Feasibility of Continuous Non-Invasive Blood Pressure Monitoring in Neonates Using a Novel Sensor

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Background

Continuous monitoring of arterial blood pressure (BP) is vital for assessing and treating cardiovascular instability in a sick premature infant. Hypotension is an ominous complication in these patients because it is associated with adverse morbidity and mortality outcomes, such as higher rates of IVH and BPD^{2,3}. Non-invasive cuff-based methods are considered inaccurate, particularly for hypotensive neonates⁴. Therefore, the standard of care is to place invasive arterial lines (IALs)¹ to monitor systolic (SBP), diastolic (DBP) and mean BP (MAP). Unfortunately, IAL placement in neonates carries the risk of serious complications such as infection, bleeding, clots and nerve damage.^{5,8-13} It is expensive (\$750-1K/placement), difficult, skill intensive¹² and time consuming. Additionally, infants may be subject to sedation and multiple painful attempts due to their small arteries.⁹⁻¹¹

There is a significant unmet need for an easy-to-use, accurate, cost-effective, continuous, non-invasive BP (cNIBP) monitoring device in neonates.

Objective

We have developed a new device to continuously and noninvasively infer the blood pressure of neonates through changes in capacitance measured over a pulse point such as a radial artery. Our objective is to evaluate the feasibility and accuracy of this novel BP sensor in preterm and term neonates and compare it against BP values measured with IALs.

Methods

Patients: Our IRB-approved study evaluated 11 preterm and term neonates < 1-week old with umbilical arterial catheters. The novel sensor was placed on an available wrist/foot.

Device: The small, lightweight (<12g), paper-thin (~50µm), flexible and extremely sensitive array of 4 sensors is incorporated into a disposable stretchable band that wraps around the wrist or foot (**Fig 1**). Reusable, lightweight, low-power electronics acquire pulse waveform data and stream it in real-time to a custom Android App. BP values are extracted from the cNIBP pulse waveform data via post-processing.

Data Collection & Analysis: IAL data were collected from the Stanford data warehouse. IAL and Boppli data were synchronized at a pulse-by-pulse level via cross-correlation methods to generate a correlation coefficient between IAL & cNIBP data.

Data Quality: To establish usability of the measured signal, a visual metric, $|Q_v|$, was developed. $|Q_v|$ scale ranges from 0 (unusable) to 4 (best). This quality scale is based on a visual assessment of secondary peak resolution & signal-to-noise ratio (SNR) by comparison to a rubric. The $|Q_v|$ data from grading a subset of the cNIBP sensor data was then used to train a convolutional neural network (CNN) to obtain an automated quality scale $|Q|$.

BP Derivation: The Android application uses proprietary and highly-efficient artificial neural network (ANN) algorithms to derive SBP, DBP, and MAP values from measured pulse waveform data.

Accuracy metrics: Since the eventual goal is to apply for FDA clearance, we chose to aim to meet the accuracy specifications outlined by the FDA, i.e. a mean average error (MAE) <±5 mmHg and standard deviation (SD) <8 mmHg.

Results

For the 11 enrolled babies, gestational age ranged from 26^{6/7}- 40^{1/7} weeks. Weight ranged from 0.9 kg to 3.6 kg. This small, lightweight device does not require intimate skin contact. It is low cost, easy-to-use and less perturbing to the patient than an IAL. In general, cNIBP sensor data (blue) correlates well with IAL data (red) taken simultaneously (**Fig. 2**). We synchronized ~100 hours of cNIBP radial sensor data and umbilical arterial line data for 11 patients under 1 week old. BP predictions (**Fig. 3**) are within FDA specifications when the sensor data $|Q| > 1$ (~15%).

Conclusion

We have demonstrated feasibility for this innovative, continuous, non-invasive blood pressure sensor in <1 week-old preterm and term neonates. We have addressed a vital unmet need in this extremely vulnerable population. Preliminary results meet FDA specifications.

Figure 1 Small form factor wrist/foot worn continuous non-invasive BP sensor in neonates.

Figure 3.

Preliminary results meet FDA specifications.