

Non-Invasive Hemodynamic Monitoring

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Overview

Hemodynamic monitoring aims to evaluate perfusion pressure, oxygen delivery, and cardiopulmonary function. Hemodynamic monitoring has routinely been achieved through invasive methods such as pulmonary artery catherization and/or a peripheral arterial line. With advancing technology, non-invasive hemodynamic monitoring has become available. With a small dedicated cuff placed on the patient's finger, the arterial pressure of the patient's finger is measured. The pulsating finger artery is compressed to a continual volume with variable counter pressure equivalent to the arterial pressure and "the resulting finger arterial pressure waveform is reconstructed into a brachial artery pressure waveform by a generalized algorithm." Cardiac output is calculated by pulse contour method (CO-TREK), utilizing measured systolic pressure time integral and heart afterload established from aortic compliance, aortic impedance (resistance and inductance of the aorta), resistance of the peripheral arteries, and compliance of the peripheral arteries.

Actions for Consideration

Partner: Identify intensivists, critical care physicians, nurses, quality personnel, and the appropriate clinical and non-clinical value analysis team members. Work with these team members to better understand current practice and procedures related to hemodynamic monitoring and potential interest in non-invasive technology.

Connect: Given that non-invasive hemodynamic monitoring is a developing technology it is important to understand efficacy of devices and impact on patient care and safety. Include available literature correlating non-invasive measurements with invasive measurements for discussions. With the addition of new technologies/methods, clinical trials may be considered. Dialogue may include appropriate patient populations for non-invasive versus invasive monitoring and assessing the need for protocols related to use.

Communicate: When converting to or incorporating these devices into practice share decisions as well as education and training resources available. Leverage supplier assistance for both clinical staff and physician support as needed. Set clear expectations. Discuss pricing, and potential to streamline products and develop strategies to manage use. Report status of initiative and any applicable quality metrics to team members at a regular cadence.

HealthTrust Resources: Access the <u>Clinical Knowledge Insights Library</u> to find other relevant documents and toolkits with actionable information. Examples for this product include resources on product conversion, value analysis, and clinical trials.⁵ Network on <u>HealthTrust Huddle</u>, our member community that shares ideas and seeks guidance from colleagues.⁶

FDA Approval

Specific 510(k) approval for individual products can be found by searching the 510(k) Premarket Notification database and can be found here.⁷



Physician Advisor Insight

A panel of critical care and anesthesia practitioners within our HealthTrust Physician Advisor Network offered the following insight with regard to non-invasive hemodynamic monitoring⁸:

- Depending on accuracy of these non-invasive finger cuff devices, they could be helpful for fluid management and hemodynamic support in critically ill patients.
 - Theoretically could replace need for arterial line and/or swan catheter, reducing risk of complications with placement of those monitors.
 - Simple way to obtain more extensive cardiac and peripheral vascular information that would normally require either direct arterial access and/or central venous monitoring.
 - Applicable for use in any patient that requires ongoing monitoring of these types, and those that
 do not require indwelling devices for the purposes of either frequent arterial or venous blood
 sampling or central administration of medications.
 - Possibly advantageous in pre-hospital settings and for transitioning acutely ill patients from lower to higher settings of care.
 - May be helpful for patients no longer requiring invasive monitors, these devices could service
 as a transitional monitoring as patients are moved to a lower level of care (step down unit). This
 might allow for increased safety and provider comfort with earlier downgrade of patients.
- There was concern expressed regarding the accuracy of non-invasive finger cuff devices compared to the current arterial line monitoring.
- The physicians noted that it would take a lot of experience with this device to trust its readings.
- Advisors suggested that possible use of this/these products alongside current standard of care would be beneficial for comparison and training, to gain confidence in the data generated, and validate accuracy.

Clinical Evidence

There are a few non-industry sponsored studies that discuss the proper use, efficacy, and safety of non-invasive finger cuff devices in particular patient populations. A sample is included below.

- A 2020 prospective self-controlled study of participants receiving elective shoulder surgery (n=20) aimed to determine the accuracy of blood pressure between the non-invasive finger cuff device, oscillometer, and arterial blood pressure monitoring. Researchers used different patients positions throughout the study "levels of agreement among the three blood pressure measurement methods (non-invasive intermittent, non-invasive continuous, and invasive continuous) were comparable between the beach chair and supine positions." Limitations of the study include small number of participants, invasive blood pressure measurements were only used on half of the study cohort, calibration was not completed for supine and chair positions, which could have resulted in an underestimation of the measurement differences. The authors also noted that due to orthopedic surgery clinical standards, blood pressure values were contained to a narrow range.
- A 2021 prospective study of 30 patients with a median BMI of 50.2 kg/m2, aimed to determine the accuracy of finger cuff non-invasive devices with invasive radial arterial monitoring in the obese population.¹⁰ All patients had laparoscopic bariatric surgery. During the procedures, monitoring was done with both non-finger cuff and radial arterial monitoring simultaneously while under anesthesia and "agreement over time was assessed using modified Bland-Altman plots and error grid analysis permitted clinical interpretation of the results. Four-quadrant plots allowed assessment of concordance in blood pressure changes".¹⁰ The study found that the finger cuffs were not as accurate and provided lower



values compared to the radial arterial monitoring. The authors noted the need for additional studies to validate their conulsions. ¹⁰

Summary

Due to the current clinical evidence provided, a careful review of patient need and population should be assessed. Understanding the environment these devices could be utilized should be discussed, and strong physician engagement would be needed. These devices would require additional training and understanding of appropriate use. Due to the lack of current clinical evidence consider use in combination with current practice.

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