

Diagnostic Ultrasound Safety

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Introduction

Although no adverse effect of ultrasound diagnosis has been reported, the safety of diagnostic ultrasound has been discussed since its introduction into clinical study in 1950s, because real-time 2D, 3D, 4D ultrasound imaging, pulsed Doppler flow wave, color Doppler, fetal monitor, fetal movement, are indispensable in obstetric and gynecologic studies, particularly in the studies on the fetus.

For example of rumor, Ian Donald listened that the hearing difficulty of children was caused by his ultrasound study in 1950s, but the truth was that no hearing difficulty children had been received ultrasound study in the city [1]. It was reported once that frequent antepartum ultrasound resulted small neonates, however, it is usual that small fetuses were repeatedly studied by ultrasound; therefore it is natural to see small neonates. There was no increase of neonatal malformation after the introduction of obstetric ultrasound [2]. The left handedness was reported after fetal ultrasonic studies, but the result was insignificant [3]. Although it was reported moderate ultrasound developed fetal animal anomaly, no anomaly appeared after the exposure to similar intensity ultrasound, where the heat of ultrasound oscillatory element did not reach pregnant animal through 37°C stabilized water, while ultrasound propagated to subjects [4]. Attachment of electrically heated ultrasound element might heat the fetus in the report to develop anomaly, because fetal anomalies developed by high temperature [5]. The sister chromatid exchange developed after ultrasound exposure, but the change appeared by the effect of toxic substance produced by the degradation of plastic cell-container, but not by the ultrasound in double check experiments.

It was recently reported that the neuronal cell migration of fetal mice brain was disturbed by the exposure to the ultrasound of commercial real-time 2D imaging device for longer than 30 min [6]. Therefore, it may be recommended to limit fetal head exposure to ultrasound less than 30 min in clinical study. Since the probe attached the pregnant mice during exposure in the experiment, the double check will be done inserting 37°C stabilized water between the probe and pregnant mice.

In another recent report, reversible increase of hepatic apoptotic activity in fetal rats after 20 or more sec exposure of ducts venous to the weak pulsed Doppler ultrasound 7 h after the exposure [7]. Since the change was transient, we would like to hear ante- and postnatal states of exposed fetuses to the Doppler for more than 20 sec. ISUOG, however, published a statement on the safe use of Doppler in 11 to 13+6-week fetal ultrasound examination, which will be introduced later in this article [8].

Someone was responsible to the safety of diagnostic ultrasound in the past, e.g. American Institute of Ultrasound in Medicine (AIUM) suggested the output intensity to be lower than SPTA 100 mW/cm², and Food and Drug Administration (FDA) regulated it below 350 mW/cm². After discussions however, the ultrasound user is responsible for the safety of diagnostic ultrasound, i.e. the user should know thermal and mechanical indices of device ultrasound at the monitor screen, and controls high output intensity to low, and the exposure duration is also controlled by the user. There is ALARA principle that is "as low as

reasonably achievable", i.e. the ultrasound intensity should be as low as possible if the diagnosis is achieved. A diagnostic ultrasound user should know ultrasound physics, device function mechanisms, thermal and mechanical indices, the statements of ultrasound organizations, and so on.

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