ULTRASOUND SAFETY
A REVIEW OF CURRENT TRENDS

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INTRODUCTION

“THERE ARE NO KNOWN HARMFUL EFFECTS ASSOCIATED WITH THE MEDICAL USE OF ULTRASOUND”
(AIUM)

Statements such as this have been the cornerstone defining the use of diagnostic ultrasound for many years.

Is this statement still totally valid?

Unless accepted doctrines are challenged progress cannot be made.

There is concern over the injudicious use of ultrasound, especially in the non-medical applications.

OBJECTIVES

To review the potential hazards associated with the use of diagnostic ultrasound.

Place the safety indices in context

To review the research problem

OBJECTIVES (cont)

To assess the role of the operator in the protection of the patient against potential bio-hazards.

To revisit the AIUM statement
BIOEFFECTS
Depend on the intensity of the beam and the duration of exposure as well as frequency
The two major effects which are considered in safety studies are:-

THERMAL
When ultrasound travels through tissue, energy is absorbed by the tissue components and converted to heat
Frequency and intensity dependence

THERMAL EFFECTS
Increased heat is considered a potential teratogen.
Affects the rate of chemical reactions.
Alters the equilibrium between chemical reactions

THERMAL SAFETY
- It is advised that tissue temperature increases should be kept below 1.5°C (but consider the febrile patient)
- Bone and the full bladder may complicate this requirement, as increased temperatures occur in their presence

NON THERMAL
Cavitation
The expansion and contraction, or collapse, of gas bubbles during the oscillatory cycle.
Streaming
The movement of complex fluids due radiation force pressures

NON THERMAL EFFECTS
The main effects of non thermal damage have been demonstrated in mammalian tissues containing gas where capillary bleeding has been observed.
This potentially pertains to the neonatal lung, intestine and also in the presence of ultrasound microbubble contrast agents
In 1993 the American Federal Drugs Administration (FDA) raised the upper Ispta limit of commercially available ultrasound devices from 94mW/cm² to 720 mW/cm².

Since this time all machines have to display two safety indices on the screen which relate to the likelihood of thermal and non-thermal effects.

The thermal index (TI) is the ratio of the power used to that required to produce a temperature rise of 1°C. There are three sub-indices –

1. Thermal index in soft tissue (TIS)
2. Thermal index in bone (TIB)
3. Thermal index in the cranium (TIC)

A thermal index of one (TI 1) indicates conditions under which the rise in temperature would be likely to be 1°C. However, the data is complicated and the rise may be higher by a factor of 2.

The mechanical index (MI) gives an estimation of the risk of the non-thermal effects (cavitation and streaming).

It is most applicable with the use of ultrasound contrast agents.

The BMUS safety guidelines state that:

- MI>0.3 = risk of capillary bleeding
- MI>0.7 = cavitation risk
- TI>0.7 = embryonic/foetal exposure limited
SAFETY STATEMENTS

Most concern for safety is directed, quite rightly, at foetal safety.

However eyes are also sensitive to thermal damage.

SAFETY STATEMENTS

The safety statements issued by relevant bodies maintain that the use of medical ultrasound is safe for B and M modes.

Reservations are expressed for Doppler, especially spectral and colour Doppler.

WHY THE CONCERN?

A great deal of the research used to formulate the safety statements and guidelines was performed before 1992.

It is becoming increasingly difficult to find control groups.

Experimentation is extensively performed on mammals and not humans.

Slight increases in a common trait are difficult to identify.

Results published are often in vitro results and not in vivo.

Technology is overtaking the research field, (3D, 4D, THI).

Research studies have not indicated intensity levels or other indices relevant to the findings.

Safety levels are known below which effects do not happen, and those at which effects will definitely happen.

(MCDICKEN, 1991, 95)
If subliminal changes are happening at the increased intensity levels currently being used the effects may not become apparent for another 20 to 30 years.

Cautious and prudent use of ultrasound is therefore advised.

THE OPERATOR

With the lack of legal regulation of the use of ultrasound the onus lies more and more on the operator to become the monitor of the safe use of ultrasound.

GUIDELINES

The BMUS has issued one of the most comprehensive set of guidelines for the safe use of diagnostic ultrasound (BMUS Guidelines for the Safe Use of Diagnostic Ultrasound Equipment. 2003)

- Medical necessity.
- Education
- Scanning mode
- Power output (ALARA principle)

- Stationary probe
- Probe self heating (esp. Endo probes)
- Sensitive tissues
- Doppler

- TI and MI
- Transcranial
- Non-diagnostic use
AIUM STATEMENT REVISITED

There are no known major adverse effects to date associated with the medical use of ultrasound, but caution is advised!

BIBLIOGRAPHY

- EFSUMB: European Committee of Medical Ultrasound Safety 2006: Clinical Safety Statement for Diagnostic Ultrasound.

BIBLIOGRAPHY cont.

- NCRP. Summary of the technical report; “Exposure Criteria for Medical Diagnostic Ultrasound” II. Criteria Based on all Known Mechanisms.