Patient Safety: reducing Ultrasound ‘Doses’

Anita J. Moon-Grady MD, FASE, FACC, FAIUM
Prudent use of Ultrasound

US is non-ionising BUT since many bioeffects of ultrasound have not yet been studied fully, ‘prudent’ use is recommended.

ALARA – as low as reasonably achievable (exposure)

In practice ‘prudent’ = justification + optimisation
Multiple Societies have issued Safety Statements (ISUOG, AIUM, BMUS, SOGC)

- No commercial demos on human subjects
- No training on students
- No ‘see baby just for fun’ or excessive screening in obstetrics
Multiple Societies have issued Safety Statements (ISUOG, AIUM, BMUS, SOGC)

- Necessary for medical diagnostics
- Performed by fully trained individuals
- Exam times as short as reasonable
- Output levels as low as reasonably achievable

From BMUS “Guidelines for the Safe Use of Diagnostic Ultrasound Equipment”
# Early Human Development

<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>-</td>
<td>-</td>
</tr>
<tr>
<td>14-28 days</td>
<td>0-14 days</td>
<td>Zygote</td>
<td>Rapid cell multiplication</td>
</tr>
<tr>
<td>29-70 days 4.1-10 weeks</td>
<td>15-56 days 2.1-8 weeks</td>
<td>Embryo</td>
<td>Organogenesis</td>
</tr>
<tr>
<td>10-11 weeks</td>
<td>8-9 weeks</td>
<td>Fetus</td>
<td>Ossification of spine starts</td>
</tr>
<tr>
<td>13-14 weeks</td>
<td>11-12 weeks</td>
<td>Fetus</td>
<td>Ossification of skull and long bone starts</td>
</tr>
</tbody>
</table>
Possible bioeffects: inactivation of enzymes, altered cell morphology, internal haemorrhage, free radical formation ... 

Mechanisms of bioeffects:

- Mechanical effects
  - Displacement and acceleration of biomolecules
  - Gas bubble cavitation (stable and transient) – see the lecture on biological effects of ultrasound

- Thermal effects
  - Absorption of ultrasound and therefore increase in temperature
  - High in lungs, less in bone, least in soft tissue

All bioeffects are deterministic with a threshold (cavitation) or without it (heating)
Output Power from Transducer

- varies from one machine to another
- Increases as one moves from real-time 2D imaging to colour flow Doppler to spectral Doppler
- M-mode output intensity is low but dose to tissue is high because beam is stationary
➢ To avoid potentially dangerous exposures, two indices were introduced. Their values (different for different organs) are often displayed on device screens and should not be exceeded routinely

➢ Thermal Index (TI): TI = possible tissue temperature rise if transducer is kept stationary
   • TIS: soft tissue path
   • TIB: bone near focus of beam
   • TIC: Cranium (near surface bone)

➢ Mechanical Index (MI): measure of possible mechanical bioeffects
More on the TI and MI

• **Thermal index** – device power divided by the power that would increased the temperature by one degree Celsius under conditions of minimum heat loss (without perfusion).

• **Mechanical index** (for assessment of cavitation-conditioned risk, increased danger when using echocontrast agents):

\[ MI = \frac{I_{uz}}{\sqrt{f}} \quad [W \cdot cm^{-2}, MHz] \]
MI: Mechanical index

Rarely an issue

Relates to threshold for cavitation
Thought to be due to rarefaction during propagation of US wave
0.7 is the value chosen for cavitation in situations where contrast agents might be present
Otherwise, the possibility of cavitation is thought to be only a theoretical possibility
0.3 is the value for capillary bleeding in tissues of gas-containing organs (lung, bowel)
TI: Thermal index

- Ratio of emitted power to the power required to raise the temperature of tissue by 1 °C

- Dependent on tissue insonated and the time exposed
  - TIS soft tissue and fetus <10wks
  - TIB most OB scanning
  - TIC
Theoretical tissue damage with elevation in temperature

But the extent to which the temperature is raised depends on scanning mode, exposure duration, and the tissue being scanned.
OBSTETRIC SCANNING

THERMAL INDEX

0.7

Recommended scanning time limits for these TIs (observe ALARA)

- Unlimited time
- Observe ALARA

Monitor TIS up to 10 weeks post-LMP, TIB thereafter.

Recommended scanning time limits:
- < 60 mins
- < 30 mins
- < 15 mins
- < 4 mins
- < 1 min

TI Guidelines
General guidelines for both

<table>
<thead>
<tr>
<th>Application</th>
<th>Values to monitor (A)</th>
<th>Thermal Index value</th>
<th>Mechanical Index value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0 - 0.7</td>
<td>0.7 - 3.0</td>
</tr>
<tr>
<td>Obstetrics up 10 weeks after LMP (and gynaecology when pregnancy is possible)</td>
<td>TIS and MI</td>
<td>✓</td>
<td>(B) restrict time to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.7&lt;TIS&lt;1.0 : 60 min</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.0&lt;TIS&lt;1.5 : 30 min</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.5&lt;TIS&lt;2.0 : 15 min</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2.0&lt;TIS&lt;2.5 : 4 min</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2.5&lt;TIS&lt;3.0 : 1 min</td>
</tr>
<tr>
<td>Obstetrics more than 10 weeks after LMP</td>
<td>TIB and MI</td>
<td>✓</td>
<td>(B) restrict time to</td>
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<td>2.5&lt;TIB&lt;3.0 : 1 min</td>
</tr>
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</table>
mWatts/cm$^2$: 720 limit

Used to be 94 mW/cm$^2$ for OB scanners

Changed to 720 in 1992

BUT

Vendors are now required to make machines able to display the MI and TI

Dependent on

- Operating mode
- B mode
- Color Doppler
- Spectral Doppler
- Power output
- PRF
- Frequency

“Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment” or ODS
<table>
<thead>
<tr>
<th>Initial power setting</th>
<th>• Should be low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>• As short as is reasonable</td>
</tr>
<tr>
<td>Probe position</td>
<td>• Should not be fixed if not acquiring information</td>
</tr>
<tr>
<td>Use of Doppler</td>
<td>• Monitor TI and use for only necessary, short times</td>
</tr>
</tbody>
</table>
Optimisation of ‘Dose’

Minimise TI and MI and use appropriate index (TIS, TIB, TIC), care in cases when these underestimate.

Check acoustic power outputs on manual.

Use high receiver gain when possible as opposed to high transmit power.

Start scan with low transmit power and increase gradually.
Optimisation of ‘Dose’

- Avoid repeat scans and reduce exposure time
- Consider avoiding scanning febrile gravidas
- Do not hold transducer stationary
- Greater care when using contrast agents as these increase the possibility of cavitation
- Exceptional care must be taken in applying pulsed Doppler in obstetrics
MI and effect of 2D focus and power output
T1b and power output-- use gain instead
increase gain instead
Tib and PW output
Use update to freeze reference image power down
Summary

Application of ALARA

- Scans must be medically necessary
- MI should be kept as low as possible without compromising image; ideally <0.7
- TI $\leq 1.0$-$1.5$ is preferable; over 3.0 should not be used
- If TI is 1.0-$3.0$, scan time should be kept as short as is reasonable (5-10 min suggested)
The recommendations are for theoretical situations based on modeling and animal work.

There is no epidemiologic support for a causal relationship between medical diagnostic ultrasound and adverse effects on the fetus.
Ultrasound Biosafety Considerations for the Practicing Sonographer and Sonologist Thomas R. Nelson, PhD, J. Brian Fowlkes, PhD, Jacques S. Abramowicz, MD, Charles C. Church, PhD. J Ultrasound Med 2009; 28:139–150

British Medical Ultrasound Society website: http://www.bmus.org

Obstetric Ultrasound Biologic Effects and Safety