

Carotid Artery HITS measurement system using the Paste-able Soft Ultrasonic Probe and its clinical application

貼付け型超音波プローブを用いた頸動脈HITS測定装置とその臨床適用

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Abstract

The cause of the cerebral infarction (CI) is embolism by large thrombi. The smaller emboli floating in blood flowing down the whole body could be the sign of presage that CI would occur. We developed class II Medical Device, the ultrasonic doppler carotid arteries monitor FURUHATAⁱ that can detect the emboli as HITS (high intensity transient signal) at the carotid artery. Clinical study was conducted for the patients and asymptomatic subjects. The results suggest that the equipment has CI prediction ability.

I. The Principle and Construction of the System

FURUHATA features Paste-able Soft Ultrasonic Probe (PSUP) that makes measure the carotid blood flow stably for a long time and is the system to detect HITS by ultrasonic Doppler with the standard of the American Stroke Society [1] and to record as an event list. PSUP, fixed on the carotid artery of the subject with a surgical tape, is driven by a burst wave of center frequency, f_0 : 2MHz and pulse repetition frequency, PRF: 5kHz. Ultrasonic beam travels into the body at an incident angle 25 deg. Fig.1 shows the schematic diagram of detecting echo scattered from blood cells and micro particles flowing in a blood vessel.

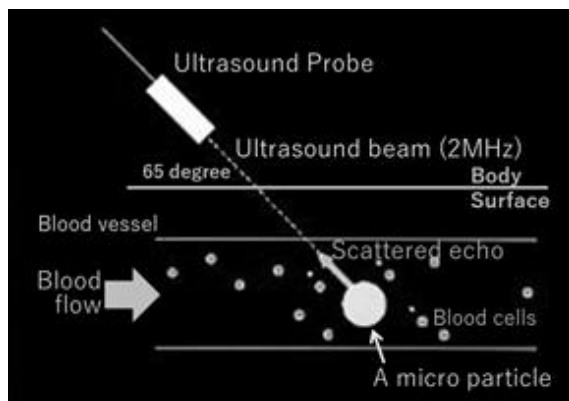


Fig.1 HITS Detection Schema



Fig.2 The Probe works as HITS Detector

The PSUP, working as HITS detector, is stored in casing as shown in Fig.2. Received echo signals scattered from the depth of the carotid artery blood flow are sampled and their Doppler shifted components (I, Q) data are discriminated through quadrature detection and low pass filtering process. The flow waveform is displayed, through FFT processing of 512 point whose intervals are 0.2 ms. Microbubbles and Emboli echoes are also detected as larger signals (HITS) than blood cells, displayed as in Fig.3, and are recorded in different color in the flow waveform from the blood cells.

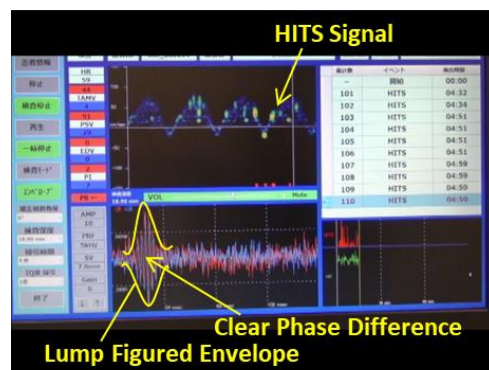


Fig.3 Detected HITS (Artificial Emboli and Bubble) by the developed system

There have appeared results in two fields of application, neurology, and medical examination.

(1) Cause investigation of CI

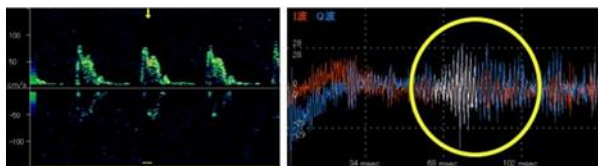
A detection test of patent foramen ovale (PFO) was performed to 84 cases among the CI inpatient with PFO detected by transesophageal echocardiography in Jikei University Hospital.

(2) Medical examination

Carotid HITS examination was performed to 522 subjects, whom deep vein thrombosis, DVT, was found through ultrasound exam for economy class syndrome prevention to residents in the earthquake hit area. Under the agreement of Institutional Review Board in Niigata University Hospital, the medical examination and treatment results has been investigated, and we studied the HITS positive people relation with cerebro- and cardio-vascular diseases (CCVDs).

II. Clinical Application

Fig.4 (a) shows the sonogram, 512 point FFT, of the detected Doppler echo signal containing HITS, and (b) I and Q orthogonal component obtained through quadrature detection process.



(a) Sonogram

(b) IQ waveform

Fig.4 Example of Carotid HITS detected by PSUP

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III. Results

(1) Large PFOs were detected significantly for certain.

(2) CCVDs were found by 30.1% of a HITS detection positive example in medical examination. It was suggested that HITS is found one of significant risk factors statistically.

IV. Conclusion of the development

It has been confirmed through in vitro, in vivo, & human volunteer tests that the system detects, distinguishes, and files HITS signals has been developed using also newly developed probe, pasted on neck, and the system passed the standard of ultrasonic monitor, certified as Japanese medical equipment.

Clinical tests are being carried out with approval of IRB of the Jikei University School of Medicine, and Niigata University.

Acknowledgment

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References

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ⁱ The abbreviated word of “FUtuRe Ultrasound HARmonic Thrombo- embolus Analyzer” proposed by the late professor of the Jikei Univ.