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The Presto 1000: A novel automated transcranial Doppler ultrasound system

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Abstract

We examined the reliability and ease of use of a novel automated transcranial Doppler (TCD) system in comparison to a conventional TCD system. TCD ultrasound allows non-invasive monitoring of cerebral blood flow, and can predict arterial vasospasm after a subarachnoid hemorrhage (SAH). The Presto 1000 TCD system (PhysioSonics, Bellevue, WA, USA) is designed for monitoring flow through the M1 segment of the middle cerebral artery (MCA) via temporal windows. The Presto 1000 system was tested across multiple preclinical and clinical settings in parallel with a control predicate TCD system. In a phantom flow generating device, both the Presto 1000 and Spencer system (Spencer Technologies, Redmond, WA, USA) were able to detect velocities with high accuracy. In nine volunteer patients, the Presto system was able to locate the MCA in 14 out of 18 temporal windows, in an average of 12.5 s. In the SAH cohort of five patients with a total of 25 paired measurements, the mean absolute difference in flow velocities of the M1 segment, as measured by the two systems, was 17.5 cm/s. These data suggest that the Presto system offers an automated TCD that can reliably localize and detect flow of the MCA, with relative ease of use. The system carries the additional benefit of requiring minimal training for the operator, and can be used by many providers across multiple bedside settings. The mean velocities that were generated warrant further validation across an extended group of patients, and the predictive value for vasospasm should be checked against the current standard of angiography.

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Conflicts of Interest/Disclosures

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Keywords

Automated; Middle cerebral artery; Subarachnoid hemorrhage; Transcranial Doppler; Vasospasm; Velocity

1. Introduction

A major contributor to morbidity and mortality associated with subarachnoid hemorrhage (SAH) is delayed cerebral ischemia caused by vasospasm. Symptomatic vasospasm occurs in up to one third of patients with SAH, and there is a strong correlation between vasospasm seen on angiography and the development of delayed cerebral ischemia [1]. Catheter angiography remains the gold standard for the diagnosis of vasospasm, but it is an invasive study and carries a risk of morbidity. Transcranial Doppler (TCD), which allows measurements of blood flow velocities in the circle of Willis vessels, has become a valuable adjunct for non-invasive detection of vasospasm, demonstrating a close correlation with angiography [2–4]. TCD is now a recommended tool for monitoring arterial vasospasm, in the current version of the American Heart Association management guidelines for SAH [5].

One limitation of TCD is that specialized operator training is required for reliable signal detection and flow measurements, and significant intra and interobserver variability can be encountered [6]. As such, the results can be highly operator dependent, as exemplified by one recent study that reported significantly greater sensitivity in diagnosing symptomatic vasospasm with TCD performed by trained operators compared to untrained operators [7]. Two of the most challenging aspects to master in order to ensure reliable measurements include the ability to consistently locate effective temporal acoustic windows and to achieve and maintain optimal probe position for maximum TCD signal strength and quality. The Presto 1000 TCD system (PhysioSonics, Bellevue, WA, USA) was developed in response to these challenges by automating these two user-dependent processes. Here, we report the results of this novel automated TCD system, which does not require a trained ultrasound technician, in comparison to a predicate conventional TCD system in preclinical and clinical settings.

2. Materials and methods**2.1. Description of the system**

The Presto 1000 TCD system is intended for use in the bedside setting as an ultrasonic fluid flow analysis system, monitoring flow through the M1 segment of the middle cerebral artery (MCA) via temporal windows. Like other Doppler devices currently in clinical application, the Presto system generates voltage pulses which are converted in the transducer to acoustic pressure pulses and then transmitted through body tissues. Echoes from moving red blood cells are received by the transducer, and converted back into electrical signals which are processed into Doppler shift frequencies corresponding to blood flow velocities. As a dedicated blood flow monitor, the Presto 1000 analyzes these Doppler signals for blood flow metrics. The unit contains two permanently connected 2D phased array transducers, which can be mounted to a headset and used for bilateral, long term monitoring as well.

The Presto system was designed for ease of use and reliability, and does not require operation by a formally trained ultrasound technician. The system interface guides the user through a two-step process, first to guide the transducer position over an optimal temporal window, then to guide the transducer orientation to maximize the strength of the MCA signal. When the transducer is placed over the temporal window, the first display on the interface guides the user to find the optimal position of the probe over the temporal window by showing the strength of the signal (Fig. 1A). The second display then shows the color-coded flow signal through the MCA, and this is used to guide the user to orient the transducer probe and maximize the quality and strength of the signal (Fig. 1B). The system automatically detects the vessel flow and follows the signal as the region of interest for flow analysis. Finally, while maintaining the probe position, the system can be switched to flow analysis mode (Fig. 2).

2.2. Preclinical testing

A phantom flow generator device was used to generate serially increasing flow velocities from 10–140 cm/s. The accuracy of the Presto system in detecting the velocity of flow produced by the flow generator at increasing velocities was tested. These results were compared to the accuracy of measurements on the Spencer 100M TCD system (Spencer Technologies, Redmond, WA, USA).

2.3. Testing in healthy volunteers

Nine healthy volunteers were recruited to determine the reliability of the Presto system in accessing the temporal window and detecting MCA flow signal, when compared to a TCD system that is currently in widespread clinical use. The volunteers were of Asian and Pacific Islander descent, both being populations that are more difficult to image through temporal windows [8]. The subjects were each examined by the two systems, the Presto 1000 and the ST3 Digital Doppler system (Spencer Technologies). All patients were examined through both temporal windows. The ability of each system to access the temporal acoustic window, and the time required to capture a measurable flow signal, were recorded for each examination.

2.4. Testing in patients with SAH

The evaluation of the SAH cohort included five inpatients treated for aneurysmal SAH during April, 2014. The Presto system was operated by two neurosurgical trainees (SJH & WCR). The patients were also examined by a conventional TCD (ST3 system), operated by a vascular lab ultrasound technologist (JLB), and performed on the same day as the Presto system testing. Two patients each underwent four sets of tests through both temporal windows, and two patients each underwent only one set of tests in both windows. One patient received two sets of bilateral measurements in addition to one unilateral measurement. The clinical testing included a total of 25 paired measurements.

3. Results

In the phantom flow generating device, both the Presto and Spencer systems were able to detect the flow velocities generated by the device with high accuracy (Fig. 3). In the nine

volunteer patients, the Presto system was able to locate the MCA signal in 14 out of 18 temporal windows, in an average of 12.5 s. The Spencer system was able to locate the MCA in 16 out of 18 windows, in average of 18.5 s (Table 1). In the SAH cohort, the Presto system was able to reliably detect the MCA signal in all patients, including over the side of a craniotomy. The mean absolute difference in flow velocities of the M1 segment between measurements recorded by the two systems was 17.5 cm/s (Table 2).

4. Discussion

The Presto 1000 offers an automated TCD system that can reliably localize and detect flow of the MCA with relative ease of use. The system has the additional benefit of the ability to be operated by clinicians at the bedside without the need of an ultrasound technician with formal training. In the bench testing using a phantom flow generator, the Presto system was able to accurately detect the flow velocities at wide ranges, similar to the Spencer system. During testing in healthy volunteers of Asian descent, the Presto system was able to reliably detect the MCA signal through temporal windows in the majority of subjects, and locating the signal took a shorter amount of time compared to the Spencer system, although this difference was not statistically significant. In two volunteers, however, the Presto system was unable to detect a measurable MCA signal on one side, while the Spencer system was successful in both of these subjects. A comparison of the Presto and Spencer systems in the clinical setting of SAH patients revealed differences in MCA flow values on the order of 10–20 cm/s. However, it remains unknown how clinically relevant this variability is, regarding the ability of the system to detect vasospasm. A previous study has reported that the interobserver variability of TCD is high, but the sensitivity in diagnosing angiographic vasospasm using a prespecified velocity threshold was similar across different operators [6]. A potential explanation for these differences in measurements is the highly variable nature of intracranial flow velocities and their measurements. Flow velocities are dependent on multiple factors, including systemic blood pressure, intracranial pressure, vascular tone, venous drainage, partial pressure of carbon dioxide, drug use, and even head position [9,10]. Although testing with the Presto system was performed on the same day as with the Spencer system, these factors that influence mean velocity measurements on a minute by minute basis could not be taken into account. Additionally, even in similar background conditions, the differences in the location along the length of MCA where the measurement was taken (the depth of measurement), as well as the angle of insonation, will result in varying velocity measurements. Both of these factors were unable to be controlled for in our analyses, and they likely contributed to the differences in the measurements between the two systems.

Other limitations in our analyses include the relatively small number of subjects in both the volunteer and SAH cohorts. This precluded any meaningful statistical analyses to determine whether there was truly a difference in the Presto system ability to detect signal through the temporal acoustic window compared to the Spencer system in volunteers, and whether the two systems may differ in their ability to detect angiographic or clinically symptomatic vasospasm in the SAH cohort.

The Presto 1000 system is designed only for flow measurements in the M1 segment of the MCA, therefore, it differs from conventional TCD systems such as the Spencer systems, in

its inability to measure flow through the anterior cerebral artery, posterior circulation arteries, and the internal carotid artery. As such, the Presto system is unable to calculate the Lindegaard ratio [11]. However, this may not represent a clinically significant deficit, as multiple studies have now demonstrated that using the Lindegaard ratio is less predictive than using absolute velocity values in identifying angiographic vasospasm [12,13]. In addition, using the absolute flow velocity values of the MCA alone appears to allow diagnosis of angiographic vasospasm with high sensitivity and specificity [14–16]. The Presto system also has the added benefit of simultaneous bilateral monitoring. This ability further strengthens the ability to diagnose ipsilateral vasospasm by measuring and comparing the two sides, and the ratio of velocities of such evaluations have been found to be more sensitive and specific for vasospasm [14].

TCD continues to have an extensive role in diagnosing pathologic conditions affecting the intracranial vasculature. The applications beyond vasospasm from SAH include vasospasm in sickle cell disease, elevations in intracranial pressure (ICP) in traumatic brain injury, microemboli in shunts, stenosis of intracranial or extracranial vasculatures and decreased perfusion in brain death [8]. One major limitation to continued widespread application of TCD is the availability of properly trained technicians. The Presto 1000 TCD system was developed in response to this challenge, and provides automated support for the user-dependent processes of locating the ideal temporal acoustic window and detecting the flow signal. This automated process also helps to limit the variability in depth and angle of measurement, and will likely reduce the intra- and interoperator variability in measurements as well. Although not evaluated in the current study, the Presto 1000 system is also able to calculate the pulsatility index (PI) based on the flow waveform morphology. Good correlation between PI and ICP has been demonstrated previously [17], and non-invasive detection of elevated ICP is another promising application of the Presto 1000 system which is currently under evaluation.

5. Conclusion

In summary, the Presto system offers an automated TCD that can reliably localize and detect flow in the MCA, without the need for a formally trained ultrasound operator. The MCA velocity measurements warrant further validation across an extended group of patients, and the predictive value for vasospasm in patients with SAH should be tested alongside formal angiography. The ease of use of the system will undoubtedly facilitate expansion of the application of TCD into more clinical settings, including traumatic brain injury.

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Fig. 1.

Display interface guiding the operator to finding the optimal position for the probe over the temporal acoustic window (left), and guiding optimal probe orientation for maximum quality and strength of the middle cerebral artery flow signal (right). This figure is available in colour at www.sciencedirect.com.

Fig. 2.

Flow analysis mode showing the transcranial Doppler waveform. This figure is available in colour at www.sciencedirect.com.

Fig. 3. Comparison of bench testing of Presto 1000 (PhysioSonics, Bellevue, WA, USA) and Spencer TCD 100M (Spencer Technologies, Redmond, WA, USA) performance on accurately measuring the flow velocity generated by a phantom flow generator.

Table 1

Flow signal detection by transcranial Doppler in healthy volunteers

Subject	Side	Ability to detect MCA signal through temporal window		Approximate time to acquire MCA signal (s)	
		Presto ^a	Spencer ^b	Presto ^a	Spencer ^b
1	R	Y	Y	18	60
	L	Y	Y	16	60
2	R	Y	Y	30	15
	L	Y	Y	10	25
3	R	Y	Y	15	15
	L	Y	Y	1	15
4	R	Y	Y	1	15
	L	Y	Y	1	1
5	R	Y	Y	15	1
	L	Y	Y	35	15
6	R	N	Y	–	1
	L	Y	Y	1	1
7	R	N	Y	–	30
	L	Y	Y	1	1
8	R	Y	Y	30	40
	L	Y	Y	1	1
9	R	N	N	–	–
	L	N	N	–	–
Total	–	Y: 14/18 N: 4/18	Y: 16/18 N: 2/18	Mean: 12.5	Mean: 18.5

^aPresto 1000 transcranial Doppler system (PhysioSonics, Bellevue, WA, USA).

^bST3 digital Doppler system (Spencer Technologies, Redmond, WA, USA).

– = not applicable, L = left, MCA = middle cerebral artery, N = no, R = right, Y = yes.

Table 2
Cerebral blood flow measurements by transcranial Doppler in patients with subarachnoid hemorrhage

Patient	Right side			Left side		
	Presto ^a (cm/s)	Spencer ^b (cm/s)	Difference (cm/s)	Presto ^a (cm/s)	Spencer ^b (cm/s)	Difference (cm/s)
1	37	47	10	61	78	17
	60	61	1	59	78	19
	57	59	2	62	78	16
	47	85	38	45	106	61
2	42	62	20	31	41	10
	39	57	18	42	41	1
	41	56	15	59	43	16
	35	79	44	52	64	12
3	61	50	11	–	–	–
	64	66	2	95	63	32
4	60	60	0	79	74	5
	66	87	21	62	73	11
5	33	57	24	44	76	32

^aPresto 1000 transcranial Doppler system (PhysioSonics, Bellevue, WA, USA).

^bST3 digital Doppler system (Spencer Technologies, Redmond, WA, USA).

– = no data.