Effects of Imaging Devices Using Acoustic Radiation Force on Living Tissues

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Ultrasound diagnostic equipment using Acoustic Radiation Force Impulse (ARFI),[1] which measures tissue stiffness by slightly displacing soft tissue using acoustic radiation force and ultrasonically measuring the amount of displacement, was approved under the Japanese Pharmaceutical Affairs Law and has been on the market in Japan since 2008.[2]
At the 82nd Annual Scientific Meeting of JSUM (2009), there were some presentations on the use of ARFI technology. In general, high-intensity ultrasound is used for generating tissue displacement with acoustic radiation force. Therefore, the Ultrasound Equipment and Safety Committee of JSUM investigated the effects of ARFI technology on living tissues, and reports the results as follows.

1. A pulsed wave with a longer duration than that of conventional ultrasound diagnostic devices is used for generating tissue displacement with acoustic radiation force.

2. The effects of diagnostic ultrasound outputs on living tissue include physical and chemical effects on tissue due to cavitation and the temperature rise due to the thermal effect of ultrasound. For these effects, there are criteria regarding ultrasound outputs for the approval by the Japanese Ministry of Health, Labor and Welfare (one of the criteria for approval by the U.S. FDA). Regarding the former effect, the MI value is limited to 1.9 or less, and regarding the latter effect, $I_{SPTA.3}$ is limited to 720 mW/cm^2 or less. It was confirmed based on data provided by the manufacturer that the ultrasonic outputs used in ARFI devices fulfill these two criteria.

3. When using long-duration pulsed ultrasound, the presence of bone at the focal point can lead to temperature rise that causes a safety concern, even if the MI and $I_{SPTA.3}$ criteria are satisfied. This possibility was predicted by Herman and Harris of the FDA.[3] In light of this problem, the duration of pulsed ultrasound is shortened as much as possible (approximately 100 to 200 μs) in ARFI devices, and a pause period for the ultrasound output is provided for lowering the increased temperature. However, the heat generation within the duration of pulsed ultrasound is larger than that of conventional ultrasound diagnostic equipment.

4. When there are microbubbles of ultrasound contrast agents and their remnants in the ultrasound

irradiation area, the occurrence of cavitation and temperature rise are enhanced.[4,5] Consequently, it is estimated that the safety threshold of acoustic output is decreased. However, it has not been elucidated yet to what extent biological effects are enhanced by the ultrasonic output used in ARFI technology.

As mentioned above, it was confirmed based on data provided by the manufacturer that ARFI devices fulfill the criteria for approval by the Japanese Ministry of Health, Labor and Welfare (one of the criteria for approval by the U.S. FDA). However, because the waveform and duration of the pulsed ultrasound used in this technology are significantly different from conventional ones, it is difficult to evaluate the effects on living tissues at this time. Therefore, the Ultrasound Equipment and Safety Committee of JSUM believes that it is necessary to further investigate the effects of ARFI technology on living tissues, especially in examinations where safety is the most desired.

In addition, when administering ultrasound contrast agents, it is recommended to wait the necessary time for microbubbles and their remnants to disappear from the body and then examine the patient carefully.[6]

References

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