Ultrasound Bioeffects

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Ang ESBC, Gluncic V, Duque A, Schaefer ME, Rakic P, Prenatal exposure to ultrasound waves impacts neuronal migration in mice, Proceedings of the National Acad of Sci, August 2006; 103: 12903-12910. Links

- 335 mice
- Ultrasound for 30 - 420 min
- A small number of neurons failed to acquire their proper position
- They remain scattered within inappropriate cortical layers
- Consequences such as epilepsy, schizophrenia and autism

Concerns have been raised in the past related to
- Autism
- Abnormal hearing, vision or language development
- Intrauterine growth retardation
- Childhood cancer
- Increase in non-right handedness

Abramowicz J, UOG 29:363, 2007

Bioeffects in Animals

- Lung hemorrhage in young mice and neonatal/adult pigs
- Intestinal hemorrhage in adult mice
- Bleeding near developing bone in young mice


Ultrasound Bioeffects: Background

- Approximately 250 million fetal ultrasound examinations performed per year in U.S.
- To date no adverse effects on fetus reported
- Fetal ultrasound considered to be safe
- Ultrasound exposure can produce bioeffects at diagnostic levels in laboratory studies
- Valid experimental studies difficult to perform
- Caution advises following ALARA principle
Ultrasound Bioeffects: Reasons for Concern

- Ultrasound is mechanical energy:
  - thermal effects
  - mechanical effects
- Energy level depends on machine setting:
  - MI - mechanical index
  - TI - thermal index
- Bioeffects studies based on old limits - 94 mW/cm²
- New equipment limits much higher - 720 mW/cm²
- Use As Low As Reasonably Achievable technique

Ultrasound Bioeffects: Background

- Ultrasound has diagnostic value
- Wider range of US studies and new technologies having higher acoustic output levels in more patients
- Current acoustic output much greater than earlier equipment
- No evidence that diagnostic ultrasound produces harm
- Subtle or transient effects not well understood
- Diagnostic ultrasound should be used prudently
- Ultrasound examinations should only be performed by trained, competent personnel
- Essential to maintain vigilance to ensure continued safety

Ultrasound Bioeffects: Background

- TI is an on-screen measure of the potential for tissue heating
- MI is an on-screen measure of the potential to induce cavitation in tissues
- 3D ultrasound does not introduce additional safety considerations
- 4D ultrasound with continuous exposure offers potential to prolong examination times

Ultrasound Bioeffects: Some Physics

Characteristics of Sound

- Sound is mechanical energy
- Propagates longitudinally through elastic media
- Alternating zones of compression and rarefaction
- Ultrasound imaging typically uses short pulses
- Energy is reflected at interfaces

Ultrasound Bioeffects: Some Physics

- Medical ultrasound basic properties:
  - frequency 1 - 15 MHz
  - pulse length 3-5 cycles
  - speed of sound in tissue ~ 1540 m/s
  - attenuation ~ 1 dB / (cm-MHz)
  - wavelength & resolution ~ 0.5 mm
  - image rates up to 150 fps (30 typical)

Doppler

- Pulses reflecting off moving interfaces, (e.g. blood cells, heart valves or contrast) exhibit a phase shift that can be used to measure the velocity of motion along the path of the sound beam.
- Typical Doppler shift range is 10 to 1000 Hz
Velocity Doppler
- Computes the velocity in each pixel and displays a color whose hue depends on the direction and whose saturation depends on the velocity component measured.

Power Doppler
- Computes the integral of the entire velocity distribution and displays the magnitude as a color and brightness value.
- Has less angular dependence and better sensitivity to slow flow.

Ultrasound Contrast Materials
- Improved visualization of vessels and tissues is possible using gas-filled micro-bubbles to produce a large impedance discontinuity.
- Contrast agents offer promise in enhancing masses, visualizing blood flow, measuring perfusion, and delivering drugs and genetic agents to specific sites.

Beam Properties
- Ultrasound propagates as longitudinal wave.
- Two primary zones:
  - Near field (Fresnel) - Complex field pattern
  - Far field (Fraunhofer) - More coherent field pattern

Focused Excitation
- Scan lines sweeping through different directions are used to produce a two-dimensional image.
**Ultrasound Bioeffects: Some Physics**

- $I_{\text{SAPA}} = I_{\text{SAT}}/\text{duty cycle}$
- $I_{\text{PA}} = I_{\text{TA}}/\text{duty cycle}$
- $I_{\text{SPTA}} = I_{\text{SAT}} (I_{\text{SP}}/I_{\text{SA}})$
  - Indicator of thermal effects
- $I_{\text{SPPA}} = I_{\text{SAT}} (I_{\text{SP}}/I_{\text{SA}})/\text{duty cycle}$
  - Indicator of potential mechanical bioeffects and cavitation
- $I_{\text{SPPA}} > I_{\text{SPTA}} > I_{\text{SAPA}} > I_{\text{SAT}}$
- $\text{SA} = \text{Spatial Average}$
- $\text{SP} = \text{Spatial Peak}$
- $\text{PA} = \text{Pulse Average}$
- $\text{TA} = \text{Temporal Average}$
- $\text{TP} = \text{Temporal Peak}$

**Attenuation**

- The lower the frequency, the more the penetration
- $I = I_0 e^{-\alpha d}$
- $\alpha = 0.5 \text{ dB/cm}$
- Distance traveled = 2 \cdot \text{penetration depth}

**Tissue Composition**

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Attenuation Coefficient (1 MHz, beam, dB/cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>0.3002</td>
</tr>
<tr>
<td>Blood</td>
<td>0.18</td>
</tr>
<tr>
<td>Soft Tissues</td>
<td>0.3 - 0.8</td>
</tr>
<tr>
<td>Brain</td>
<td>0.3 - 0.5</td>
</tr>
<tr>
<td>Liver</td>
<td>0.4 - 0.7</td>
</tr>
<tr>
<td>Fat</td>
<td>0.5 - 0.8</td>
</tr>
<tr>
<td>Smooth Muscle</td>
<td>0.2 - 0.6</td>
</tr>
<tr>
<td>Tendons</td>
<td>0.9 - 1.1</td>
</tr>
<tr>
<td>Bone, cortical</td>
<td>13 - 26</td>
</tr>
<tr>
<td>Lung</td>
<td>40</td>
</tr>
</tbody>
</table>

Ultrasound Bioeffects: Some Physics

**Attenuation**

\[ I(x) = I_0 e^{-\alpha x} \]

- **SPTA** = Spatial peak temporal average
- **SPPA** = Spatial peak pulse average

<table>
<thead>
<tr>
<th>Mode</th>
<th>Pressure (MPa)</th>
<th>( I_{\text{Temp}} ) (mW/cm²)</th>
<th>( I_{\text{max}} ) (W/cm²)</th>
<th>Power (mW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-scan</td>
<td>1.68</td>
<td>19</td>
<td>174</td>
<td>18</td>
</tr>
<tr>
<td>M-mode</td>
<td>1.68</td>
<td>173</td>
<td>174</td>
<td>4</td>
</tr>
<tr>
<td>Pulsed Doppler</td>
<td>2.48</td>
<td>149</td>
<td>288</td>
<td>31</td>
</tr>
<tr>
<td>Color Flow</td>
<td>2.59</td>
<td>234</td>
<td>325</td>
<td>81</td>
</tr>
</tbody>
</table>

**FDA Output Limits**
- \( I_{\text{SPTA}} < 100 \text{ mW/cm}^2 \)
- \( I_{\text{SPTA}} \) can exceed 1000 mW/cm² for Doppler

**Indices**
- **Thermal Index (TI)**
  - Ratio of acoustic power produced to power required to raise tissue by 1°C
  - \( TI_s \) - soft tissue, \( TI_b \) - bone, \( TI_c \) - cranium
- **Mechanical Index (MI)**
  - Estimate of likelihood of cavitation
  - Related to intensity

**Ultrasound Bioeffects: Thermal Hazard**

- Thermal hazard exists with some equipment if used imprudently
- Temperature elevation < 1.5°C does not present harm to embryo
- Temperature elevation > 1.5°C may cause harm
- Temperature elevation > 4°C for 5 minutes potentially hazardous to embryo
- Spectral pulsed Doppler modes can reach these levels
- Color Doppler modes may reach these levels
- TI provides rough guide to sonographer/sonologist regarding thermal hazard

Ultrasound Bioeffects: Non-thermal Hazard

- Non-thermal hazard exists with some equipment if used imprudently.
- Damage demonstrated in tissues with gas pockets at MI > 0.3.
- Avoid unnecessary exposure to neonatal lung.
- Keep MI as low as possible.
- MI provides rough guide to sonographer/sonologist regarding non-thermal hazard.
- Contrast agents increase probability of cavitation.
- Single beam modes (A-mode, M-mode and spectral pulsed Doppler) more likely than scanned modes (B-mode, Color Doppler).


Ultrasound Bioeffects: Pregnancy Exposure

- Embryo/fetus is particularly sensitive.
- Little information available regarding possible subtle biological effects at diagnostic levels.
- Temperature rise greatest at bone surfaces and adjacent soft tissues.
- Increasing mineralization raises possibility of heating sensitive tissues such as brain and spinal cord.
- Care should be taken to minimize eye exposure. Important to limit exposure time and the MI and TI commensurate with acceptable diagnostic evaluation.
- No reason to withhold diagnostic scanning during pregnancy provided it is medically indicated and is used prudently by fully trained operators.


Ultrasound Bioeffects: Ultrasound Contrast Agents

- Ultrasound contrast agents typically are stable gas-filled microbubbles.
- Potentially produce cavitation and micro-streaming.
- Microvascular damage or rupture is possible (animal studies).
- Premature ventricular contractions induced in contrast enhanced echocardiography with high MI and triggered excitation.
- Risk increases with increasing MI.


Ultrasound Bioeffects: Literature Studies

Sheiner et al. Increased TI can be achieved during Doppler OB Sonography, J Ultrasound Med 2007: 26:71-76.

- Patients with suspected fetal growth problems undergoing Doppler studies of the fetal circulation in addition to B-mode sonography.
- Examinations took place between 21 and 40 weeks' gestation.
- HDI 5000 scanners (Philips Medical Systems, Bothell, WA).
  - Transvaginal (4-8 MHz) probe.
  - Transabdominal (2-5 MHz) probe.
- 63 examinations were evaluated.
- Gestational age was 31.6 ± 5.1 weeks.
- Total examination time was 17.6 ± 8.6 minutes.
- Doppler examination time was 0.9±0.8 minutes.

Ultrasound Bioeffects: Literature Studies

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Ultrasound Bioeffects: Literature Studies

- Increased acoustic output levels, as expressed by TI levels, are reached during obstetric Doppler studies.
- TI levels may reach 1.5 and higher.
- Doppler procedures should be performed with caution.
- Doppler procedures should be as brief as possible during obstetric sonography.

MI = 1.0 and TIT = 0.2
Ultrasound Bioeffects: Literature Studies

- Color and pulsed Doppler should be avoided in the first trimester of pregnancy due to potential for tissue heating.


Ultrasound Bioeffects: Literature Studies

- 11 first-trimester
- 14 second-trimester
- 12 third-trimester examinations were evaluated
- First-trimester examination was 8.9 minutes
  - MI was 0.73; range 0.3-1.3
  - TI was 0.34; range 0.1-1.7
- Second-trimester examination was 31.8 minutes
  - MI was 1.04; 0.5-1.5
  - TI was 0.28; 0.1-2.4
- Third-trimester examination was 16.3 minutes
  - MI was 1.06; 0.2-1.5
  - TI was 0.32; 0.1-2.4

Ultrasound Bioeffects: Literature Studies

- Statistical significance existed across trimesters with regard to examination durations and MI (P < .001)
- No statistical significance existed in the TI across trimesters
- 3.5% of third trimester examinations had a TI of greater than 1.0
  - 2.4% were between 1.0 and 1.49
  - 1.1% were greater than 1.5
- TI ≥ 1 changes were brief (0.17 ± 0.08 minutes)
- TI changes were observed during color Doppler imaging

Ultrasound Bioeffects: Literature Studies

- Output levels during routine obstetric ultrasound examinations, as expressed by the MI and TI, are generally low
- However, higher output levels, particularly TI levels of greater than 1.5, can be achieved
- TI greater than 1.5 typically account for only a small proportion of the examination time
- Prudent use requires ALARA principles
  - Minimize study time consistent with diagnostic goals

First Trimester Pulsed Doppler

- Tricuspid valve interrogation for aneuploidy risk
- Requires certification
- Should be done rapidly, by experienced sonographers

MI = 0.7

TI ≥ 1.1, TIB = 3.4
### Ultrasound Bioeffects: Literature Studies


- Determine end users' knowledge regarding safety aspects of diagnostic ultrasound during pregnancy

- A questionnaire was distributed to ultrasound end users attending review courses and hospital grand rounds between April and June 2006

- 130 end users completed the questionnaires (63% response rate).
  - 63% were physicians
  - 81.7% were obstetricians
  - ~18% of participants routinely performed Doppler ultrasound examinations during the first trimester

- 32.2% of the participants were familiar with the term TI
  - only 17.7% correctly described the nature of TI

- ~22% were familiar with the term MI
  - only 3.8% correctly described the nature of MI

- 80% of end users did not know where to find the acoustic indices
  - Only 20.8% knew they are displayed on the sonographic display

- Ultrasound end users are poorly informed regarding safety issues during pregnancy

- Further efforts in the realm of education and training are needed to improve end user knowledge about the acoustic output of the machines and safety issues

- That's why we are here today!

### Ultrasound Bioeffects: Guidelines for Safe Use

- Doppler for fetal heart monitoring. The power levels used for fetal heart monitoring are sufficiently low that use of this modality is not contra-indicated, on safety grounds, even when it is to be used for extended periods.

- Peripheral pulse monitoring. The output from CW Doppler devices intended for monitoring peripheral pulses is sufficiently low that their use is not contra-indicated, on safety grounds.

- Transcranial ultrasound investigations. Transcranial ultrasound investigations may require higher acoustic output than other applications. Safety guidelines should be applied for both imaging and stand-alone Doppler equipment. TIC should be monitored.

### Check out the MI and TI

<table>
<thead>
<tr>
<th>MI</th>
<th>TIB</th>
<th>TIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>0.7</td>
<td>0.2</td>
<td>0.9</td>
</tr>
</tbody>
</table>

TIB = 0.6, TIS = 0.6  
TIB = 0.2, MI = 0.9  
MI = 0.7, TIS = 1.0

Thank you
Ultrasound Bioeffects: AIUM Guidelines

- Diagnostic ultrasound studies of the fetus are generally considered to be safe during pregnancy.
- This diagnostic procedure should be performed only when:
  - there is a valid medical indication
  - the lowest possible ultrasonic exposure setting should be used to gain the necessary diagnostic information under the as low as reasonably achievable (ALARA) principle.
- The promotion, selling, or leasing of ultrasound equipment for making “keepsake fetal videos” is considered by the US Food and Drug Administration to be an unapproved use of a medical device.
- Use of a diagnostic ultrasound system for these purposes, without a physician’s order, may be in violation of state laws or regulations.

Ultrasound Bioeffects: Background

- This Output Display Standard (ODS) consists of the thermal index (TI) and the mechanical index (MI).
- The TI expresses the potential for a rise in temperature at the ultrasound’s focal point.
- The MI indicates the potential for the ultrasound to induce inertial cavitation in tissues.
- There are 3 TIs:
  - the TI for soft tissues (TIS), when the ultrasound beam does not impinge on bone, appropriate mostly for the first trimester
  - the TI for bones (TIB), when the beam impinges on bone at or near its focus, which should be displayed in the second and third trimesters
  - TI for cranial bone (TIC), when the transducer is very close to the bone, such as when scanning in the adult.

Ultrasound Bioeffects: Guidelines for Safe Use

- Medical endorsement. Ultrasound should only be used for medical diagnosis if endorsed by a medical practitioner.
- Operator training. Diagnostic ultrasound procedures should be carried out only by persons who are fully trained in the use of the equipment, the interpretation of its results and images and in the safe use of ultrasound, including an appreciation of its potential hazards.
- Awareness of machine factors influencing hazard. Operators should understand the likely influence of the machine controls, the operating mode (e.g. B-mode, color Doppler imaging or spectral Doppler) and probe frequency on the thermal and cavitation hazards.

Initial power setting. Machines should be set up so that the default (switch-on) setting of the acoustic output power control is low. If a low default setting cannot be achieved, a low setting should be selected after switching on. A low setting should be selected for each new patient. The output should only be increased during the investigation if this is necessary to produce a satisfactory result.
- Exposure time. The overall examination times should be kept as short as is necessary to produce a useful diagnostic result.
- Stationary probe. The probe should not be held in a fixed position for any longer than is necessary, and should be removed from the patient whenever there is no need for a real-time image or spectral Doppler acquisition.
  - For example, using the freeze frame or cine loop facilities allows images to be reviewed and discussed without continuing the exposure.
Ultrasound Bioeffects: Guidelines for Safe Use

- Probe self-heating. Endo-probes (e.g. vaginal, rectal or oesophageal probe) should not be used if there is noticeable self heating of the probe when operating in air.
- Applies to any probe.
- Particular care should be taken if trans-vaginal probes are to be used to investigate a pregnancy during the first eight weeks post-conception.
- Pre-existing temperature elevation. Particular care should be taken to reduce output and minimise exposure time of an embryo or fetus when the temperature of the mother is already elevated.
- Sensitive tissues. Particular care should be taken to reduce the risk of thermal hazard when exposing the following to diagnostic ultrasound:
  - an embryo less than eight weeks after conception;
  - the head, brain or spine of any fetus or neonate;
  - an eye (in a subject of any age).

Ultrasound Bioeffects: Guidelines for Safe Use

- Thermal and Mechanical Indices.
- MI > 0.3 There is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, try to reduce the exposure time as much as possible.
- MI > 0.7 There is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used.
- There is a theoretical risk of cavitation without the presence of ultrasound contrast agents.
- The risk increases with MI values above this threshold.
- TI > 0.7 The overall exposure time (including pauses) of an embryo or fetus should be restricted in accordance with Table 1.
- TI > 1.0 Eye scanning is not recommended, other than as part of a fetal scan.
- TI > 3.0 Scanning of an embryo or fetus is not recommended, however briefly.

Ultrasound Bioeffects: Guidelines for Safe Use

- Non-diagnostic uses of diagnostic ultrasound equipment. Examples include repeated scans for training, equipment demonstration using normal subjects, and production of fetal souvenir pictures or videos.
- For equipment that display safety indices:
  - TI should always be less than 0.5
  - MI should always be less than 0.3
- For equipment that do not display safety indices:
  - Tmax should be less than 1°C.
  - MI should be less than 0.3.
  - Frequent exposure of the same subject is to be avoided.
  - Follow safe scanning guidelines and ALARA.
- First trimester scans should not be carried out for:
  - the sole purpose of producing souvenir videos or photographs.
  - their production should not increase exposure levels or extending the scan times beyond those needed for clinical purposes.

Ultrasound Bioeffects: Guidelines for Safe Use

- Pulsed Doppler. The use of spectral pulsed Doppler, or color Doppler made with a narrow write-zoom box selected, is not recommended for the investigation of any sensitive tissues, unless an estimate of the maximum likely temperature elevation has been obtained and considered in relation to the anticipated exposure time.
- Thermal and Mechanical Indices: For machines which display on-screen thermal index (TI) and mechanical index (MI) values, operators should continually monitor their values and use control settings that keep them as small as is consistent with achieving diagnostically useful results.
- In obstetric investigations, TIS (soft tissue thermal index) should be monitored during scans carried out in the first eight weeks after conception, and TEB (bone thermal index) thereafter.
- In applications where the probe is very close to bone (e.g. trans-cranial applications), TIC (cranial thermal index) should be monitored.
- For eye scanning TIS should be monitored. In other applications, TEB should be monitored.

Ultrasound Bioeffects: Guidelines for Safe Use

Thermal and Mechanical Indices

- Where an on-screen thermal index (TI) or mechanical index (MI) is not displayed, try to obtain worst case estimates (considering all possible combinations of control settings) of temperature elevation (Tmax) and mechanical index (Mimax) for the particular probe and mode in use.
- If these can be obtained, assume that the MI value is equal to Mimax and the TI value is equal to 0.5 Tmax and refer to Table 1.

<table>
<thead>
<tr>
<th>TI</th>
<th>Maximum exposure time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7</td>
<td>60</td>
</tr>
<tr>
<td>1.0</td>
<td>30</td>
</tr>
<tr>
<td>1.5</td>
<td>15</td>
</tr>
<tr>
<td>2.0</td>
<td>4</td>
</tr>
<tr>
<td>2.5</td>
<td>1</td>
</tr>
</tbody>
</table>

Ultrasound Bioeffects: Mechanical Index

- The mechanical index (MI) is intended to offer a rough guide to the likelihood of the occurrence of cavitation.
- The MI is constantly updated by the machine, according to the control settings, using the formula:
  \[ MI = \frac{\text{maximum value of peak negative pressure}}{\text{pulse centre frequency}} \]
- NB: the maximum value of peak negative pressure anywhere in the ultrasound field measured in water is reduced by an attenuation factor equal to that which would be produced by a medium having an attenuation coefficient of 0.3 dB cm⁻¹ MHz⁻¹.
Ultrasound Bioeffects: Thermal Index

- The thermal index (TI) is intended to give a rough guide to the likely maximum temperature rise that might be produced after long exposure.
- Three forms of TI may be displayed, according to the application.
  - TIS assumes that only soft tissue is insonated.
  - TIB assumes bone is present at the depth where temporal intensity is greatest.
  - TIC assumes bone is very close to the front face of the probe.
- However, note that errors in calculating TI values, and the limitations of the simple models on which they are based, means that TI values can underestimate the temperature elevation by a factor of up to two.

Ultrasound Bioeffects: Sensitive Tissues

<table>
<thead>
<tr>
<th>Gestation From LMP</th>
<th>Gestation from Conception / Fertilisation</th>
<th>Title of Conceptus</th>
<th>Major relevant events</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14 days</td>
<td>NIL</td>
<td>Zygote</td>
<td>Rapid cell multiplications</td>
</tr>
<tr>
<td>14-28 days</td>
<td>0-14 days</td>
<td>Embryo</td>
<td>Organogenesis</td>
</tr>
<tr>
<td>29-70 days</td>
<td>15-56 days</td>
<td>Embryo</td>
<td></td>
</tr>
<tr>
<td>41-10 weeks</td>
<td>2.1-8 weeks</td>
<td>Fetus</td>
<td>Ossification of spine starts</td>
</tr>
<tr>
<td>10-11 weeks</td>
<td>8-9 weeks</td>
<td>Fetus</td>
<td>Ossification of skull and long bone starts</td>
</tr>
<tr>
<td>13-14 weeks</td>
<td>11-12 weeks</td>
<td>Fetus</td>
<td></td>
</tr>
</tbody>
</table>

Ultrasound Bioeffects: Conclusions

- Study results at our perinatal, academic medical center suggest that 3DUS targeted studies are shorter than general 2DUS studies, especially for complex cases.
- Extended scanning to watch fetal movement has the potential to increase fetal US exposure without benefiting diagnosis or management and thus caution is needed for these procedures.

- Technological advances enhance fetal scanning opportunities by providing improved visualization and image quality that potentially improves fetal visualization, diagnosis and management
- Notably, 3DUS equipment provides clear images of the developing fetus that are recognizable to family and physician.
- 4DUS equipment further facilitates observing fetal movements similar to real-time 2DUS imaging - potentially inviting longer fetal viewing.