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Detecting the Change in Total Circulatory Flow with a Wireless, Wearable Doppler Ultrasound Patch: A Pilot Study

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OBJECTIVE: Measuring fluid responsiveness is important in the management of critically ill patients, with a 10–15% change in cardiac output typically being used to indicate "fluid responsiveness." Ideally, these changes would be measured noninvasively and peripherally. The aim of this study was to determine how the common carotid artery (CCA) maximum velocity changes with total circulatory flow when confounding factors are mitigated and determine a value for CCA maximum velocity corresponding to a 10% change in total circulatory flow.

DESIGN: Prospective observational pilot study.

SETTING: Patients undergoing elective, on-pump coronary artery bypass grafting (CABG) surgery.

PATIENTS: Fourteen patients were referred for elective coronary artery bypass grafting surgery.

INTERVENTIONS: Cardiopulmonary bypass (CPB) pump flow changes during surgery, as chosen by the perfusionist.

MEASUREMENTS: A hands-free, wearable Doppler patch was used for CCA velocity measurements with the aim of preventing user errors in ultrasound measurements. Maximum CCA velocity was determined from the spectrogram acquired by the Doppler patch. CPB flow rates were recorded as displayed on the CPB console, and further measured from the peristaltic pulsation frequency visible on the recorded Doppler spectrograms.

MAIN RESULTS: Changes in CCA maximum velocity tracked well with changes in CPB flow. On average, a 13.6% change in CCA maximum velocity was found to correspond to a 10% change in CPB flow rate.

CONCLUSIONS: Changes in CCA velocity may be a useful surrogate for determining fluid responsiveness when user error can be mitigated.

KEY WORDS: cardiopulmonary bypass; carotid arteries; Doppler ultrasound; Fluid responsiveness; hemodynamic monitoring; wearable technology

Assessing preload responsiveness is important when managing cardiac surgery patients (1). Typically, a 10–15% change in stroke volume (SV_Δ) is used as a reference standard to determine whether the heart is "preload responsive" (2). However, some authorities recommend change in cardiac output (3). Regardless, how this change at the left ventricular outflow tract translates to a surrogate at the common carotid artery (CCA) is a relatively new field of study with broad implications for cardiology and critical care.

Using SV_Δ as the reference standard, we have previously observed that a 15–18% change in the CCA velocity time integral accurately detects a 10% SV_Δ in healthy volunteers undergoing central hypovolemia and simulated blood transfusion (4, 5) and in a case study of two patients undergoing coronary

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KEY POINTS

Question: How does common carotid artery (CCA) maximum velocity change with total circulatory flow?

Findings: CCA maximum velocity was measured using a hands-free Doppler patch in coronary bypass surgery patients undergoing cardiopulmonary bypass pump flow changes. Changes in maximum CCA velocity tracked well with pump flow changes. A mean CCA maximum velocity change of 13.6% was found to correspond to a 10% change in pump flow.

Meaning: CCA maximum velocity changes measured by Doppler ultrasound track well with total circulatory flow changes when user error is minimized. A 13.6% CCA maximum velocity change suggests a 10% change in total circulatory flow.

artery bypass grafting (CABG) with native cardiac function (6). As a subanalysis of the ongoing comparison between the carotid Doppler signal and SV_{Δ} in elective CABG patients (6), we sought to delineate the relationship between changes in total circulatory flow and CCA velocity by comparing known changes in cardiopulmonary bypass (CPB) flow rate to those measured by a wireless, wearable Doppler ultrasound patch placed over the CCA.

The results of this study were presented at the 2022 American Heart Association Scientific Sessions in Chicago, IL (7).

MATERIALS AND METHODS

A convenience sample of 14 adult patients undergoing elective CABG was analyzed as part of a larger study. Patient characteristics are shown in **Table 1**. Written and informed consent was obtained for all subjects and the study was reviewed and approved by the Health Sciences North Research Ethics Board (REB# 20-023; Title: The relationship between changes in stroke volume and carotid blood flow during perioperative coronary artery bypass grafting; September 15, 2020). The study was conducted in accordance with the statement outlined in (8), and with the Helsinki Declaration of 1975.

Anesthesia was induced with 0.5 mg/kg propofol, 1.2 mg/kg rocuronium, and 1.0 μg/kg sufentanil and maintained with sevoflurane of 0.5–0.7 minimum alveolar concentration. Continuous IV infusions of both 3 mL/kg/h saline and 0.2 μg/kg sufentanil were maintained throughout the study. All patients were ventilated with the following baseline settings: tidal volume 8 mL/kg, respiratory rate 15 breaths per minute, positive end-expiratory pressure 5 cm H_2O.

A wearable, wireless, U.S. Food and Drug Administration-cleared, continuous wave 4 MHz Doppler ultrasound patch was placed over the CCA (**Fig. 1*A***; Flosonics Medical, Sudbury, ON, Canada). Adhesive straps fix the transducer angle relative to carotid blood flow. While on CPB intraoperatively, at least two changes in blood flow (one negative, one positive) were made. These changes were made at the discretion of the perfusionist. Occlusivity was assumed to be negligible. The blood flow information measured by the Doppler patch was displayed as a spectrogram on a tablet to facilitate patch placement and ensure signal quality, and later transmitted to a cloud-based database for postprocessing.

TABLE 1.
Patient Characteristics ($n = 14$)

Absolute value ± SD	
Age (yr)	65.6 ± 9.6
Weight (kg)	97.4 ± 17.9
Height (cm)	170.6 ± 8.8
Body-mass index (kg/m²)	33.5 ± 5.7
Ejection Fraction (%)	55.3 ± 6.5
Absolute value (%)	
Sex (female)	2 (14.3)
Hypertension	13 (92.9)
Myocardial infarction	10 (71.4)
Current/previous tobacco use	8 (57.1)
Diabetes	8 (57.1)
Obesity (body mass index > 30)	7 (50)
Preoperative drugs, absolute value (%)	
β-blockers	7 (50)
Angiotensin-converting enzyme inhibitors/ Angiotensin receptor blockers	11 (78.6)
Neprilysin inhibitor	0 (0)
Diuretics	5 (35.7)
Vasodilators	5 (35.7)

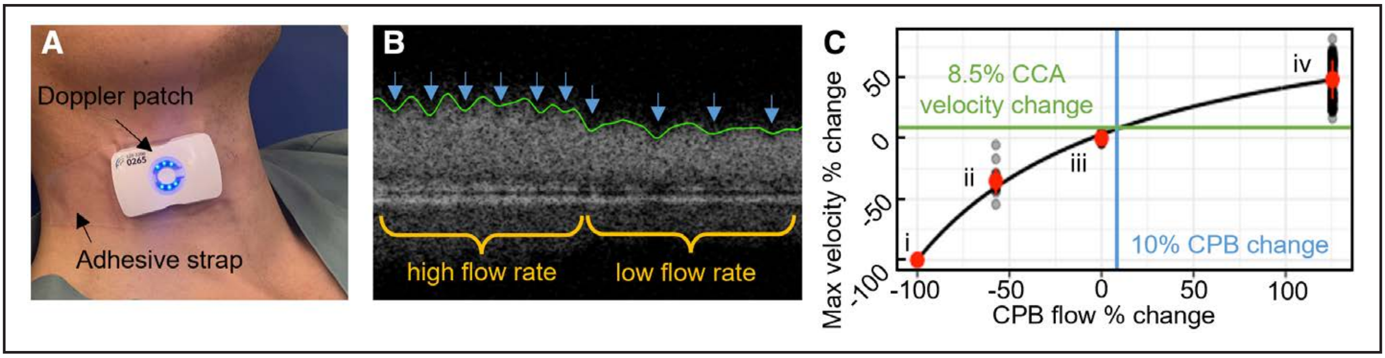

Figure 1. Using the Doppler patch to compare changes in common carotid artery (CCA) velocity to changes in cardiopulmonary bypass (CPB) pump flow rate. **A**, CW Doppler patch in place over CCA. **B**, Displayed spectrogram during a change in flow rate, showing maximum CCA velocity trace (*green line*) and CPB pump pulsations (*blue arrows*). **C**, Dose-response curve (*black line*) fitted to changes in CPB pump flow and corresponding changes in CCA maximum velocity for a single subject. (i) Inferred point representing zero flow, (ii) negative CPB pump flow change, (iii) baseline CPB pump flow and baseline CCA maximum velocity, (iv) positive CPB pump flow change. The *red* points indicate the overall mean CCA velocity change for each of the time windows, while the *black* points show the variability of each 0.5 s segment of the corresponding windows. The change in CCA velocity corresponding to a 10% change in CPB pump flow was determined from the equation of the dose-response curve to be 8.5% with a 95% CI of (5.0–12.0%).

We simultaneously measured known changes in CPB pump speed (i.e., total circulatory flow) and CCA velocity using the wireless, wearable Doppler ultrasound system. CPB flow changes were determined from the displayed spectrogram by the change in peristaltic pulsation duration, since the pump flow rate is directly proportional to the frequency of peristaltic pulsations (i.e., rotations of the pump head), and these pulsations were readily visible in the recorded spectrograms. An example is shown in **Figure 1*B***, where the frequency of pulsations (indicated by blue arrows) decreases with a decrease in flow rate. To ensure correctness, CPB flow rates as shown on the console were also recorded as a check of the spectrogram-derived CPB pump flow rate change. CCA velocity changes were calculated from the averaged automated maximum velocity trace (Fig. 1*B*, green trace). Five to ten seconds windows pre-CPB and post-CPB speed changes were selected, each with sufficient signal quality to determine both relative CPB flow and CCA velocity, in which the mean of the maximum CCA velocity and CBP flow were calculated. In addition to the two or more observed flow changes, two datapoints were inferred for each subject, namely: 1) in the absence of CBP flow, CCA velocity would be zero (i.e., –100% and –100% change, respectively), and 2) if no change in CBP flow occurred no change in CCA velocity would be expected (i.e., 0% and 0% change, respectively). A nonlinear "dose-response" curve using the Michaelis–Menten equation was fitted to the relative changes in flow and velocity for each subject, and the CCA velocity changes corresponding to a 10% change in CPB flow were calculated. An example of a single subject is shown in **Figure 1*C***.

RESULTS AND DISCUSSION

The characteristics of the patients studied are shown in Table 1. CPB flow ranged from 0.5 to 6.3 L/min. Mean relative flow changes were –66% and 323%, corresponding to mean CCA velocity changes of –46% and 109%. Among all subjects, a mean CCA velocity change of 13.6% was found to correspond to 10% CPB flow change, ranging from 1.5 to 27.8%.

CCA velocity measured with the wearable Doppler patch successfully tracked changes in CPB flow. We observed that a CCA velocity change of 13.6% intimates a 10% change in total circulatory flow as a surrogate for cardiac output. This observation is consistent with our previous work in healthy volunteers undergoing preload reduction and augmentation via various means (4, 5). Although others have found only moderate correlation between changing cardiac output and carotid blood flow (9, 10), the current paradigm mitigates some sources of error. Specifically, affixing the Doppler patch to the neck of a paralyzed patient limits measurement variability caused by 1) human factors (e.g., angle of insonation, Doppler gate placement) and 2) physiological factors (e.g., hemodynamic variation induced by the respiratory cycle). For example, we have shown that hand-held studies typically sample too few cardiac cycles to detect change with statistical confidence because of respiratory cycle variation (11). Further, our chosen gold standard is also largely free from measurement error as CPB pump speed was known and directly observed in the Doppler spectra (Fig. 1*B*). Thus, we instantaneously synchronized change in the reference standard with the carotid signal. This is in distinction to other reference standards where there can be clinically significant algorithm lag (12). Indeed, classical transpulmonary thermodilution does not have the temporal resolution needed to assess preload responsiveness (13).

We could not quantify carotid diameter during pump speed change, therefore, CCA flow (mL/min) was not calculated. We suspect that the "bend" of the total circulatory flow-carotid velocity curve that we observed (Fig. 1*C*) could be due to carotid artery distention. In other words, departure of the carotid artery velocity curve from the line of identity may be driven by changing carotid artery area. We note that most of the common carotid blood flow moves up the internal carotid, which is subject to autoregulation. Accordingly, while there is a direct relationship between left ventricular outflow tract and CCA flow, this is mediated by changing body-to-head impedance (e.g., downstream autoregulation) (14). Nevertheless, others have found that SV_{Δ} is correlated with changing internal carotid blood flow (15, 16). Thus, autoregulation does not completely abolish changes in cardiac output from being expressed in the carotid artery.

CONCLUSIONS

Changing carotid artery velocity accurately tracks changing cardiac output when the Doppler insonation angle is constant, human factors are mitigated, and when the gold standard is accurate and measured instantly with carotid artery velocity. These results support that carotid Doppler can be used as a "window" to the left ventricle during cardiac bypass.

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REFERENCES

1. Bednarczyk JM, Fridfinnson JA, Kumar A, et al: Incorporating dynamic assessment of fluid responsiveness into goal-directed therapy: A systematic review and meta-analysis. *Crit Care Med* 2017; 45:1538–1545
2. Kenny J-ES, Barjaktarevic I: Letter to the editor: Stroke volume is the key measure of fluid responsiveness. *Crit Care* 2021; 25:104
3. Monnet X, Shi R, Teboul J-L: Prediction of fluid responsiveness. What's new? *Ann Intensive Care* 2022; 12:46
4. Kenny J-ES, Barjaktarevic I, Mackenzie DC, et al: Carotid Doppler ultrasonography correlates with stroke volume in a human model of hypovolaemia and resuscitation: Analysis of 48 570 cardiac cycles. *Br J Anaesth* 2021; 127:e60–e63
5. Kenny J-ES, Barjaktarevic I, Mackenzie DC, et al: Carotid artery velocity time integral and corrected flow time measured by a wearable Doppler ultrasound detect stroke volume rise from simulated hemorrhage to transfusion. *BMC Res Notes* 2022; 15:7
6. Kenny JS, Clarke G, Myers M, et al: A wireless wearable Doppler ultrasound detects changing stroke volume: Proof-of-principle comparison with trans-esophageal echocardiography during coronary bypass surgery. *Bioengineering (Basel)* 2021; 8:203
7. Munding CE, Kenny J-ESS, Yang Z, et al: Detecting change in cardiopulmonary bypass blood flow rate with a novel, wireless, wearable Doppler ultrasound patch: A pilot study. *Circulation* 2022; 146(Suppl_1):A12774–A12774.
8. Canada Go: Tri-council policy statement: Ethical conduct for research involving humans—TCPS 2. In: Canadian Institute of Health Research, 2018
9. van Houte J, Mooi FJ, Montenij LJ, et al: Correlation of carotid Doppler blood flow with invasive cardiac output measurements in cardiac surgery patients. *J Cardiothorac Vasc Anesth* 2022; 36:1081–1091
10. Ma IW, Caplin JD, Azad A, et al: Correlation of carotid blood flow and corrected carotid flow time with invasive cardiac output measurements. *Crit Ultrasound J* 2017; 9:10

11. Kenny J-ES, Barjaktarevic I, Mackenzie DC, et al: Carotid Doppler measurement variability in functional hemodynamic monitoring: An analysis of 17,822 cardiac cycles. *Crit Care Explor* 2021; 3:e0439
12. Kenny JS, Barjaktarevic I, Eibl AM, et al: Temporal concordance between pulse contour analysis, bioreactance and carotid Doppler during rapid preload changes. *PLoS One* 2022; 17:e0265711
13. Monnet X, Teboul J-L: Passive leg raising: Five rules, not a drop of fluid!. *Criti Care* 2015; 19:18
14. Kenny J-ES: A theoretical foundation for relating the velocity time integrals of the left ventricular outflow tract and common carotid artery. *J Clin Monit Comput* 2023. [online ahead of print]
15. Skytioti M, Søvik S, Elstad M: Internal carotid artery blood flow in healthy awake subjects is reduced by simulated hypovolemia and noninvasive mechanical ventilation. *Physiol Rep* 2016; 4:e12969
16. Skytioti M, Elstad M, Søvik S: Internal carotid artery blood flow response to anesthesia, pneumoperitoneum, and head-up tilt during laparoscopic cholecystectomy. *Anesthesiology* 2019; 131:512–520