



Discussion Summary

Utility of Wrist and Finger Blood Pressure Devices in the Management of Hypertension

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High-level Overview

Hypertension is a global health problem. Left uncontrolled, hypertension can cause damage to blood vessels and, consequently, the brain, kidney, liver, and heart. One key to management of hypertension is monitoring of blood pressure in the home, away from the clinical setting. For years, upper arm cuff-based measurement devices have been the standard for patient self-monitoring. However, some patients may not find them convenient or comfortable to use and instead use wrist or finger cuff devices. It is important to learn the impact and reliability of such devices and their role in managing hypertension in the population to improve outcomes.

Featured Experts

Steven Yarows, MD - Physician at IHA

JORDANA COHEN, MD, MSCE - Assistant Professor of Medicine and Epidemiology at University of Pennsylvania

Bruce Alpert, MD - Retired Pediatric Cardiologist at UTHSC

Sarah Melville - Translational Research Associate at Dalhousie Medicine New Brunswick (DMNB)/ CardioVascular Research New Brunswick (CVR-NB)

Vivek Bhalla, MD - Director, Stanford Hypertension Center at Stanford University

Richard Dart, MD - MD at Denver Health/University of Colorado

Alberto Avolio - Professor at Macquarie University

Jan Basile, MD - Professor of Medicine at Medical University of South Carolina

James Shaman, PhD - Senior Research Fellow at University of Tasmania

Keith Brunt, PhD - Associate Professor at Dalhousie University Faculty of Medicine

J. Byrd, MD, MS, FAHA, FACC - Assistant Professor of Medicine at University of Michigan Medical School

Featured Moderators

Raj Padwal, MD - Director, University of Alberta Hypertension Clinic at University of Alberta

Summary

- Consensus is that validation is essential and that more needs to be done to help individuals understand the importance of validation, alert consumers/patients/providers to what is validated and what is not, and advocate for regulators to increase oversight of this critically important issue. There is also an urgent need to have a global validated device registry.
- In certain niche cases, where an upper arm cuff cannot be placed, a wrist device may be useful as a substitute.
- The group questioned whether it is acceptable for product manufacturers to claim that BP devices screen blood pressure, then have a disclaimer that it is for recreational purposes only.
 - Until congress changes the 510(k) Law it is legal to misrepresent in this manner. It is important for industry thought leaders and clinicians to rally and demand that congress modify this law.
 - Submitting complaints to the FDA and FTC may be a beneficial next step. However, it is unlikely that they will act unless they receive a large amount of protests.
 - FTC "Reasonable Basis" Requirement, and Complaint Link:
<https://www.ftccomplaintassistant.gov/GettingStarted?NextQID=275&%3BUrl=%23%26panel1-9#crnt>
- The group also expressed their concerns as to why new devices for monitoring blood pressure have not been developed.
 - Much of the problem comes from the huge variation in large artery hemodynamics between individuals that may occur with ageing and disease (pressure and flow dynamics from different heart rate, stroke volume, arterial diameters/stiffness). Standard algorithms aren't sophisticated enough to deal with this variation and predict BP with accuracy. I think you are right to suggest that combinations of other methods could help create descent new BP devices.
 - It's hard to measure blood pressure without a cuff. i.e. it's a surrogate, rather than an actual measurement. Most device companies utilize the pulse wave velocity, however captured, and train an algorithm based on known relationships between this tracing and the pressure in the blood. however, a cuff measures a physical parameter of pressure.
- There is an overall agreement that a single organization is needed to provide a list of validated devices.
- There was question on which validation protocol should be used.
 - If BP was the same between the central and peripheral large arteries within an individual there would be less issue of finding the best validation protocol.
- There is less disagreement on the set of validation criteria, however, there may be a need for different protocols. For example, if a company is making changes to what a device yields or how it operates.
- The group feels that organizations should partner with the AMA to launch the Validated Device List for US-based clinicians and patients.
- Individuals choose to monitor their blood pressure for a gamut of reasons. Some are using these devices as a preventative measure. Others are advised to do so by their PCP to avoid medication. Hypertensive patients may want to keep their levels in check. A few may screen out of convenience (family or friend already possesses a cuff).
- Providers and experts can advocate for proper validation and proper measurement.

- To ensure clinical accuracy and validation, professionals should inform the company of any issues with the device & if possible suggest potential solutions. This is particularly important for devices that are known not to meet validation standards &/or for devices in which there is no data to show that the device satisfies clinical accuracy requirements. This is particularly important if the device is licensed & if there is no data to justify the license as a Class II medical device &/or if there is data that shows the device does not meet the requirements of the license.
- Need to inform the company/sponsor that this reporting is mandatory & if they do not report it, then it will be reported on their behalf.
- Forums and professional discussions via Twitter are important to increase awareness among professionals, although the public should also be well-informed of inaccurate devices on the market. Reporting is key with deterring consequences/ penalties for the company for non-compliance, & the mandatory reporting should be encouraged & enforced by clinicians, scientists, federal regulatory agencies, & the professional medical associations.
- The group is cautious of integrating the results of wrist and finger devices into practice. Current recommendations by the American Heart Association (AHA) is to use upper arm cuffs to monitor BP, the accuracy of wrist and finger cuffs have not been validated. In rare circumstances, where an upper arm reading cannot be obtained, a wrist device may be an option.
- Blood Pressure Devices Recommended by Hypertension Canada:
<https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/>
- Even if a device is FDA approved it still does dissuade clinicians from wanting to see the data that cleared the device.
- Even if a patient monitors their BP with an invalid device, the clinician should obtain blood pressure counts in the office using a validated cuff to ensure accuracy. Gold standard for hypertension is out-of-office measurements using a validated cuff.
- Instances in which a clinician would consider using a non-traditional upper arm cuff:
 - Physical limitations
 - Disability
 - Inability to self-administer a monitor on the upper arm in both the inpatient and outpatient settings.
 - Frail elderly patients experiencing pain or bruising due to repeated vital monitoring of their blood pressure
 - Continuous monitoring in the ICU/CCU and in general, may be less disturbing to sleep patterns
 - Obese conical upper arms
 - Military physicians that encountered challenges getting blood pressures in times of trauma or with burns. In these instances, a digit cuff may have some utility
- Prescribing a device, like any prescription, should account well for the likelihood of a patient being compliant and that the information be reliable enough to inform medical decision making.
- When it comes to wrist or finger BP devices, we need to know exactly what BP is being measured by these techniques. The clinical standard of upper arm cuff BP is designed to measure the BP exposure to the organs that are the target of damage from high BP, especially

the heart, brain and kidneys. This is the BP in the central vasculature (i.e. aorta, carotid artery) that is in direct interaction with the organs - this is the BP that causes strokes and heart attacks and is most clinically relevant. Validated upper arm cuff BP devices generally give a good estimate of the central aortic systolic BP (albeit with some caveats but this is a huge side topic), but is it possible to get a good estimate of a clinically relevant BP reading in the wrist or finger? We know that systolic BP can undergo a variable degree of change from the aorta to the upper arm and out to the extreme periphery of the wrist and finger (termed systolic BP amplification). This means that the systolic BP in the wrist and finger may not be a good representation of the most clinically relevant BP that can be estimated at the upper arm

- Brachial and Radial Systolic Blood Pressure Are Not the Same.
<https://www.ncbi.nlm.nih.gov/pubmed/30905194>
- The real problem with wrist monitors is the position in relation to heart level. In addition, the extent of pronation of the wrist will alter cuff inflation and so affect the oscillogram and BP values given by the device.
- It is also important to consider patient specific variability. every device we use in clinical care needs to be validated according to the AAMI/ISO protocol. However, there is not guarantee that a device (validated or not) will function as it should on any specific patient. Therefore, the results of that device may be unreliable in clinical decision making.
- The bottom line is that we should NOT be advising usage of wrist and finger BP devices when there are more accurate and less variable options (upper arm oscillometric).
- It is important see the device the patient is using and, if possible, have them calibrated in our office.
- What role should regulatory authorities play in policing products that purport to measure BP as a premise to collect data? What role, if any, should organizations like the AMA play in this regard?
 - Any BP device for which there are no available clinical data to review, (whether upper arm-wrist, finger, or other measurement site), should be considered “recreational.”
 - It is the responsibility of the government (i.e. FDA) to enforce clearer, accurate packaging.
 - AMA/AHA/AAMI/APHA Validated Device List is due to appear in a few months. It will list all FDA 510(k) filings in which REAL validation data are available either through a peer-reviewed publication or provided by the manufacturer with an affidavit of "reality" of the data.

Conclusion

Value and utility of a cloud based device registries:

- Tag and mark validated device data
- Annotate device certification
- Isolate measurements for clinical decision making
- Protect providers and patients from unnecessary complications
- Scalability
- Business continuity
- Collaboration efficiency
- Access to real time updates

Next Steps

- Focus our energy on solutions like the AMA's Validated Device List, education and advocacy.
- Submitting complaints to the FDA and FTC may be a beneficial next step - <https://www.ftccomplaintassistant.gov/GettingStarted?NextQID=275&url=%23%26panel1-9#crnt>

Resources

- <https://www.ftccomplaintassistant.gov/GettingStarted?NextQID=275&url=%23%26panel1-9#crnt>
- <https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/>
- <https://www.ncbi.nlm.nih.gov/pubmed/30905194>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3376431/>
- <https://www.nature.com/articles/s41371-018-0053-2.pdf>
- <https://www.ahajournals.org/doi/10.1161/HYPERTENSIONAHA.119.12674>
- <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2492134>
- <https://www.cbsnews.com/news/top-selling-blood-pressure-measuring-app-very-inaccurate/>
- <https://www.businesswire.com/news/home/20180605006652/en/Federal-Court-Denies-Fitbits-Motion-Dismiss-Class>
- <https://onlinelibrary.wiley.com/doi/full/10.1111/jch.12782>