Title: Non-clinical Database for Dynamic Characterization of Pulse Contour Cardiac Output Monitoring Systems

Presenting author: Masoud Farahmand, U.S. Food and Drug Administration
Coauthors: Gavin A. D'Souza; Luke H. Herbertson; Christopher G. Scully

Background: Pulse contour cardiac output monitoring systems allow real-time and continuous estimation of hemodynamic variables such as cardiac output (CO) and stroke volume variation (SVV) by analysis of arterial blood pressure waveforms [1]. Clinical use of these systems has involved tracking rapid changes in CO, and SVV to monitor patient responses to treatment, distinguish between fluid responders and non-responders, and guide fluid therapy. However, evaluating the performance of CO monitoring systems to measure the small variations in these variables is a challenge due to limitations in clinical reference methods for tracking the hemodynamics in patients. We developed a non-clinical database of pressure and flow waveforms with known perturbations as a potential tool for assessing the dynamic attributes of pressure-based CO monitoring systems, including CO response time, and CO and SVV resolutions.

Methods: We developed a mock circulatory loop (MCL) that can simulate rapid changes in different parameters, such as CO and SVV (Figure 1A). The MCL was configured to simulate three different hemodynamic states (i.e., normovolemic, cardiogenic shock, and hyperdynamic) representing a range of flow and pressure conditions. For each state, we simulated controlled stepwise changes in the MCL flow and collected a dataset for characterizing dynamic attributes of pressure-based CO systems. Nine datasets were generated in all, which contain several hours of central (aortic) flow, central pressure, and peripheral (radial) pressure waveforms. We demonstrate how the database can be used to characterize dynamic attributes with a bench top system (Figure 1B). The bench system (referred to as the system under test or 'SUT') consists of fluid-filled tubing, a disposable pressure transducer, a pressure monitor, and a pulse contour algorithm (i.e., $CO = k \times (MAP/60) \times \ln(SBP/DBP) \times PR$; where MAP is mean arterial pressure, SBP is systolic pressure, DBP is diastolic pressure, PR is pulse rate, and k is a calibration constant calculated from MCL flow data) implemented in MATLAB. Pressure-based CO measurements were calculated via the SUT using MCL-generated pressure waves in each step and were compared to the MCL flow data.

Results: Three types of datasets were collected for each hemodynamic state: 1) CO resolution, 2) SVV resolution, and 3) CO response time datasets. Overall, the nine datasets contain peripheral pressure, central flow and central pressure waveforms for the three hemodynamic states (Figure 1C). We have plotted the datasets for the normovolemic state in Figure 1D. The database was used to determine the dynamic attributes of the SUT. Following a Bland-Altman analysis, we determined the upper and lower limits of the CO resolution of the SUT as 8.4% (95% CI: [6.1%, 9.9%]) and -9.1% (95% CI: [-11.0%, -7.2%]), respectively. A similar analysis was performed to determine the SVV resolution of the SUT. For the SVV resolution, the upper and lower limits were 5.0% (95% CI: [4.0%, 5.9%]) and -3.8% (95% CI: [-4.7%, -2.9%]), respectively. The CO response time of the SUT was 10 seconds.

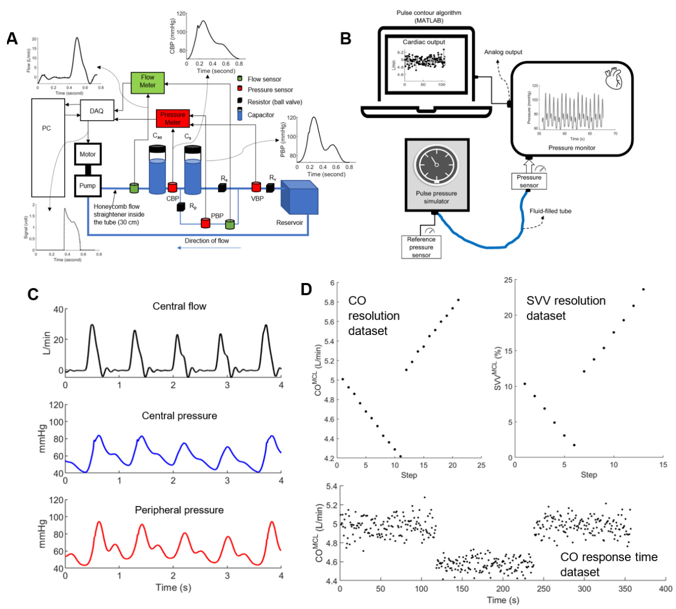

Figure 1. (A) Schematic diagram of the mock circulatory loop (MCL). (B) Schematic diagram of the setup for evaluating a bench pulse contour CO monitoring system. **(C)** Example flow and corresponding pressure waveforms produced by the MCL. **(D)** Normovolemic datasets for quantifying three dynamic attributes of pulse contour CO monitoring systems.

Conclusions: We presented nine MCL-generated datasets for evaluating key dynamic attributes of pressure-based CO monitoring systems and demonstrated how the database can be used for evaluating the dynamic attributes of a benchtop pulse contour monitoring system. This benchtop testing approach enables the characterization of a CO monitoring system and accounts for the effects of different equipment (e.g., sensors and monitors with different settings, bandwidths, resolutions, accuracies, fluid-filled tubing with different damping properties, and different interface connections) on the dynamic attributes of the system. This database is intended to be a potentially useful tool for characterizing dynamic attributes of pressure-based CO monitoring systems and algorithms (i.e., CO response time, CO resolution, and SVV resolution) and provides insight into the performance of these attributes.

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Reference

[1] J. A. Alhashemi, M. Cecconi, and C. K. Hofer, "Cardiac output monitoring: an integrative perspective," (in eng), *Crit Care,* vol. 15, no. 2, p. 214, 2011, doi: 10.1186/cc9996.