Health Canada Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

NOTICE TO HOSPITALS

from the Marketed Health Products Directorate, Therapeutic Products Directorate, and the Health Products and Food Branch Inspectorate

April 2, 2003

To: Hospital Chief of Medical Staff

Please forward to the relevant Departments of Physiotherapy, Occupational Therapy, Medicine, Radiology, Rehabilitative Medicine, Dentistry, Nursing, Surgery, Neurosurgery, Orthopaedic Surgery, Biomedical Engineering, Emergency, and involved professional staff and **post this NOTICE** in your institution.

Important safety information regarding DIATHERMY THERAPY in patients with implanted leads and implanted systems with leads

Patients with implanted metallic (electrical) leads risk serious injury or death from diathermy treatments. Diathermy therapy may also damage some implanted systems. Patients are at risk even if the leads are not connected to an implanted device or even if the device is off.

This is to advise you that shortwave (radiofrequency) and microwave diathermy therapy are contraindicated for patients who have an implanted metallic (electrical) lead or any implant that may contain such a lead[1-6]. Interaction of the energy released by the diathermy device with the implanted lead may cause excessive heating in the surrounding tissue, resulting in serious injury and death. Under certain conditions, described below, ultrasound diathermy is also contraindicated[7, 8]. Any type of diathermy may also cause damage to some implanted systems. Electrocautery devices are not included in this Notice.

HPFB is aware of two incidents, which occurred outside Canada in 2001. Two patients implanted with deep brain neurostimulation systems suffered severe and irreversible brain damage after receiving diathermy therapy. One patient received diathermy following oral surgery, the other for treatment of chronic scoliosis. As a result of these incidents, several manufacturers of implanted neurostimulators[4, 5] issued safety alerts warning about the dangers of using diathermy on patients with implanted neurostimulation devices. Health Canada's Safety Code 25*, Short-wave diathermy guidelines for limited radiofrequency exposure,*[6] published in 1983, also advises against shortwave diathermy therapy for patients with metal implants.

There is risk of injury whether the diathermy machine is used in the heating or the non-heating mode, even if an active implant is not turned on, and even if the lead or other component is no longer connected to an implanted system. The patient is still at risk if only a small portion of the implanted lead or electrode remains in the body. Diathermy can also damage some implanted systems, causing them to malfunction. For microwave and shortwave diathermy, it is not known if there is a safe distance between the diathermy applicator and the implanted system. Under certain conditions, ultrasound diathermy is also contraindicated ,[7, 8] but is expected to be hazardous only if it is applied over or near the implant or its leads. Examples of implanted systems that may contain a lead include cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, spinal cord stimulators, and other nerve stimulators.

RECOMMENDATIONS

1. If you administer or prescribe diathermy therapy:

    - Ensure that the patient does not have ANY implanted lead or an implanted system containing a lead.

    - Do not administer or prescribe shortwave or microwave diathermy therapy to patients who have any implanted metallic lead or an implant with a lead, even if the implant has been turned off.

    - Do not administer or prescribe shortwave or microwave diathermy therapy if the patient has had an implanted lead in the past unless you are sure that the implant and all leads in their entirety have been removed. Note that leads are often left implanted after the implant is removed.

    - Do not administer or prescribe the application of ultrasound diathermy therapy over or near the implant or its leads.

2. If you implant leads or monitor patients with any implanted system with a lead:

    - Explain to patients what diathermy is, and warn that they should not receive either shortwave or microwave diathermy therapy.

    - Explain to the patient that ultrasound diathermy therapy may be received only if it is not applied over or near the implant or its leads.

Health Canada asks that you share these recommendations with your staff or membership and encourage their implementation in the interest of patient safety.

The identification, characterization and management of medical device-related adverse events are dependent on the active participation of health care professionals in medical device adverse event reporting programmes. Health care professionals are asked to report any suspected adverse reactions, concerns, problems or complaints pertaining to medical devices, to Health Canada at the address below, or through a toll-free Hot Line at 1-800-267-9675.

Health Products & Food Branch Inspectorate
Health Canada
Tower "A", Holland Cross
11 Holland Ave.
Address Locator: 3002C
Ottawa, Ontario K1A 0K9

References

1. Nutt JG, Anderson VC, Peacock JH et al. DBS and diathermy interaction induces severe CNS damage. Neurology 56:1384-1386, 2001.
2. Patients with Active/Powered Implants: Risk of Serious Injury from Therapeutic Diathermy Treatment. MDA Safety Notice, August 2001.
3. FDA Public Health Notification: Diathermy Interactions with Implanted Leads and Implanted Systems with Leads. December 19, 2002. http://www.fda.gov/cdrh/safety/121902.html
4. Safety Alert for Physicians, Medtronic, May 16, 2001. http://www.medtronic.com/neuro/diathermy_alert/alert_physicians.html
5. Safety Alert, Cybronics, August 27, 2001. http://www.cyberonics.com/physician/diathermy-clinicians-us.htm
6. Health and Welfare Canada, Safety Code 25 - Short-wave diathermy guidelines for limited radiofrequency exposure, 83-EHD-98, 1983. Available from the website: http://www.hc-sc.gc.ca/hecs-sesc/ccrpb/83ehd98.pdf
7. Health Canada. Safety Code 23. Guidelines for the Safe Use of Ultrasound, Part 1 – Medical and Paramedical Applications, 1989.
8. Belanger AY. Evidence Based Guide to Therapeutic Physical Agents. Chapter 10. Lippincott, Williams and Wilkins, Philadelphia, 2002.