TITLE: Heating Standards for Magnetic Resonance Conditional Medical Devices: Clinical Evidence

DATE: 26 June 2013

RESEARCH QUESTIONS

1. What is the evidence regarding acceptable limits on temperature and duration of heating before clinically significant tissue damage for patients undergoing magnetic resonance imaging (MRI)?

2. What is the evidence regarding different heating limits depending on tissue type for patients undergoing MRI?

3. What is the clinical evidence for the use of CEM43 criteria as a limit on acceptable tissue heating?

4. What are the guidelines and standards regarding acceptable local and average heating for patients undergoing MRI?

KEY MESSAGE

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, or evidence-based guidelines were identified regarding limit on acceptable tissue heating for patients undergoing MRI.

METHODS

A focused search (with main concepts appearing in title, abstract or major subject heading) was conducted on key resources including PubMed, The Cochrane Library (2013, Issue 5), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2003 and June 20, 2013. Internet links were provided, where available.

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RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, or evidence-based guidelines were identified regarding limit on acceptable tissue heating for patients undergoing MRI.

References of potential interest are provided in the appendix.

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials
No literature identified.

Non-Randomized Studies
No literature identified.

Guidelines and Recommendations
No literature identified.

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Guidelines – methodology not specified

   See: Pacemakers and medical implants, page 5

   See: H. Time-Varying Radiofrequency Magnetic Field-Related Issues: Thermal

   See: 2.4 Radio Frequency Magnetic Fields, page 15

Standards Documents

Canadian

   See: chapter VIII. MRI SAFETY


International

7. BS EN 60601-2-33:2010+A11:2011-- Medical electrical equipment. Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis [Internet]. British-Adopted European Standard;


Review Articles


   See: II.4.2.1 MR safety and MR compatibility, page 10

Additional References

   See: Heating of Implants and Devices at 3-Tesla