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● *Clinical Note*

FUNCTION AND SAFETY OF SLOW*FLOW*HD ULTRASOUND DOPPLER IN OBSTETRICS

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Abstract—Slow*flow*HD is a new ultrasound Doppler imaging technology that allows visualization of flow within small blood vessels. In this mode, a proprietary algorithm differentiates between low-speed flow and signals attributed to tissue motion so that microvessel vasculature can be examined. Our objectives were to describe the low-velocity Doppler mode principles, to assess the bone thermal index (TIb) safety parameter in obstetric ultrasound scans and to evaluate adherence to professional guidelines. To achieve the latter goals, we retrospectively reviewed prospectively collected ultrasound images and video clips from pregnancy ultrasound scans at >10 wk of gestation over 4 mo. We used a custom-built optical character recognition-based software to automatically identify all images and video clips using this technology and extract the TIb. Overall, a total of 185 ultrasound scans performed by three fetal medicine physicians were included, of which 60, 54 and 71 scans were first-, second- and third-trimester scans, respectively. The mean (highest recorded) TIb values were 0.32 (0.70), 0.23 (0.70) and 0.32 (0.60) in the first, second, and third trimesters, respectively. Thermal index values were within recommended values set by the World Federation for Ultrasound in Medicine and Biology American Institute of Ultrasound in Medicine and British Medical Ultrasound Society in all scans. (E-mail: aris.papageorghiou@wrh.ox.ac.uk)

Key Words: **Slow*flow*HD, Doppler ultrasound, Superb Microvascular Imaging, Ultrasound safety, Safety index, Thermal index.**

INTRODUCTION

Ultrasound imaging innovation is an ever-growing process (Drukker et al. 2020a, 2020b, 2020c; Abramowicz 2021). Slow*flow*HD is a new Doppler mode that enables the visualization of low-velocity blood perfusion in small-diameter vessels (Figs. 1 and 2). Recent studies have presented the diagnostic value of Slow*flow*HD in the assessment of fetal abdominal microvasculature and diagnosis of congenital heart disease in the first trimester (Athanasopoulos et al. 2020; Hata et al. 2020a, 2020b).

The value of blood flow Doppler measurements in obstetric medicine blood is well established, aiding the identification of pregnancies at risk for complications, managing fetuses affected by growth restriction and diagnosing fetal abnormalities. Conventional color flow Doppler displays color-coded information concerning the relative velocity and direction of fluid motion in large vessels (Fig. 3a). As the diameter of the vessels decreases, their number in the body increases so that the total cross-sectional area increases; hence, smaller blood vessels are characterized by slower blood flow velocity (Chaudhry et al. 2020). Until recently, technical limitations have meant that visualization of small blood vessels using conventional Doppler modes was poor. In theory, lowering the pulse repetition frequency (PRF, the sampling speed) or the wall motion filter (WMF, the interpretation of fast-moving signals as blood flow and slow-moving signals as artifacts) in color Doppler mode should allow the visualization of small blood vessels

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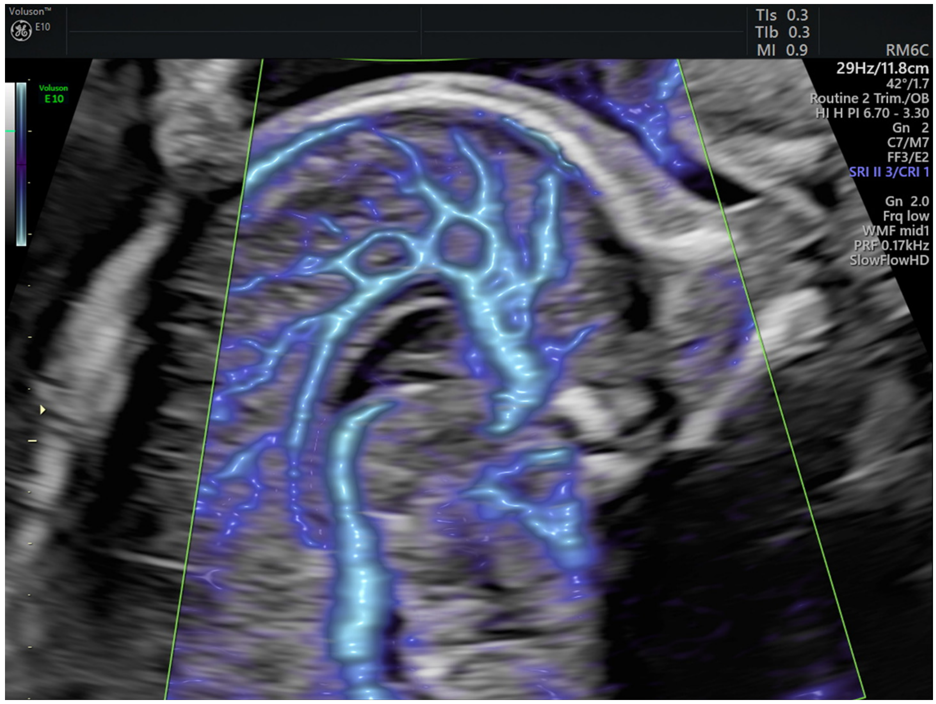

Fig. 1. Fetal cranial circulation using Slow*flow*HD.

(Martins et al. 2018). However, as most practicing ultrasound operators know, the disadvantages of reducing the PRF are aliasing and color flash artifacts, which limit visualization of the small blood vessels. Aliasing, which results in flow velocity and direction misinterpretation artifacts, occurs when the blood velocity exceeds the maximum measurable velocity, causing the flow to be visualized as a mixture of blue and red (Fig. 3b) (Merritt et al. 2018;

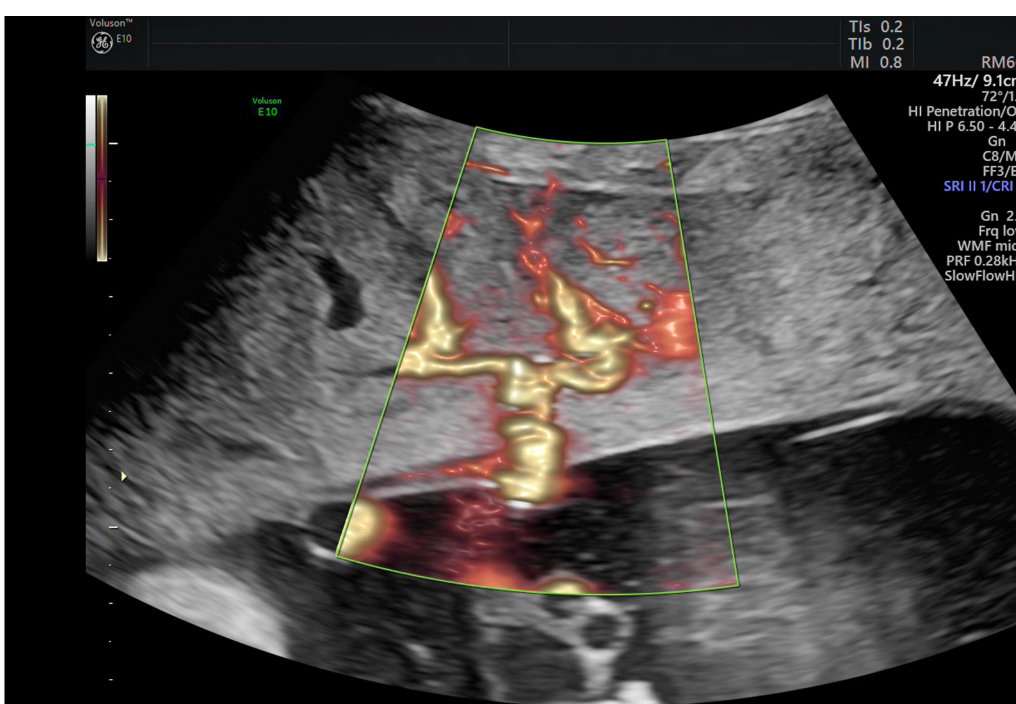

Fig. 2. Placental vasculature using Slow*flow*HD, revealing the villous trees.

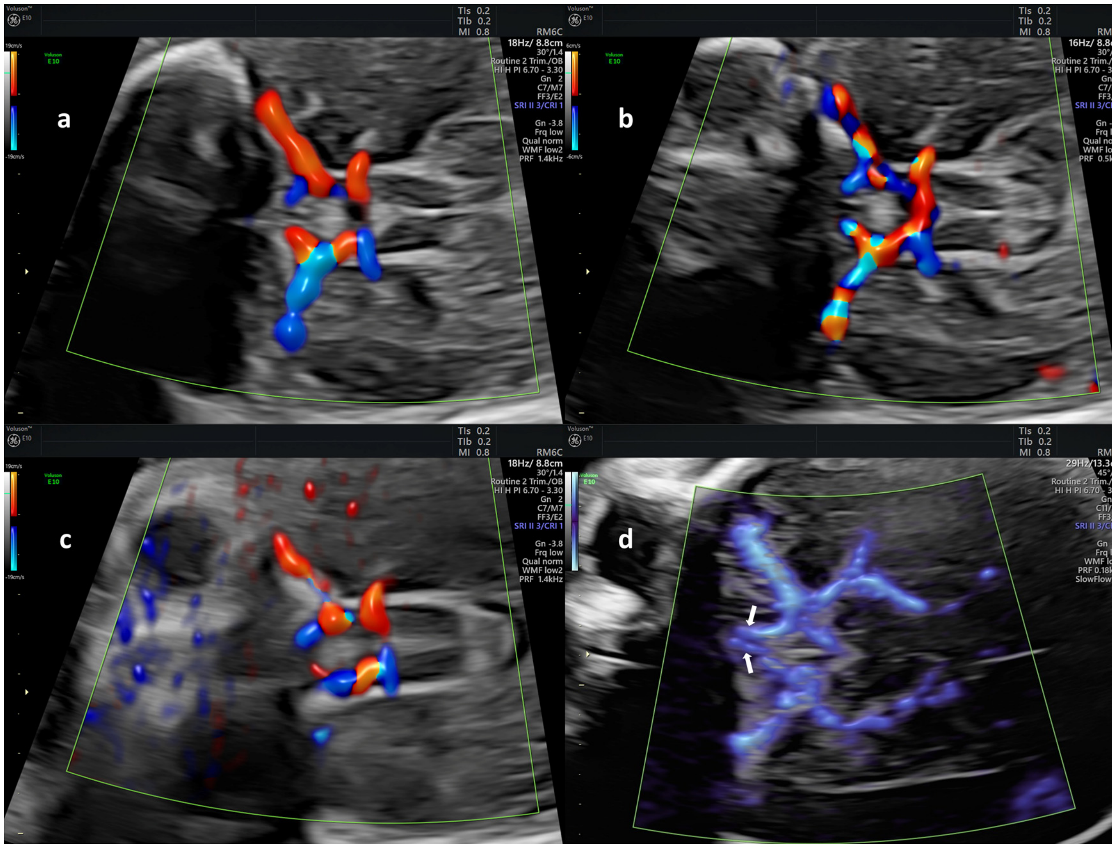

Fig. 3. Fetal circle of Willis obtained using conventional ultrasound Doppler and its artifacts versus Slow*flow*HD small vessel visualization. (a) Conventional color Doppler with correct Doppler adjustments. (b) Conventional color Doppler with aliasing artifact evident owing to pulse repetition frequency (PRF) set to 0.5Khz (too low). (c) Conventional color Doppler with color flash artifact caused by a tiny fetal movement with a low PRF set to 1.4 kHz. (d) Slow*flow*HD Doppler correctly revealing slow-velocity vessels with the PRF set to 0.18 kHz, most notably evident for the clearly visualized bilateral anterior cerebral arteries (d, *white arrows*), which are not visualized in (a)−(c).

Drukker et al. 2020a, 2020b, 2020c). The color flash artifact occurs where movement of the fetus or tissue is erroneously translated to flow, evidenced by even tiny motion of the fetus or probe appearing as blurry "bleeding" into the tissue (Fig. 3c). Both artifacts become more prominent with further reductions of the PRF.

Slow*flow*HD is a blood flow examination technique optimized to visualize the microvasculature. This new Doppler mode uses a low PRF continuous (instead of the traditional ensemble-based) Doppler imaging acquisition scheme, and wall filters that adapt to tissue movement and can subtract the tissue signature from the ultrasound signals. In standard color Doppler imaging, the wall or tissue filter is usually set to remove most tissue motion artifacts. However, these filters not only remove tissue motion from the ultrasound signals but also remove the low-velocity flow. Hence, Slow*flow*HD has a higher sensitivity to slow flow (Fig. 3d).

Similar advanced flow-detection imaging techniques are also currently marketed under various trademarks (Hasegawa et al. 2019; Mack et al. 2019; Hata et al. 2020a, 2020b; Jabak et al. 2020; Sainz et al. 2020). These applications include Superb Microvascular Imaging (SMI) by Canon Medical Systems (formerly Toshiba Medical Imaging), Detective Flow Imaging (DFI) by Hitachi Medical Systems, microflow imaging (MFI) by Philips and MV-Flow by Samsung Health Care.

Because of the relative novelty of the technique, we aimed to describe the principles of the technology, evaluate the thermal index of bone (TIb) bio-effect safety parameters with Slow*flow*HD usage in obstetric ultrasound scans and determine adherence to safety guidelines recommendations during real-world scanning (Safety Group of the British Medical Ultrasound Society [BMUS] 2010; World Federation for Ultrasound in Medicine and Biology [WFUMB] 2013; Miller et al. 2020).

METHODS

This was a retrospective study of prospectively collected data of pregnant women who underwent ultrasound imaging at the Oxford Fetal Medicine Unit, John Radcliffe Hospital, Oxford University Hospitals National Health Service (NHS) Foundation Trust, a large tertiary referral unit in the United Kingdom. As part of pregnancy care, referred women are offered targeted ultrasound scans if referral criteria are met, such as a high risk for chromosomal anomaly, suspected fetal structural anomaly or fetal growth abnormality. These scans are carried out by fetal medicine specialists using a commercial Voluson E10 BT19 (General Electric, Zipf, Austria) equipped with standard curvilinear (C2-9-D) and 3D/4D (RCM6) probes. Scan results are recorded and coded prospectively using commercially available archiving software (Viewpoint version 5.6.25.281, GE Healthcare).

We included all pregnant women who had a scan in any trimester between November 1, 2019, and February 29, 2020, and who had one or more saved scan image or clips taken using the Slow*flow*HD Doppler mode during an ultrasound scan.

To evaluate the relevant safety index associated with the use of Slow*flow*HD using real-world data, we identified all scans employing this technology carried out after 10 wk of gestation and then extracted the TIb documented in the safety box (Drukker et al. 2020a, 2020b, 2020c), the most relevant index of safety at this gestation (Sande et al. 2013). Ultrasound images were extracted from the ultrasound machine and the archiving database (Viewpoint version 5.6.25.281, GE Healthcare). To automatically identify all saved images and clips where Slow*flow*HD mode was used and to extract the TIb values, we purpose-built a program implemented in Python (www.python.org, version 3.8.3). Images and clips that were taken in the Slow*flow*HD mode contain the text "SlowFlowHD" on the right side of the screen, and the TIb value is displayed in the output display standard, which is located at the upper right side of the screen (Figs. 1 and 2). The custom-built program employed optical character recognition via a deep learning-based EasyOCR library (github.com/JaidedAI/EasyOCR, version 1.1.7), which allows detection of the presence of the text indicator and reading of the TIb values. We verified the function of the program by visual assessment of a subset of 50 scans.

Results were analyzed, and adherence to the WFUMB, American Institute of Ultrasound in Medicine (AIUM) and BMUS guidelines was evaluated (Safety Group of BMUS 2010; WFUMB 2013; Miller et al. 2020). The fetal medicine physicians who performed the scans included in the current study had not been informed of the aim of the analysis that was established after completion of data acquisition, meaning we were able to capture their routine practice while acquiring the scans.

Ethics approval

This study was granted ethical approval (Reference No. 17/SC/0374) by the National Health Services (NHS) Health Research Authority (HRA). Requirement of informed consent from human subjects was waived as the images and clips were acquired for routine clinical diagnostic purposes and were fully anonymized prior to analysis.

Statistics

Statistical analyses were performed using the statistical software package SPSS 25.0 (IBM, Armonk, NY, USA). We report descriptive statistics.

RESULTS

During the study period, a total of 185 ultrasound scans included at least one image or short video clip acquired using the Slow*flow*HD Doppler mode. Visual assessment confirmed that the software detected Slow*flow*HD mode correctly in all cases and that TIb was accurately extracted. Additionally, we did not identify any cases in which Slow*flow*HD was not detected.

There were 60, 54 and 71 ultrasound scans performed in the first, second and third trimesters, respectively. Overall, there were 240 images and 218 five-second clips available for analysis.

The median number of images and videos using Slow*flow*HD Doppler mode in the included scans was 4 (IQR: 2−9). All Doppler examinations were carried out by one of three fetal medicine physicians.

The mean TIb values in Slow*flow*HD Doppler mode were 0.32, 0.23 and 0.32, in the first, second and third trimesters, respectively, and the highest values were 0.7, 0.7 and 0.6, respectively. The WFUMB Ultrasound Exposure During Pregnancy guideline recommends that care should be taken to limit the exposure time and the thermal and mechanical indices to the minimum commensurate with an acceptable clinical assessment, particularly when the thermal index exceeds 0.7. Both AIUM and BMUS recommendations stipulate that there should be no maximal scanning time limit in obstetric scans while the thermal index exposure is $\leq$0.7. These thresholds were kept in all scans included in the analysis.

DISCUSSION

Here we report on a novel Doppler mode that displays low-velocity flow that characterizes small vessels with high detail and definition by overcoming some of the limitations of conventional Doppler. We have introduced this technique into our practice and found that during real-world scanning, in a representative clinical setting where obstetric scans are performed throughout pregnancy, the thermal index was within recommended ranges (Safety Group of BMUS; WFUMB 2013; Miller et al. 2020).

Clear visualization of small blood vessels may facilitate detailed examination of the fetus earlier in pregnancy. Therefore, use of such novel imaging applications may aid the trend of earlier detection of fetal abnormalities (Karim et al. 2017).

In a previous study (which preceded the release of Slow*flow*HD), we evaluated ultrasound safety indices in more than 600 full-length routine obstetric scans in the first, second and third trimesters (Drukker et al. 2020a, 2020b, 2020c). According to our results, the recommended exposure times of TIb were kept in accordance with the current guidelines (Safety Group of BMUS 2010; WFUMB 2013; Miller et al. 2020) in all scanning modes including B-mode, color/power Doppler and pulsed wave Doppler. Additionally, using operator eye-tracking, we found that operators infrequently visually checked the bio-effect indicators on the ultrasound machine display.

Although we were able to illustrate that the thermal output of Slow*flow*HD is within the recommended range, it is crucial to remember that as with any other ultrasound mode, scanning time should be limited to the shortest duration possible to obtain adequate clinical information, in concordance with the ALARA (as low as reasonably achievable) principle (Kollmann et al. 2020). Additionally, it is important to understand that pulsed wave Doppler, the graphical representation of flow velocity over time and quantification of flow velocity, uses a higher PRF than any other Doppler modes, including Slow*flow*HD. Therefore, pulsed wave Doppler may transfer more heat to the tissue if superimposed on color Doppler, and should be used only with clear indication; this is particularly relevant in the first trimester, where the recommended highest TIb should not exceed 1.0 (Salvesen et al. 2011; WFUMB 2013)

The main strength of the study is that we performed a real-life assessment of prospectively collected data in all obstetric scans, performed by operators unaware of the aims of the current analysis. This strength was achieved by using a custom-built program that used a deep learning-based library for optical character recognition, allowing detection of the presence of the text indicator and reading of the TIb values automatically, as verified on a subset of images. This method could serve as a model for gathering large-scale safety data from examinations; such data are also more likely to be representative of real-world scanning behavior than data from laboratory-based testing, where sonographers are aware of the purpose of the evaluation. Thus, although data collection occurred at one maternity unit and a relatively limited number of scans were done, it is likely to be generalizable to other settings using similar ultrasound systems. It should also be noted that we evaluated the safety parameters on stored still images and clips, and although it is possible that in some scans the safety indices differed from those of "live" scanning, this is unlikely. Additionally, we did not record the amount of time used toward the capture of stored acquisitions; however, there is no upper limit to the maximum exposure time for TIb $\leq$0.7.

CONCLUSIONS

We report that the recently introduced Slow*flow*HD Doppler mode meets safety recommendations during real-time obstetric ultrasound. Although this tool is available mainly in high-end ultrasound machines at present, many technological advancements have become more widespread over time, and Slow*flow*HD and the data are reassuring as this is integrated into standard ultrasound machines in the future.

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