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Do Not Test The Safety of Diagnostic Ultrasound Attaching The Probe to Pregnant Small Animals

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Abstract

A research reported abnormal fetal neuronal migration after irradiation of diagnostic ultrasound attaching the probe to the abdomen of pregnant small animal. Another irradiation of low intensity ultrasound resulted infantile brain damage followed by reduced learning ability. Fetal hepatic cellular apoptosis increased after short irradiation of Doppler ultrasound. Fetal ultrasound examination was restricted after the report.

Keywords: Fetus; Diagnostic ultrasound; Brain damage; Apoptosis; Direct probe attachment; Insulation of probe heat

1. Introduction

The safety of widely utilized B-mode ultrasound was studied to pregnant small animals Some experimental low intensity or short Doppler examination developed fetal abnormality. Early pregnancy Doppler fetal study was restricted. How shall we do? Heating artifact is analyzed in this report as an answer.

2. Methods and Results

The temperature of transvaginal ultrasound probe was limited below 41℃, Abdominal diagnostic ultrasound probe may be heated 41°C because its structure is the same as a vaginal probe. Animal fetus will be heated until 41°C via maternal abdominal wall, if the probe is directly attached maternal animal abdomen, while there is limitation of time

to be heated without hazardous effect.The heat exposure time was limited by following equation by by National Council on Radiation Protection and Measurement (NCRP);

$$t<4^{(43-T)} \qquad [1]$$

T is the maximum anticipated temperature (T in °C), t is the duration of the exposure time (min).

As T is 41°C, t should be shorter than $4^{(43-41)}=4^2=16$ min, namely, duration of 41°C temperature exposure should be less than 16 min to obtain normal outcome [1]. Thus, the small pregnant animal should not touch the ultrasound probe for 16 or more min, where the migration of neuronal cell was delayed, when the probe was attached to the animal for 30 min [2], where heating time was definitely longer than 16 min. It is natural to develop fetal abnormality due to heating artifact. Although the equation 1 was presented to study the thermal index of diagnostic ultrasound, the same temperature rise time is discussed also in the estimation of heating artifact in this report (Figure 1).

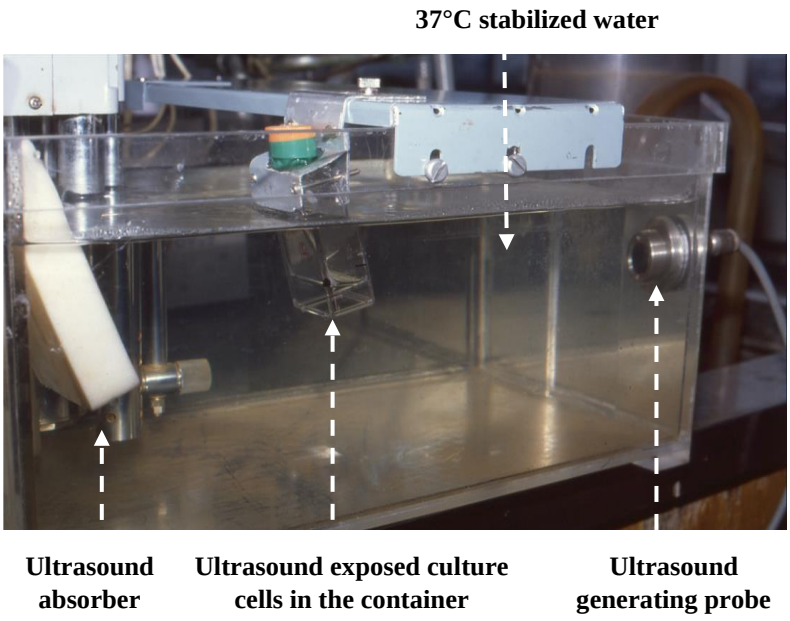

Figure 1: Experimental ultrasound was exposed to the subject, but avoiding the heat of ultrasound probe with 37℃ stabilized water in Japanese study group of diagnostic ultrasound safety in 1970s. No anomaly developed after exposure of pregnant animal with intense ultrasound using the system.

Ultrasound probe attachment was unknown in another ultrasound exposure experiment [3], The abnormality after short exposure of Doppler ultrasound to fetal animal was transient increase of hepatic cell apoptosis, however, the phenomenon can appear by other reasons, thus, it is difficult to decide to be caused limitedly only by ultrasound exposure [4]. It is natural to achieve abnormal outcome after thermal artifact exposure longer than the equation of

NCRP report [1]. It is hoped to avoid heat artifact longer than the limit of NCRP. The radical method to avoid probe heat artifact is to insulate the probe heat with 37°C stabilized water, then experimental subject is exposed only to ultrasound, but not to heating artifact of the ultrasound generating probe. Small pregnant animals and growing cultured cells were exposed to ultrasound without heating of ultrasound probe in the Japanese national ultrasound safety study group in 1970s. Anomalous animal fetus did not develop, and the threshold of cultured cell growth suppression was 240 mW/cm^2 , which was the thermal index (TI)=1 intensity level which is the threshold of clinical ultrasound exposure [5]. As human pregnant uterus is large in size filled with amniotic fluid, thus, no abnormality is expected in human case with diagnostic ultrasound exposure.

3. Discussion

A researcher to test the safety of diagnostic ultrasound safety should not attach the probe to pregnant small animal abdomen, but should test the experimental radiation within safe temperature limit, or totally shut off the heat with 37°C stabilized water, purely radiating the ultrasound without heating experimental animal with ultrasound probe. The limit of ultrasound exposure was tested by the growth curve suppression of cultured cells where the threshold was 240 mW/cm^2 under the heat insulation with 37°C stabilized water [5], and threshold ultrasound intensity was the level of Thermal Index = 1. Fetal animal exposure was also done in the same radiation environment developing no anomaly in the 1970s experimental ultrasound group.

Present trend of ultrasound safety is "As low as reasonably achievable (ALARA) principle" by which further ultrasound safety is expected, e. g. our actocardogram ultrasound is 1 mW/cm^2, which separates physiologic sinusoidal from pathologic one, that was unable by the CTG. Undisturbed pulse Doppler flow wave was recorded by 0.1 Thermal Index intensity [6], which was around 1/10 of 240 mW/cm^2=20mW/cm^2, which was CW ultrasound intensity, by which the author recorded world first CW Doppler fetal arterial blood flow wave by using own frequency demodulation system at the sound output of Doppler fetal heart beat listener *Doptone*, where the CW ultrasound intensity was 20mW/cm^2, by which CW Doppler fetal arterial flow wave was traced too[7].

4. Conclusion

The author who reported neurological damage of small animal fetus after direct attachment of diagnostic B-mode ultrasound probe for 30 minutes to pregnant small animal would be recommended to perform the experiment excluding direct attachment of the probe by separating the probe by 37°C water to avoid the heating artifact of the probe, because of the doubt of artifact of heating the animal fetus. A pregnant small animal should be exposed to experimental diagnostic ultrasound separating 41°C warmed ultrasound probe heat with 37°C water, where the animal is purely exposed to ultrasound without heating artifact, namely, according to NCRP equation of $t<4^{(43-T)}$, small animal fetus tolerates 16 or less min of 41°C probe heat [1], Please attach ultrasound probe less than 16 min in the safety experiment to avoid heat artifact, if directly attach the probe to the animal abdomen. Furthermore, it is recommended to expose experimental ultrasound, insulating the heat of ultrasound probe with 37°C water,. which is inserted between the animal and ultrasound probe.

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