Diagnostic Ultrasound Safety 2: Physical Property of Diagnostic Ultrasound

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Abstract
Ultrasound is a mechanical vibration of its propagating medium and it is a kind of sound but not such ionizing radiation as X-ray. It is inaudible by human ear, due to its very high frequency, higher than 20,000 Hz, and usually several 1,000,000 Hz (MHz) in medical diagnosis. There are two kinds of diagnostic ultrasound. It is common to use regularly oscillating very short ultrasound pulses in ultrasonic imaging device, to measure the reflection time of ultrasound pulses from an interface to form image of interface. Since oscillation time is very short and the interval is long, the time averaged intensity of pulse wave ultrasound is as weak as some mW/cm², while its instantaneous intensity is as large as several 10 W/cm². Continuous wave, however, used in Doppler fetal heart detector and fetal heart rate monitor has no peak and only continuous and weak vibration, i.e. time average and instantaneous intensities are the same in continuous wave. Since heating effect of ultrasound is measured by time average intensity, pulse wave and continuous wave have similar heating (thermal) effect, while mechanical effect of pulse wave ultrasound is large, and it is small in continuous wave.”

Introduction
Diagnostic ultrasound had been frequently compared to X-ray in old time, because both media were used for the medical imaging in the diagnosis. However, ultrasound is a sound, which is mechanical vibration of propagating materials, but not such ionizing radiation as the X-ray. Ultrasound is a sound, which does not make resonance with human ear due to its high frequency higher than 20 kHz. However in wild life, some animals produce low ultrasound to communicate each other, or measures the distance to the subject to avert the collision, i.e. animal ultrasound is useful device in the living, but not a hazard of life. Diagnostic ultrasound frequency is as high as several Mega Herz, inaudible by human ear, and its intensity is higher than audible sound. Ultrasound of very high intensity has some bio effect, but also it prepares a threshold, below which no bio effect is reported, like as audible sound, while such ionizing radiation as X-ray prepares no threshold, i.e. any level weak radiation prepares some bio effect, which is parallel to the intensity decreasing its grade. Therefore, weak ultrasound below the threshold has no effect on biological tissue. This character is the principle of medical imaging of the embryo and fetus.

Two Kinds of Diagnostic Ultrasound in the Imaging and Functional Studies
The continuous wave ultrasound, which generates the constant amplitude ultrasound to develop continuous wave (CW) Doppler ultrasound to detect fetal heart, to measure fetal movement (actogram) or to trace fetal heart rate (FHR) in fetal monitor, and so on. Peak and average intensities are the same value (Figure 1B). Another one is pulse wave, which is a group of a few high ultrasound waves forming repeated pulse wave (PW) (Figure 1A), which is produced by ultrasound oscillating unit (vibrator), propagate the tissue, reflected from an interface between the tissue and tissue or liquid, come back to the vibrator and produce electric pulse signal in the vibrator unit, where the distance is measured between the vibrator and interface by the propagation time, and the interface image is formed on the screen by repeated oscillation of ultrasound pulses. This is the principle of ultrasound image. The interface between the scanning lines and focusing made the real-time B-mode image clear (Figure 2).

Studies on the Bioeffect Threshold of Ultrasound in Tottori University
Japanese study group on ultrasound safety was held by the Ministry of Health & Welfare in 1970s, where the uniform ultrasound generator and exposure system were commonly used in the ultrasound exposure experiments using heat insulation between ultrasound generating unit and the exposure subjects by immersing them in 37°C stabilized water, where ultrasound was exposed, but did not heated experimental

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subjects by ultrasound generating units. Ultrasound generators of pulsed and continuous ultrasound were also common in the study group. Maeda planned to irradiate amniotic cell origin strain of cultured cells by watching the growth curves of the cells, because the generation was more quickly changed when compared to experimental animal. Ultrasound intensity was shown by Prof. Ide the supervisor of experiments, while we confirmed it by ourselves using steel ball moving method. Thus, the culture cell growth curve was suppressed by the exposure to SPTA 1,000 or more mW/cm² intensity CW ultrasound for 20-30 min, and no suppression by the exposure below the intensity CW ultrasound. In PW ultrasound exposure, the cell growth was suppressed by SPTA 240 mW/cm² or more, and there was no suppression by the exposure to the PW ultrasound below the intensity [1].

The bioeffect threshold was 4 times larger in CW than PW. The difference may be explained by the nature of PW ultrasound, i.e., mean intensity is similar between the CW and PW ultrasound, peak intensity of PW is usually more than 10 W/cm², which may increase the bioeffect of PW ultrasound, and experimental bioeffect threshold is lower in PW than CW. Since most diagnostic ultrasound devices work using PW, diagnostic ultrasound safety should be regulated by the threshold of 240 mW/cm². We calculated output ultrasound intensity in the device of thermal index [1], where it was approx. 210 mW/cm², and it was not much different from our PW threshold intensity. The similarity was a reason to accept the thermal index.

The works and results in the bioeffect threshold were authorized by Japan Society of Ultrasonics in Medicine, and Japanese Industrial Standard regulated the diagnostic ultrasound intensity below 10 mW/cm² [2]. Although the ultrasound intensity is enlarged, e.g. for three times in the distortion of ultrasound wave form, the enlarged regulation intensity is lower than our bioeffect threshold.

References