Scientific Initiatives Committee

EHRA Summit

April 2 – 3, 2007

Committee Members

- Almedral Jesus (ES)
- Auricchio Angelo (CH)
- Blanc Jean-Jacques (FR)
- Brignole Michele (IT)
- Lip Gregory (UK)
- Santomauro Maurizio (IT)

Core Competence

- Inter-societies events (initiated by the EHRA board)
  - Execute and coordinate
- Consensus conference
  - Initiate and coordinate
- Scientific document (position papers)
  - Promote and develop

Completed Initiatives

- Cardiac Rhytm Management Product Performance Conference
  - EHH (Nice, Fr), January 11 – 12, 2006

- Consensus Conference on End Points for Atrial Fibrillation Trials: Joint initiative of AFNET (Network on Competence on Atrial Fibrillation, funded by the German Federal Ministry for Education and Research (BMBF) and EHRA
  - EHH (Nice, Fr), January 22 – 23, 2007

Cardiac Rhythm Management Product Performance

Europace (2006) 8, 313–322
doi:10.1093/europace/eul043

GUIDANCE DOCUMENT

European Heart Rhythm Association Guidance Document on cardiac rhythm management product performance

Angelo Auricchio*, Michael Gropp, Susanne Ludgate, Panos Vardas, Josep Brugada, and Silvia G. Priori, Writing Committee for the European Heart Rhythm Association Guidance Document on Cardiac Rhythm Management Product Performance

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KEYWORDS
Pacemakers;
Implantable cardioverter-defibrillators;
Field safety corrective actions;
Cardiac rhythm management

Introduction

The comparatively large number of field safety corrective actions (FSCAs) recently issued by different device manufacturers has attracted attention to cardiac rhythm management (CRM) device performance.[1–4] It has also prompted questions as to the basis for the scientifically proven efficacy of implantable cardioverter-defibrillators, pacemakers, and cardiac resynchronization therapy devices. The broad worldwide media coverage of these FSCAs demonstrates the tremendous interest in CRM products in both the scientific community[5,6] and the lay public.

The European stakeholders such as clinicians, CRM device industry representatives, National Competent Authorities (regulators), and the scientific society including arrhythmia experts and electrophysiologists [European Heart Rhythm Association (EHRA)] gathered recently to discuss these issues. Participants considered how to improve CRM device technology, its performance and adverse event reporting, and market surveillance as well as how to increase the flow of appropriate information from manufacturer to physician and from physician to patient in Europe. Other international scientific groups have discussed or begun similar processes with the intention of presenting recommendations applicable to their own health care and regulatory systems.

Significant differences in clinical practice exist in device monitoring, regulatory requirements, and vigilance processes between the European Union (EU) and non-EU countries, as well within the EU, which creates a role for EHRA in helping to coordinate dialogue among stakeholders. Moreover, because of well-known differences in regulatory requirements and approval processes, a new CRM product is frequently clinically tested and brought to market much earlier in Europe than elsewhere. Therefore, active monitoring of CRM products in Europe is mandatory and should be conducted independently from other international monitoring or registry activities, although data sharing is highly desirable. The European field experience data may be of great importance to manufacturers as well as to regulatory authorities elsewhere in the world. Such data may allow early identification of a difference between expected and actual product performance and allow prompt corrective and preventive actions. This has the potential for improving patient safety worldwide.

In the recent past, communication about CRM device performance among stakeholders has been less than optimal. Indeed, it is unfortunate that many patients with such devices first learned about reported problems from articles in the lay press or from the internet much earlier than from their physician. This has caused widespread misunderstanding about potential device failures and, more importantly, suspicion and lack of confidence between physicians and patients, between professionals and industry, and between regulators and industry.

During the policy conference convened by EHRA, several current issues and potential areas of improvement were identified (*Table 1*). Taken together, these observations

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- Attended by
  - EU Physicians (25)
  - EU Competent Authorities (7)
  - Industry Members (14)
  - Statisticians (3)
  - HRS (1)
- Staff of the Heart House, Sophia Antipolis: Keren Deron
- EHH Assistant: Letizia Giacomoni

Outcome Parameters for Trials in Atrial Fibrillation

- Recommendations from a consensus conference organized by the German Atrial Fibrillation Competence NETwork (AFNET) and the European Heart Rhythm Association (EHRA)
  - P Kirchhof, A Auricchio, J Bax, H Crijns, J Camm, H-C Diener, A Goette, G Hindricks, S Hohnloser, L Kappenberger, K-H Kuck, GYH Lip, B Olsson, T Meinertz, G Steinbeck, E Svernhage, J Tijssen, A Vincent, G Breithardt

Additional contributors

- S. Berkowitz (Bayer), R. Bilke (Boehringer Ingelheim), C. Blomstrom-Lundqvist, A. Bollmann, M. Brignole, J. Brugada, N. Edvardsson (AstraZeneca), T. Fetsch, G. Häusler, W. Haverkamp, H. Heidbüchel, E. Hoffmann, A. Huemmer (St. Jude Medical), C. Israel, E. Köfüncü (Sanofi-Aventis), K.-H. Kuck, K.-H. Ladwig, S. Lévy, F. Lindemans (Medtronic), F. Misselwitz (Bayer), M. Näbauer, M. O' Donnell (Biosense Webster), M. Oeff, N. Osypka-Rubenstein (Osypka), R. Peeters (Sorin), P. Ramge (Sanofi-Aventis), U. Ravens, S. Schepels (Biosense Webster), M. Schwertfeger (Sanofi-Aventis), G. Steinbeck, C. Stoeppler (St. Jude Medical), R. Sutton, I. Van Gelder, P. Vardas, T. Weiß, S. Willems, R. Woker (Boehringer).

- EMEA

- Staff of the Heart House, Sophia Antipolis: Keren Deron
- EHH Assistant: Sophie Janiszewski

Outcome Parameters for Trials in Atrial Fibrillation

- General considerations
  - Patient characterization
  - Choice of outcome parameters in AF trials
- Assessment of specific outcome parameters
  - Death
  - Stroke
  - Symptoms and AF-related quality of life
  - Proposal for a new symptom classification scheme for AF
  - Left ventricular function and heart failure
  - Emerging surrogates as outcome parameters
  - Health economics
- Specific design issues in AF trials
  - Composite outcome parameter in AF
  - Further interventions, time-based assessment of outcome parameters, and “blanking periods”

Ongoing Iniatives

- EHRA Consensus guideline on antithrombotic terapy use in patients undergoing electrophysiological procedures for atrial arrhythmias
  - JJ Blanc, J Almedral

- EHRA Position paper: Magnetic resonance imaging in individuals with Pacemakers or Implantable cardioverter defibrillator systems
  - A Rougin

Ongoing Initiatives

- EHRA Consensus Guideline on Antithrombotic Therapy Use in Patients Undergoing Electrophysiological Procedures for Atrial Arrhythmias
  - JJ Blanc, J Almedral
  - Further support from Gregory Lip and Michele Brignole.
- Publication of the guideline document is expected by September 2007
- A special session at Europace Lisbon is planned

Ongoing Initiatives

- EHRA Position paper: Magnetic Resonance Imaging in individuals with Pacemakers or Implantable cardioverter defibrillator systems
  - A Rougin, T Sommer, C Vahlhaus, J Schwitter
- Advanced draft has circulated on Feb 10th, 2007 and a final document for EHRA review expected any time
- Content:
  - Hazards and Safety concerns
  - In-Vitro and Animal Studies
  - Human Studies
    - MR Imaging in Pacemaker-Dependent Patients
    - Safety Issues in Patients with Retained Pacing Leads
    - Electrical reset in the MR environment
    - MR Imaging in Patients with Implantable Cardioverter Defibrillators (ICD)
    - MR Image quality and MR compatibility definitions

Planned Initiatives

- **Remote Data and Implant System Management**
  - **Consensus Conference**

- **Driving with ICD**
  - **Position Paper**
    - **Triggered by BWGCPE**

EHRA Needs You !

- Helping in distribution of the documents and its content
- Sessions at national congresses addressing the content of the document
- Reference to documents
- Join us……..
- …and with new ideas (!)