

4427 '99 SEP 20 P1:25

Since Last We Met.....

An Update of the last 12 months of activities regarding the interaction of Medical Devices and Security Systems.

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Objectives

- Provide background on standards development and other cooperative efforts between FDA and the effected industries
- Continued need for comprehensive *in vitro* and *in vivo* studies

Industry Trends

- Medical Devices
 - ↑ use of implantable devices
 - ↑ use of sophisticated micro circuitry
- EAS and Metal Detector Systems
 - ↑ use for security purposes
 - incorporation into architecture

Our Sources for Concern

- Medical Device Reporting Database (MDR)
- Peer Review Literature
- FDA Laboratory Investigations

Medical Device Reporting Database (MDR)

Assessment of MDR Reports

- Review MDR Report
- Assess Level of Severity
 - Severe
 - Fatal / Life-Threatening
 - Resulted in Permanent or Significant Impairment
 - Required Surgical Intervention
 - Required Patient Hospitalization
 - Moderate
 - Resulted in Patient Discomfort without Significant Impairment
 - Resulted in Device Reprogramming (e.g., ICD INACTIVE Mode)
 - Mild
 - Resulted in Detectable Device Interaction without Patient Symptoms (e.g., Start VVI pacing)
- Assess Credibility

354953

Pacemaker

Spinal Stimulator

Denbrillator

Hearing Aid

Intrusion Pump

Airport Metal Detector



Pt. Felt "Shock" 53

MONITOR Only 29
MONITOR Only 31

← Increasing Number of Occurrences

Hand-Held Metal Detector



MONITOR Only 32
MONITOR Only 33
Inapprprt. Shock 48

Metal Detector

Dizziness / IPG Reset 3
Inappropriate ↑ in rate 35
Battery Depletion 7

INACTIVE Mode 22
ICD turned OFF 4



Electronic Article Surveillance (EAS)

Pulse ↑ to 120 bpm 1
Pulse ↑ to 175 bpm 37
Presyncope 44
Maximum Rate Pacing 47
Maximum Rate Pacing 50
Reverted to STAT-1 VVI 21
Required Reprogramming 24
Pacemaker "affected" 43

ICD Fired 30
ICD Fired 54

Security System

Faintness / Chest Pain 45
Presyncope / ↑ HR 34
Presyncope 46
Near Syncope 56
Reverted to STAT-1 VVI 5
Pacemaker Reverted 19
Reverted to STAT-1 VVI 20



INACTIVE Mode 45

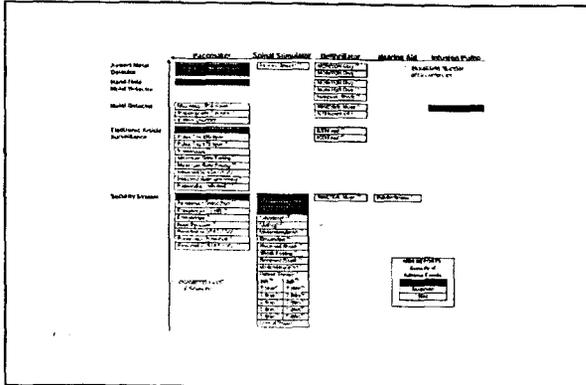
Painful Noises 2

"Shocking" 26
"Jolting" 27
Understimulation 36
Discomfort 38
Received Shock 39
Shock Feeling 40
Received Shock 42
Understimulation 51
Patient Thrown 61
Jolt 58 | Jolt 59
↑ Stim 9 | ↑ Stim 10
↑ Stim 11 | ↑ Stim 12
↑ Stim 15 | ↑ Stim 16
↑ Stim 17 | ↑ Stim 18
↑ Stim 23 | ↑ Stim 25
Loss of Power 57

↑ Increasing Level of Severity

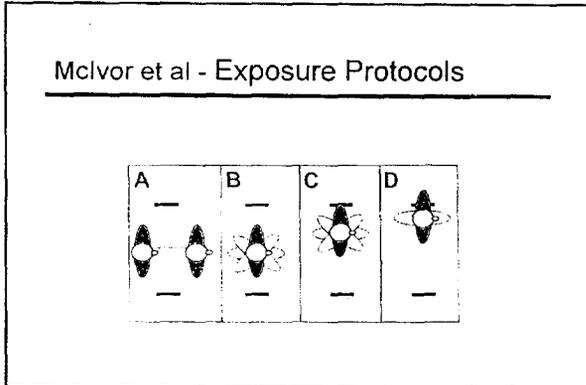
MDR REPORTS:
Severity of Adverse Events

Severe
Moderate
Mild



References:

- The Effect of Metal Detector Gates on Implanted Permanent Pacemakers, Copperman et al, PACE, October, 1988, Vol. 11, pp. 1386 - 1387
- Electronic Article Surveillance: A Possible Danger for Pacemaker Patients, Dodinot et al, PACE, January, 1993, Vol. 16, pp. 46 - 53
- Interferences entre les simulateurs cardiaques et les systemes de detection anti-vol, Mugica, Stimucœur, 1997, Tome 25, No. 4, pp. 287 - 8
- Interactions Between Pacemakers and Security Systems, Wilke et al, PACE, September, 1998, Vol. 21, pp. 1784 - 1788
- Study of Pacemaker and Implantable Cardioverter Defibrillator Triggering by Electronic Article Surveillance Devices, McIvor et al, PACE, October, 1998, Vol. 21, pp. 1847 - 1861
- Interactions Between Electronic Article Surveillance Systems and Implantable Cardioverter-Defibrillators, Groh et al, Circulation, July 27, 1999, Vol. 100, No. 4, pp. 387 - 392



McIvor et al

Protocol	Asynchronous Pacing	Atrial Oversensing	Ventricular Oversensing	EAS Induced Pacing
A	8	4	2	2
B	10	5	4	1
C	15	8	4	2
D	36	21	10	3

- ### Groh et al
- 169 ICD Patients
 - 3 Sensormatic EAS Systems
 - Ultra Max (acoustomagnetic/LF Pulsed Magnetic)
 - Aisle Keeper (73Hz non-modulated field/MLF)
 - P-Magnetic (525 Hz continuous wave magnetic)
 - interactions
 - none during a 10-15s walk through
 - 19 responses during 2 minute exposure @ 6 inches
 - 3 likely to have resulted in inappropriate shocks
 - 4 possibly could have resulted in inappropriate shocks

Case Reports

- Spinal Cord Stimulator Activation by an Anti-theft Device, Eisenberg et al, J. Neurosurgery, December, 1997, Vol. 87, pp. 961 - 2
- Environmental Electromagnetic Interference from Electronic Article Surveillance Devices: Interactions with an ICD, McIvor, PACE, December, 1995, Vol. 18, pp. 2229 - 2230
- Interaction Between Electronic Article Surveillance Systems and Implantable Defibrillators, Mathew et al, PACE, November, 1997, Vol. 20, pp. 2857 - 2859
- Interference with an Implantable Defibrillator by an Electronic Anti-theft-Surveillance Device, Santucci et al, NEJM, November 5, 1998, Vol. 339, No. 19, pp. 1371 - 1374

Where do we go from here?

- installed base of products
- designs for future products

Installed base of products

Last year we reported that Industry could:

- develop safety recommendations
- perform "in vivo" testing
- develop "in vitro" surrogates for clinical testing
- report adverse events to FDA

Installed Base of Products (cont'd)

Last year we reported that FDA could:

- issue advisory to physicians
- target information to special groups
- monitor adverse event reports
- continue laboratory assessments
- evaluate regulatory options

New/Future products

Industry:

- increase communication across industries
- include EMI as design consideration
- report adverse events to FDA

FDA:

- evaluate premarket submissions/labeling
- monitor adverse event reports

New/Future products (cont'd)

Industry and FDA together:

- share scientific/engineering information (e.g. workshops)
- propose/revise/use consensus standards

Conclusion



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Pacemaker Response to Electromagnetic Interference

- Oversensing resulting in the inhibition of either or both chambers
- atrial oversensing resulting in ventricular pacing at the frequency of the interference
- reversion to an asynchronous pacing ("noise reversion") mode

Copperman et al

- 103 Patients
- No interactions observed in 3 passes by patient with the single "Airport Metal Detector Gate" tested

Mugica

- 178 Patients
- 2 Sensomatic EAS Systems
 - Ultra Max (acoustomagnetic/LF Pulsed Magnetic)
 - Aisle Keeper (73Hz non-modulated field/MLF)
- 29 interactions (19 patients)
 - 17 in Ultramax; 10 in Aisle Keeper; 2 in both
 - interactions reported included:
 - atrial oversensing with maximum rate ventricular pacing (n=3)
 - 1 patient responded with operation in the "DDD rapid stimulation mode"
 - 3 patients classified as "other" whose ECG were difficult to analyze

Dodinet et al

- 32 Patients
- 4 EAS formats
 - radiofrequency (continuous 2 - 10 MHz)
 - pulsed electromagnetic (132kHz modulated @ 15 Hz)
 - magnetic (300 Hz)
 - magnetic (10kHz)
- Pacemaker Response
 - none to radiofrequency or pulsed electromagnetic formats
 - Inhibition: 7/32 in the 10 kHz field, 6/32 in the 300 Hz field
 - Acceleration: 1/32 in the 300 Hz field

Wilke et al

- 53 patients
- 4 systems with differing field strengths representing
 - 2 Security Systems
 - an Antitheft Device
 - an Electromagnetic Access Device
- Interactions
 - High Powered Security System
 - 5 cases of inhibition
 - 2 atrial oversensing with ventricular pacing
 - Low Powered Security System
 - 2 cases of inhibition

McIvor et al

- 75 Patients: 25 ICD and 50 Pacemaker
- 3 EAS technologies
 - Magnetic Audio Frequency Systems (VLF Continuous Wave Magnetic)
 - Knogo MM-85
 - Sensormatic Aisle Keeper
 - Swept Radiofrequency (HF Swept RF)
 - Checkpoint QS2000
 - Sensormatic Saver
 - Knogo 1301
 - Acoustomagnetic (LF Pulsed Magnetic)
 - Sensormatic Ultramax

McIvor et al

Interactions

- No ICDs responded
- 2 Telectronics Pacemakers did not respond to any EAS
- No device interactions seen in the Swept RF devices

EAS Technology	Model	Pacemakers Interacting	Asynchronous Pacing	Ventricular Oversensing	Atrial Oversensing	EAS Induced Pacing
Magnetic Audio Frequency	Knogo MMR5	2/50	2	0	0	0
	Sensormatic Aisle Keeper	0/50	0	0	0	0
Acousto-magnetic	Sensormatic Ultra Max	48/50	36	12	21	3



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Important Information on Anti-Theft and Metal Detector Systems and Pacemakers, ICDs, and Spinal Cord Stimulators
(For more complete and detailed information)

September 28, 2008

To: Cardiologists Cardiovascular Surgeons Emergency Physicians
Neurologists Neuro Surgeons

I am writing to let you know that the operation of certain medical devices, including pacemakers, implantable cardioverter-defibrillators and spinal cord stimulators, may be affected by the electromagnetic fields produced by anti-theft systems and metal detectors. The number of reported significant patient injuries is very low, and we are working with both the manufacturers of medical devices and the manufacturers of anti-theft systems and metal detectors to resolve this issue. In the meantime, you may use the following information and recommendations to help your patients prevent or minimize any adverse effects.