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment, and recommends ABPM as being the best for doing this, but if this is not available or suitable, HBPM is a reasonable alternative.”

Such a recommendation would also be in keeping with the 2015 Canadian Hypertension Education Program (CHEP) recommendations for the diagnosis and assessment of hypertension which states: “For patients with elevated office readings, CHEP is recommending early use of out-of-office BP measurement, preferably ambulatory BP measurement, in order to identify early in the process those patients with white-coat hypertension.”

USPSTF Recommendation in the Context of European Recommendations

UK NICE Recommendations
The USPSTF recommendation is in essence identical with the UK NICE recommendation published in 2011, and this concurrence of international opinion is acknowledged by
the statement: “Despite some methodological differences between our reviews, the NICE report concluded that ABPM was most often the best predictor of clinical outcomes…. The report further stated that obtaining multiple BP measurements away from the clinic setting (potentially including HBPM, despite sparse data) is the best predictor of BP-related clinical outcomes. It also recommends offering ABPM (or HBPM if ABPM is declined or not tolerated) after an elevated BP measurement ≥140/90 mm Hg….” NICE not only performed a detailed survey of the relevant literature on measurement techniques but also conducted a comprehensive cost/benefit analysis (which was not in the remit of USPSTF) and concluded that ABPM was more cost effective than either OBPM or HBPM.13 The cost effectiveness of ABPM derives from 3 substantial benefits: first, the technique identifies white-coat hypertension in some 20% of patients, who would have been diagnosed as hypertensive on OBPM, and thereby prevents unnecessary and costly medication being prescribed; second, masked hypertension is identified in some 10% of the population, who would have been diagnosed as normotensive on OBPM, and thereby denied the BP-lowering medication to prevent future cardiovascular events; and third, in treated patients, in whom OBPM might be normal, ABPM may reveal masked uncontrolled hypertension, which carries serious adverse consequences, especially for high-risk patients.5 To explore the cost effectiveness further, Lovibond et al13 compared CBPM, HBPM, and ABPM using a hypothetical cost-effectiveness model of a primary-care population aged ≥40 years with a screening blood pressure measurement >140/90 mm Hg and risk-factor prevalence equivalent to the general population. They concluded unequivocally that when ABPM was performed as a diagnostic strategy for hypertension in patients who had had an initial raised reading with OBPM, misdiagnosis would be reduced with cost savings, and that the additional costs for ABPM would be offset by those from better targeted treatment. On the basis of this analysis, the authors of this study recommend ABPM before starting antihypertensive drug treatment in hypertensive patients.11

European Society of Hypertension Position Paper on ABPM
In 2013, 34 international experts in BP measurement carefully assessed the literature on ABPM and concluded that “ABPM should be performed whenever possible in all patients with suspected hypertension in whom it is necessary to confirm the diagnosis of sustained hypertension (ie, to exclude white-coat hypertension), to assess the severity of hypertension throughout the 24-hour period, to detect nocturnal hypertension, to detect patterns of BP behavior such as isolated systolic hypertension, nondipping, and autonomic failure….13” In relation to HBPM, the conclusion was that ABPM was more appropriate for the initial evaluation, because it provides information within 24 hours and without need for training, and commitment, as required for HBPM but that when ABPM was not readily available, HBPM was a reasonable alternative. However, one of the problems with HBPM is that the procedure is often not defined. The ESH Position Paper was careful to stipulate that HBPM required duplicate morning and evening measurements for 7 days with averaging of the past 6 days after discarding the first day of measurement, so as to obtain a measurement approximating to average daytime ABPM.5 This procedure may be considered onerous in comparison with a 1-day ABPM, which also provides nocturnal BP levels.

Conclusions
It is time to move away from the all-too-comfortable notion that BP measurement is arrived at as easily as weighing a stone of potatoes, or estimating total cholesterol. We know, and have known for nearly half a century, that, more often than not, the measurement of BP is not only inaccurate but also downright misleading. Not alone have we demonstrated the inaccuracy of so-called office BP but we have shown that serious errors in diagnosis, prognosis, treatment, demographic assessment, and national apportionment of resources are inevitable unless BP is measured over time, preferably with ABPM. Now, we have the Magic Grail—the evidence! Why then we might ask, is ABPM not as readily available to patients with hypertension as an ECG is to patients with chest pain? The recommendations from the United States and Canada and from NICE and the ESH in Europe are so overwhelming that change must surely ensue. If this does not happen, we stand culpable as clinical scientists, which is bad enough, but it may not be long before we are found wanting in another forum for failing to provide a methodology of measurement that carries diagnostic and management benefits of immense magnitude for all hypertensive patients.14

Disclosures
I have advised and validated blood pressure measuring devices for several device manufacturers.

References


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