Original research

Portable cerebral blood flow monitor to detect large vessel occlusion in patients with suspected stroke

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ABSTRACT

Background Early detection of large vessel occlusion (LVO) facilitates triage to an appropriate stroke center to reduce treatment times and improve outcomes. Prehospital stroke scales are not sufficiently sensitive, so we investigated the ability of the portable Openwater optical blood flow monitor to detect LVO.

Methods Patients were prospectively enrolled at two comprehensive stroke centers during stroke alert evaluation within 24 hours of onset with National Institutes of Health Stroke Scale (NIHSS) score ≥2. A 70 s bedside optical blood flow scan generated cerebral blood flow waveforms based on relative changes in speckle contrast. Anterior circulation LVO was determined by CT angiography. A deep learning model trained on all patient data using fivefold cross-validation and learned discriminative representations from the raw speckle contrast waveform data. Receiver operating characteristic (ROC) analysis compared the Openwater diagnostic performance (ie, LVO detection) with prehospital stroke scales.

Results Among 135 patients, 52 (39%) had an anterior circulation LVO. The median NIHSS score was 8 (IQR 4–14). The Openwater instrument had 79% sensitivity and 84% specificity for the detection of LVO. The rapid arterial occlusion evaluation (RACE) scale had 60% sensitivity and 81% specificity and the Los Angeles motor scale (LAMS) had 50% sensitivity and 81% specificity. The binary Openwater classification (high-likelihood vs low-likelihood) had an area under the ROC (AUROC) of 0.82 (95% CI 0.75 to 0.88), which outperformed RACE (AUC 0.70; 95% CI 0.62 to 0.78; P=0.04) and LAMS (AUC 0.65; 95% CI 0.57 to 0.73; P=0.002).

Conclusions The Openwater optical blood flow monitor outperformed prehospital stroke scales for the detection of LVO in patients undergoing acute stroke evaluation in the emergency department. These encouraging findings need to be validated in an independent test set and the prehospital environment.

WHAT IS ALREADY KNOWN ABOUT THE TOPIC

⇒ Early detection of LVO facilitates triage to a comprehensive or thrombectomy-capable stroke center to reduce treatment times and improve outcomes, but prehospital stroke scales are not sufficiently sensitive.

WHAT THIS STUDY ADDS

⇒ The Openwater optical blood flow monitor outperformed prehospital stroke scales for the detection of LVO in patients who presented to the emergency department for acute stroke evaluation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ The Openwater optical blood flow addresses a significant clinical need for a reliable prehospital LVO detector. Future studies need to validate these findings in the prehospital environment in patients with suspected stroke.

INTRODUCTION

Endovascular therapy (EVT) has revolutionized the treatment of acute stroke with large vessel occlusion (LVO)[1] but is only available at a minority of stroke centers.[2] Early LVO recognition during prehospital care presents an opportunity to route patients to endovascular-capable centers and thereby reduce treatment times and improve outcomes.[3 4] In fact, the American Heart Association along with its Mission: Lifeline Stroke algorithm recommends that emergency medical services (EMS) route patients with a high likelihood of LVO to comprehensive or thrombectomy-capable stroke centers, depending on the additional transportation time.[5] In current practice, the likelihood of LVO is most often determined by one of several prehospital stroke severity scales for which diagnostic accuracy is suboptimal and implementation in clinical practice is inconsistent.[6] Thus, several non-invasive portable technologies have been explored with a goal of developing a wearable LVO detector.[7] Transcranial Doppler (TCD), volumetric impedance phase shift spectroscopy (VIPS), and electroencephalography (EEG) have been studied to this end with varying degrees of diagnostic accuracy.[8–10] In addition to performance metrics, it is important to consider cost, size, efficiency, and ease of use in the prehospital setting.

A direct cerebral blood flow (CBF) monitor is an intuitive choice for the development of LVO detectors. TCD-based CBF waveform morphology is reasonably sensitive and specific for LVO,[11] but the technique is limited by time, cost, and the need

for technical expertise. A robotic TCD may resolve the need for technical expertise[12] but at a higher unit cost; furthermore, nearly 20% of the population does not have adequate temporal acoustic windows.[13] Biomedical optical imaging (ie, diffuse optical monitoring) offers a promising alternative for directly probing tissue-level physiology,[14] and prior work has demonstrated the ability for monitoring acute stroke physiology at the bedside.[15] The Openwater optical blood flow monitor (Openwater; San Francisco, California, USA) is a novel wearable device that leverages measurements of speckle contrast and light intensity to continuously monitor microvascular hemodynamics and resolve a pulsatile CBF waveform in a cost-effective portable instrument.[16] In this study we evaluate the diagnostic performance of the Openwater optical blood flow monitor to detect the presence of LVO in patients presenting for acute stroke evaluation.

METHODS

Participants

Eligible patients were prospectively enrolled in this observational cohort at two comprehensive stroke centers (Hospital of the University of Pennsylvania and Rhode Island Hospital) if they presented to the emergency department or were transferred from another facility for acute stroke management within 24 hours of symptom onset and underwent emergent neurovascular imaging as per routine care to evaluate for possible LVO. Eligible patients had a National Institutes of Health Stroke Scale (NIHSS) score ≥2. Patients were excluded if they had a known intracranial mass, a skull defect that would interfere with optical monitoring, or clinical suspicion for bilateral infarcts. Patients were enrolled between August 22, 2022 and May 30, 2023.

Clinical and neuroimaging data

Patient demographics and baseline characteristics, stroke timing, presenting NIHSS score (determined by the evaluating neurologist), rapid arterial occlusion evaluation (RACE) scale score, and Los Angeles motor scale (LAMS) score were extracted from the electronic health record. RACE and LAMS scores were abstracted from EMS documentation, and if they were not explicitly provided, scores were calculated with the initial emergency department examination. Given the potential relevance of skin pigmentation to optical data quality, the Fitzpatrick scale was used to categorize skin color for each patient. Baseline CT results were reviewed to confirm the presence or absence of intracerebral hemorrhage. Baseline CT angiography results were reviewed to confirm the presence or absence of LVO (interpretation provided by a neuroradiologist). For study purposes, LVO was defined as occlusion of the cervical or intracranial internal carotid artery (ICA), M1 segment of the middle cerebral artery (MCA), M2 segment of the MCA, or tandem occlusion. For non-LVO patients, the final diagnosis was confirmed by the treating neurologist at discharge, and non-LVO patients were further categorized as (1) ischemic stroke without LVO, (2) intracerebral hemorrhage, or (3) stroke mimic (mimics were further sub-categorized as seizure, migraine, conversion disorder, or other).

Openwater optical blood flow monitor

The hemodynamic measurement device Openwater consists of a wearable headset and a console (figure 1). The headset contains two modules that collect data simultaneously from both sides of the head. The headset size is adjustable via a built-in dial. Each module contains a built-in optical fiber for the delivery of low average power laser light to the surface of the brain, and each light source is associated with three custom cameras for the measurement of light escaping from the subject. The console contains the laser, electronics, touchscreen, and computer. The optical methodology has been previously described in detail.[16]

Optical CBF evaluation

Each patient underwent a 70 s bedside optical blood flow evaluation with the Openwater system after presenting to the comprehensive stroke center for acute stroke evaluation. All evaluations were performed within 24 hours of symptom onset. If the exact time of onset was unknown, the time last known well was used as a surrogate for onset time. For patients with LVO, the CBF evaluation was completed prior to EVT (if applicable). With the patient lying supine on a flat hospital bed or stretcher, the Openwater headset was placed on the patient's head and positioned such that the optical probes were at the superior aspect of the forehead. The built-in dial was adjusted to position the dial at the lateral margin of the forehead (while avoiding hair). The elastic strap was then tightened to ensure adequate contact between the skin and optical probes. Instrument set-up took less than 1 min, after which a 70 s scan was performed across the six detectors. The speckle contrast-derived CBF waveform was acquired at 40 Hz. Representative waveforms are shown in figure 1D.

After data acquisition, two data quality checks were performed. First, ambient light and laser light levels were assessed to ensure

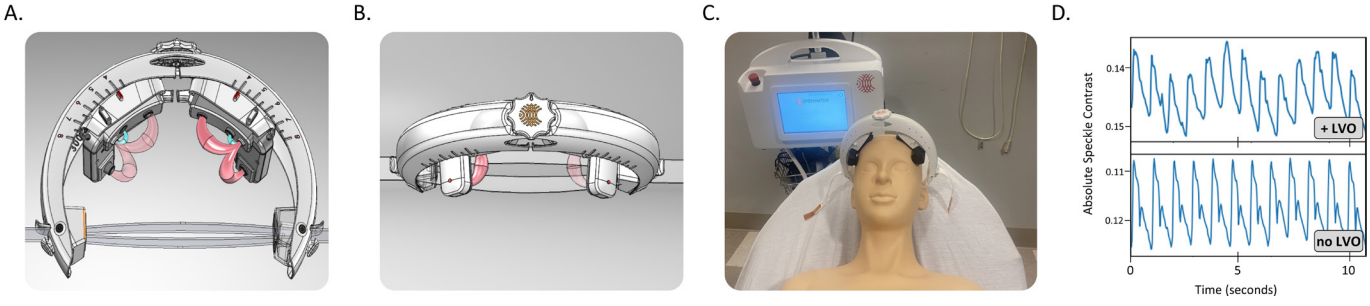

Figure 1 Instrumentation and waveform data. (A) Schematic of the Openwater headset showing the light source/detector positioning and the theoretical light path and (B) an anterior view. (C) Photograph showing the Openwater headset positioning on the head with the console in the background. (D) Speckle contrast-derived cerebral blood flow waveforms from two representative subjects (one with large vessel occlusion and one without).

probe contact was appropriate throughout the scan. The scan was considered a technical failure if more than two (of six) cameras failed this quality check. Next, the frequency spectrum of the data from each sensor was analyzed, and if a consistent pulse was not detected across four or more detectors, the pulse check was considered a failure and the data were rejected.

LVO detection model

For classification, we used a previously described deep learning model that effectively recognizes ECG waveform abnormalities.[17] This model employs a transformer architecture, which effectively extracts distinctive feature representations from the speckle contrast waveform data. We leverage self-attention pooling on the outputs of the transformer layers to enhance the model's performance.[18] The network's output is then converted into a probability score for either the LVO or the non-LVO class using the SoftMax function.[19] To mitigate the data scarcity issue, the network was trained on all patient data using a fivefold cross-validation, randomly dividing the data into five testing sets. Five independent models are trained and the reported results are based on the performance on these five independent testing folds using patients who were not included in the corresponding fold during training.

Design and statistical analysis

To better generalize study results to the prehospital setting, patients with LVO were compared with non-LVO patients who underwent the same acute stroke evaluation (rather than comparing healthy controls). Specifically, to maximize sensitivity and specificity estimation, an enriched sample was collected where LVO accounted for 38% (51/135) of cases and non-LVO cases accounted for 62% (84/135) of the cohort (non-LVO ischemic stroke, hemorrhage, or stroke mimic). As a reference standard for diagnostic performance, RACE and LAMS scores were collected and used with their established thresholds of ≥5 and ≥4, respectively. No power analysis was conducted since this work was a pilot study to determine the initial performance of the Openwater device. Data observed here will inform future analyses.

Diagnostic performance was examined using receiver operator characteristic curve area under the curve (AUROC) with the LOGISTIC procedure. Youden's J was estimated for the Openwater device using the %ROCPLOT macro and was used to determine the mathematically optimal performance of sensitivity and specificity. Prediction score, sensitivity, and specificity were estimated using a generalized linear model assuming a binary distribution with the GLIMMIX procedure. Positive and negative predictive values (PPV and NPV) were derived from the sensitivity and specificity estimates along with a prevalence of 5% and 10%, respectively, using Bayes theorem. Alpha was set at the 0.05 level, and all interval estimates were estimated for 95% confidence. All analyses were conducted using SAS 9.4.

RESULTS

A total of 162 patients underwent an optical CBF evaluation as part of emergency department stroke alert workflow. Ten patients were excluded due to poor headset contact, 16 were excluded due to failed pulse detection, and one was excluded due to a data storage error. The remaining 135 patients contributed to the final analysis. Based on clinical vascular imaging, 52 (39%) were ultimately found to have an LVO (18% ICA, 40% M1, 24% M2, 18% tandem ICA/MCA). Patient enrollment and network classification are summarized in online supplemental figure S1. The trained neural network categorized 54 (40%) patients as high likelihood LVO, 41 of whom were found to have LVO on clinical vascular imaging. The network classified 81 (60%) as low likelihood LVO, 11 of whom were found to have LVO on clinical imaging. The cohort demographics, baseline characteristics, and final diagnosis are summarized in table 1. Patients who were excluded based on a failed optical CBF scan were similar to those who were included in the final cohort (online supplemental table S1) but excluded subjects who had more severe strokes (NIHSS score 19 (8–22) vs 8 (4–14), P=0.002) and were more likely to have LVO (67% vs 38%, P=0.006).

Table 1 Cohort characteristics

	Final cohort (n=135)
Age, years	70 (15)
Sex, % female	46%
Race, %	
Asian	1%
Black or African American	28%
White	66%
Unknown	5%
Ethnicity, % Hispanic or Latino	2%
Fitzpatrick scale	2 (2–4)
NIHSS	8 (4–14)
Received IV thrombolysis, %	24%
Time from onset to Openwater scan, hours	7.8 (3.0–14.9)
Diagnostic categorization, %	
Large vessel occlusion	39%
Ischemic stroke without occlusion	24%
Intracerebral hemorrhage	10%
Stroke mimic	27%

Continuous variables are reported as mean (SD), ordinal variables are reported as median (IQR) and categorical variables are reported as proportions.
If symptom onset was unwitnessed, time last known well was used as a surrogate.
NIHSS, National Institutes of Health Stroke Scale.

As summarized in table 2, the Openwater optical blood flow monitor demonstrated superior diagnostic performance relative to RACE and LAMS. More specifically, the Openwater system was significantly higher in sensitivity for LVO (0.789, 95% CI 0.655 to 0.880) compared with RACE (0.596, 95% CI 0.457 to 0.721; P=0.038) and LAMS (0.500, 95% CI 0.366 to 0.634; P=0.0032), and it was higher in specificity but did not achieve statistical significance. Prehospital diagnostic performance was examined based on an estimated LVO prevalence of 5% and 10%. For 1000 patient encounters, the Openwater optical blood flow monitor is expected to reduce both the number of false positives and false negatives compared with RACE or LAMS (table 2).

AUROC of Openwater was the largest when the full spectrum of data was considered (figure 2A). The relationship between Openwater performance and LVO cases using a logit function is shown in online supplemental figure S2. For every increase of one unit in the positive prediction score, the odds of LVO increased 18-fold (OR 18.8, 95% CI 7.52 to 47.14; P<0.001). To reflect potential use in clinical practice (ie, to bypass or not to bypass the nearest primary stroke center), the optimal Openwater threshold (Youden's J) for LVO detection was applied, and the performance of the binary Openwater classification (high

Table 2 Diagnostic performance

			Based on 5% LVO prevalence in a sample of n=1000				Based on 10% LVO prevalence in a sample of n=1000			
	Sensitivity	Specificity	PPV	NPV	FP, n	FN, n	PPV	NPV	FP, n	FN, n
Openwater	0.789 (0.655 to 0.880)	0.843 (0.747 to 0.907)	20.9%	98.7%	149	11	35.8%	97.3%	141	21
RACE	0.596 (0.457 to 0.721) P=0.038 (vs Openwater)	0.807 (0.707 to 0.879) P=0.54 (vs Openwater)	14.0%	97.4%	183	20	25.5%	94.7%	174	40
LAMS	0.500 (0.366 to 0.634) P=0.0032 (vs Openwater)	0.807 (0.707 to 0.879) P=0.54 (vs Openwater)	12.0%	96.8%	183	25	22.4%	93.6%	174	50

Sensitivity and specificity (with 95% CI) are reported for each diagnostic tool. The reported PPV and NPV are based on an estimated LVO prevalence of 5% and 10% in a prehospital setting, and the reported FPs and NPs are based on a sample of 1000 patients.
FN, false negative; FP, false positive; LAMS, Los Angeles motor scale; NPV, negative predictive value; PPV, positive predictive value; RACE, Rapid arterial occlusion evaluation scale.

likelihood or low likelihood LVO) was compared with the clinically established RACE and LAMS thresholds of ≥5 and ≥4, respectively (figure 2B). The Openwater classification had an AUROC of 0.82 (95% CI 0.75 to 0.88), which outperformed RACE (AUC 0.70, 95% CI 0.62 to 0.78; P=0.04) and LAMS (AUC 0.65, 95% CI 0.57 to 0.73; P=0.002). The device performance for each of the five folds (ie, used to facilitate the five-fold validation) is shown in online supplemental figure S3, and the Openwater performance was relatively consistent across all five models. Openwater performance was similar in patients with light and dark skin pigmentation (Fitzpatrick scale 1–3 vs 4–6; see Online supplemental figure S4).

DISCUSSION

The Openwater optical blood flow monitor outperformed both RACE and LAMS for the detection of LVO in patients presenting for acute stroke evaluation. A clinically relevant increase in sensitivity was observed for the Openwater blood flow monitor without a cost to specificity, which ultimately yielded fewer false negatives and false positives. Reducing false negatives is critical to early notification and routing of patients with a high likelihood of LVO to thrombectomy-capable or comprehensive stroke centers. Reducing false positives is similarly critical as it may reduce unnecessary patient routing and additional transport

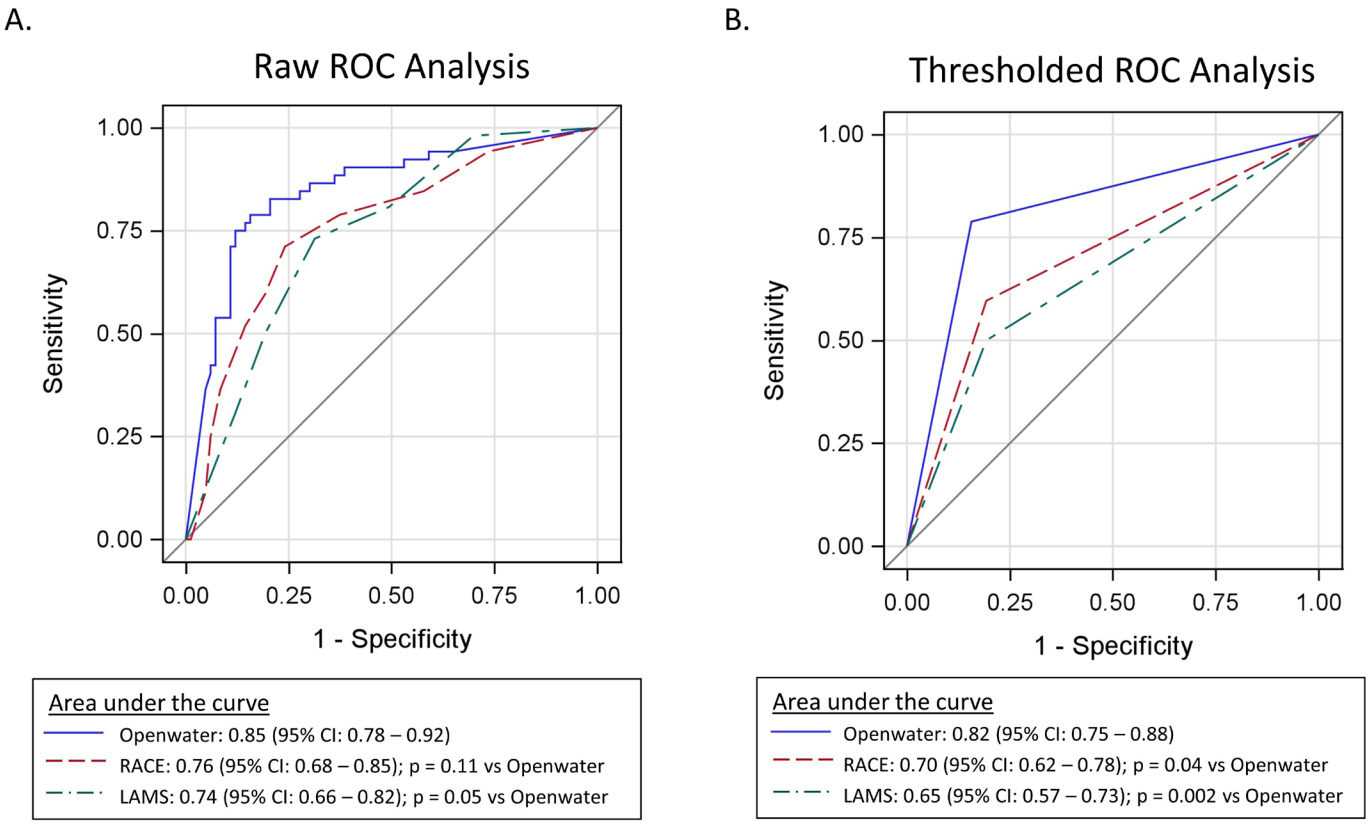

Figure 2 Receiver operator characteristic (ROC) analysis for detection of large vessel occlusion. (A) ROC area under the curve depicted when using raw scores. The area under the curve for the Openwater optical blood flow monitor is larger than that of LAMS. (B) ROC area under the curve depicted when using thresholded (ie, binary) scores. The Openwater threshold was ≥0.80, the RACE threshold was ≥5 and the LAMS threshold was ≥4. RACE, rapid arterial occlusion evaluation scale; LAMS, Los Angeles motor scale.

time. This capability is particularly relevant to non-LVO patients who are potentially eligible for IV thrombolysis. These encouraging results require validation using an independent test set followed by validation in a prehospital cohort of patients with potential stroke.

The clinical relevance of false positives and false negatives is expected to vary geographically. For example, in urban environments, bypassing a primary stroke center may add minimal added travel time whereas additional time may be expected in suburban and rural communities.[2] Furthermore, excessive bypassing may present a burden to comprehensive or thrombectomy-capable centers while leaving primary stroke centers underused. Future work may address the fact that the Openwater threshold can be titrated to emphasize either specificity or sensitivity to optimize care according to regional practices and logistics.[20]

Given the clinical demand, several techniques have been explored as potential prehospital LVO detectors.[7] Some mobile stroke units are capable of performing CT angiography, which presents a good opportunity to diagnose LVO in the field,[21] but limitations—most notably cost—have hindered widespread implementation. Wearable or portable devices are appealing as they can be built into existing EMS infrastructure. Forest Devices (Pittsburgh, Pennsylvania, USA) developed a wearable cap that merges EEG and somatosensory evoked potentials. In an enriched cohort, similar to the current study, superior diagnostic accuracy was observed when compared with prehospital stroke scales.[8] Although the EEG cap requires less than 5 min of set-up time, EEG may present additional logistical challenges in prehospital use. The Openwater optical blood flow monitor provides a simpler patient interface and can be set up in less than 1 minute. Cerebrotech (Pleasanton, California, USA) developed a headset that leverages VIPS, a novel technology that uses low-power electromagnetic waves to detect asymmetry in bioimpedance, which in turn informs the likelihood of a large area of tissue injury.[9] Although easy to use, the Cerebrotech device does not differentiate LVO from large hemorrhage or large ischemic stroke without LVO. In a single small study, transcranial ultrasound only detected 54% of LVOs.[22] Although the combination of ultrasound and clinical examination improved the diagnostic performance,[22] ultrasound requires a degree of expertise that may not be reasonable to expect among EMS providers. Thorpe *et al* used TCD to recognize CBF waveform features (quantified as the velocity curvature index and velocity asymmetry index) that achieved good diagnostic accuracy for LVO.[11] Because the required technical expertise may limit broad implementation in the prehospital setting, Neural Analytics (NovaGuide TCD, NeuraSignal, USA) developed an autonomous system that obviates the need for an expert sonographer,[23] but its potential role in detecting LVOs in clinical practice remains unclear.

Cost is critical when considering the potential for widespread implementation. One advantage of the Openwater system is that the major components (ie, camera sensors, semiconductor lasers, computer chips) are similar to components found in everyday commercial devices such as cell phones. These components are produced at very low cost so, at scale, the system itself stands to be very inexpensive. Given the stage of development, the eventual market cost of the Openwater system is not yet specified. Furthermore, the cost of alternative approaches discussed above is also unclear as they are not currently marketed for this indication.

Biomedical optical techniques are particularly appealing in this context given the ability to directly probe microvascular hemodynamics in a portable and easy-to-use device. Cerebral oximetry-based near-infrared spectroscopy (NIRS) is the most widely available optical technique and is often used as a surrogate of CBF,[24] but changes in the NIRS signal may not mirror changes in CBF in the context of fluctuations in arterial oxygen saturation or cerebral metabolism,[25] which may be a particularly relevant limitation in acute stroke. Another optical technique, diffuse correlation spectroscopy (DCS), provides a direct measure of CBF by quantifying the speckle intensity fluctuations of near-infrared light that is scattered by tissues.[26] Indeed, speckle fluctuations in space or time are the source of data for all emerging optical CBF methods. DCS has been used to monitor acute stroke physiology at the bedside,[15] but signal-to-noise and acquisition frequency have to date limited the ability of DCS to discern a high resolution CBF waveform for large source detector separations.[27] Speckle contrast optical spectroscopy (SCOS) uses a camera to measure speckle ensembles which in turn reflect changes in CBF but, again, to date the signal-to-noise ratio is not sufficient to resolve a high resolution CBF waveform.[28] The Openwater optical blood flow monitor has some similarities to traditional SCOS but it also incorporates important methodological differences that allow it to overcome key limitations. In particular, short pulses of very intense laser light (rather than continuous light) permit signal-to-noise improvements and facilitate probing of tissue dynamics at very short time scales.[16] The system also incorporates the cameras within the headset (instead of the console), which mitigates artifacts caused by cable motion. The ease of use and small portable design are also critical when considering the possibility of prehospital use. The Openwater system has previously been reported to resolve pulsatile CBF waveforms during the cardiac cycle, comparable to that of other high resolution instruments such as TCD.[16]

The technical failure rate of the optical scan requires further consideration. 6% of patients were excluded due to poor headset contact which resulted in insufficient laser light and/or excess ambient light detected. Another 10% were excluded due to excessive patient movement which resulted in failure of the automated pulse detection. The exclusion strategy ensured the final analysis consisted of high quality data, but this limits generalizability, and these technical challenges need to be resolved before using the instrument in the prehospital environment where technical failures may be different or potentially more frequent. However, issues related to simultaneous clinical care (ie, patients being moved or examined during the scan) may be less problematic in the prehospital setting where there are fewer providers. Poor headset contact can be eliminated by implementing a (<15 s) pre-scan data quality check which will prompt users to adjust the headset as needed. This workflow was developed in response to the observed limitation but needs to be applied in a validation set to confirm utility. The 10% who failed the automated pulse detection could be reduced by providing immediate feedback to the user that the scan has been rejected and needs to be repeated. Again, the pre-scan quality check described above includes automated pulse detection in order to alert the user to adjust the headset until the issue is resolved. Additional end-user training may help ensure the scan is not performed while the patient is being moved or examined. Minimizing these limitations with a brief pre-scan will likely be critical to instrument feasibility in the prehospital environment where patient movement may be more problematic. The simple user interface was designed based on feedback from inexperienced users to ensure feasibility in the hands of a wide range of personnel, but EMS personnel cannot be expected to troubleshoot in the field. Hence, the effect of the pre-scan quality check needs to be independently studied and, if necessary, iteratively improved on prior to use in the prehospital environment. The rate of subject exclusion reported here was

comparable to that of prior studies using novel approaches to LVO detection in the emergency department. For example, when using a combination of EEG and SSEP data in the EDGAR study, nearly all of the 12% excluded were due to poor data quality.[8] In the ELECTRA-STROKE study, an 8-lead EEG cap had a failure rate of 35%,[29] and the Cerebrotech Visor had a 10% failure rate in the hands of trained operators at two stroke centers.[30]

Excluded patients had more severe strokes, and it is likely that patient movement and concomitant clinical care contributed to the scan failure in these cases. Importantly, a high rate of LVO was observed in patients who had a failed scan, which may be attributable to the fact that patients were often scanned while the stretcher was moving or while the patient was being moved between a bed and stretcher. Both enrolling centers go to great lengths to minimize the door-to-device time, which in turn introduces a challenge when collecting data prior to endovascular intervention. This issue was noted in several excluded subjects but was not routinely collected in the case report form, so we are unable to quantify its relevance. Interestingly, a similar phenomenon was observed in the ELECTRA-STROKE study, in which patients who were excluded due to poor EEG data quality were nearly three times more likely to have a LVO.[29] The same observation with two unrelated techniques implies this is not likely to be attributable to the technique itself.

Several additional limitations should be recognized. First, the optical scans were performed on arrival in the emergency department rather than in the prehospital setting. By enrolling patients during the acute stroke evaluation, the cohort is reflective of the eventual target patient population but the cohort was enriched with LVOs because of the large number of LVO transfers at the enrolling centers. Model performance may be limited by the relatively small sample size, but the fivefold validation offers added efficiency. The results are not reflective of a true test set, but similar performance across each fold provides some reassurance. In future work, a prespecified model derived from these pilot results should be applied to an independent test cohort, after which prehospital feasibility and performance can be evaluated. The diagnostic performance is unknown in small distal occlusions and may be clinically relevant to healthcare systems that routinely pursue EVT in such circumstances. The instrument probes the anterior circulation so is not expected to be sensitive to posterior circulation LVO, but no posterior circulation LVOs were enrolled in this study so this may be directly explored in future work. There is also an opportunity to explore the subgroup of patients with mild clinical deficits in whom prehospital scales are particularly insensitive.[31]

CONCLUSION

The Openwater optical blood flow monitor outperformed prehospital stroke scales for the detection of LVO in patients who presented to the emergency department for acute stroke evaluation. Future studies need to first validate these findings using an independent test set followed by a cohort of patients with suspected stroke in the prehospital environment. If validated, subsequent work can determine how to incorporate the results into routing workflow, and with further evaluation to clarify how the Openwater threshold can be titrated to meet the regional needs of different EMS and healthcare systems.

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Competing interests CGF and RAM received an investigator-initiated grant from Openwater. AGY has patents related to biomedical optical imaging but not directly relevant to this work (US patents 10,342,488; 10,827,976; 8,082,015; and 6,076,010) that do not currently generate income. SK and KG are employees of Openwater.

Patient consent for publication Not applicable.

Ethics approval All study procedures were approved by the University of Pennsylvania (protocol #828249) and Lifespan (protocol #00004624) Institutional Review Boards, conform to institutional research standards, the principles outlined by the Declaration of Helsinki, and STROBE guidelines. Informed consent was provided by each subject (or legally authorized representative).

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Data availability statement Data are available upon reasonable request. The de-identified data that support the reported findings are available from the corresponding author upon reasonable request.

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