

EHRA Summit 2011

- Meeting objectives

EHRA Summit 2011
Medical Innovations in Arrhythmias.
The expectations, the barriers, the developments

21-22 March 2011 – European Heart House Sophia Antipolis

DAY 1 – 21st March 2011

12:00 – 13:00 Arrivals / Buffet Lunch

13:00 – 13:30 Introductory Part

Welcome address, EHRA Statu Quo & Quo Vadis P. Vardas

Meeting objectives C. Wolpert

13:30 – 14:30 **Innovations in Medical Technology in Arrhythmias.**

Chairs: A. Auricchio / L. Kappenberger

- The developments in the CRM Devices. The last 50 years history... R. Sutton

- The Profile of a significant innovation. The electro-anatomic
mapping development L. Gepstein

14:30 – 15:30 ***Analysis of the barriers to innovation in medical devices.***

Chairs: K.H. Kuck / J. Kautzner

- The limited funding of Research & Development P. Calle
- The restricted affordability of the health care systems:
 - the view of the profession G. Boriani
 - the view of the industry M. Siebert

15:30 – 16:00 Coffee break

16:00 – 17:45 ***GAPS in the implementation of Guidelines for CRM Devices in ESC country members.***

Chairs: C. Blomström Lundqvist / M. Brignole

- The case of United Kingdom S. Furniss
- The case of Russia M. Medvedev
- The case of Serbia G. Milasinovic
- The case of Israel M. Glikson
- The case of Spain I. Fernandez Lozano
- The case of Poland Z. Kalarus

17:45 – 18:15 *Chairs: J. Morgan*

Economics & Medical Innovation:
closer to reality or is it out of reach ?..... R. Tarricone

18:15 Transfer to Hotel

DAY 2 – 22nd March 2010

08:15 Transfer to Heart House

09:00 – 09:30 Chair: H. Heidbuchel

Expectation in arrhythmias treatment.

What kind of innovations do we wish to see?..... J. Camm

09:30 – 11:00 **Innovations in Arrhythmias. What's in the pipeline?**

Chairs: E. Aliot / C.Linde

- Leadless CRM Devices G. Milasinovic
- Implantable loop recorders, the current and futures role
in Arrhythmias and beyond R. Hatala
- Advanced Mapping systems G. Hindricks
- Genetics for Personalised Medicine in Arrhythmias P. Schwartz

11:00 – 11:30 Coffee break

11:30 – 13:30 **Break out sessions**
Proposal for the 3 break out task forces:

Break out task force 1 – Room 6:

What defines innovation in medical Devices? What are the stages of the innovation process?

Chairs: P. Persson / S. Nisam

Break out task force 2 – Room 7:

Who are the stakeholders in innovation?

Chairs: A. Bruls / J. Morgan

Break out task force 3 – Room 8:

The affordability of the Health Care Systems for medical technology innovation, Where does it stand? – Where is it going?

Chairs: M. Jansen / B. Merkely

13:30 – 13:40 Closing comments: P. Vardas

13:40 1st Bus Departure to airport

13:40 – 14:30 Lunch

14:30 – 2nd Bus Departure to airport
Bus departure to Hotel

Albania • Algeria • Armenia • Austria • Belarus • Belgium • Bosnia & Herzegovina • Bulgaria • Croatia
Cyprus • Czech Republic • Denmark • Egypt • Estonia • Finland • Former Yugoslav Republic of Macedonia
France • Georgia • Germany • Greece • Hungary • Iceland • Ireland • Israel • Italy • Kosovo • Latvia
Lebanon • Libya • Lithuania • Luxembourg • Malta • Montenegro • Morocco • Netherlands • Norway • Poland
Portugal • Republic of Moldova • Romania • Russian Federation • San Marino • Serbia • Slovakia
Slovenia • Spain • Sweden • Switzerland • Syria • Tunisia • Turkey • Ukraine • United Kingdom

The EHRA White Book 2010

The Current Status of Cardiac Electrophysiology
in ESC Member Countries

P. Vardas, A. Auricchio, C. Wolpert



EHRA White Book 2011

José Mérimo

In collaboration with
BIOTRONIK

Process (timelines to be confirmed)

Jan-
Feb

- **Collection of data= Questionnaire**

- Step 1: Questionnaire* to be approved by Biotronik and by JM before EHRA send it out to all the NS
- Step 2: Data are collected by EHRA and send to Biotronik for Cross checking and formating

Feb-
March

- **Authorization process and first draft**

- Authorisations should start as soon as cross check data from questionnaire is complete. EHRA will send the formatted data to the NS asking for authorization to publish
- As soon as EHRA received authorisations from the NS, Biotronik will prepare the first draft version

April

- **Final draft:**

- Finalise content and design
- Reviewing process by JM and EHRA
- Green light for printing to given by both JM and EHRA

May

- **Production and delivery (mid of June the latest)**

- Distribution at EHRA Europace 26-29 June 2011 in Madrid, Spain

* In 2011, we may consider sending a prefilled questionnaire, to be discussed with Biotronik for validation

Nadine Eynaud

www.escardio.org/EHRA





EUROPEAN
Heart Rhythm
ASSOCIATION

A Registered Branch of the ESC




Main goal

- to demonstrate the benefit and efficacy of the prevention of sudden cardiac death (SCD), as at an annual level SCD is responsible for a significant part of the deceases and it is the leading cause of death in industrial countries.
- to reflect on the regional disparities, their political, economical, financial and last but not least, their educational background through a series of lectures held by the representatives of countries with low, medium and high implantation rates
- to build bridges between the medical, political and industrial sectors in order to procure greater political and economical care and support for the primary and secondary prevention of sudden cardiac death, heart failure and arrhythmias

**197 registered participants from
31 countries participated**





Örizzük meg
a szívünket

A man in a dark suit and glasses is speaking into a microphone. He is positioned on the right side of the frame. In the foreground, the back of a man's head and shoulders are visible, looking towards the speaker. To the left, a large professional video camera on a tripod is partially visible. The background is a blue wall with white text.





Faculty

- Angelo Auricchio (Switzerland)
- Imre Benedek (Romania)
- Tatsiana Burmistrava (Belarus)
- John Camm (UK)
- Zoltán Csanádi (Hungary)
- George Andrei Dan (Romania)
- Alexandru Deutsch (Romania)
- Roland Dieckmann (Germany)
- Dan Dobreanu (Romania)
- Kakhaber Etsadashvili (Georgia)
- Péter Gaál (Hungary)
- József Gajdácsi (Hungary)
- Nikola Gjorgov (F.Y.R.O. Macedonia)
- Michael Glikson (Israel)
- Robert Hatala (Slovakia)
- Ashot Hovhannesian (Armenia)
- Charles Jazra (Lebanon)
- Péter Józán (Hungary)
- Stefan Kääb (Germany)
- Oskars Kalejs (Latvia)
- Josef Kautzner (Czech Republic)
- Miran Kenda (Slovenia)
- Pavla Kristofova (Czech Republic)
- Karl-Heinz Kuck (Germany)
- Andrzej Kutarski (Poland)
- Trudie Lobban (UK)
- Andrzej Lubinski (Poland)
- Germanas Marinskis (Lithuania)
- Béla Merkely (Hungary)
- Goran Milasinovic (Serbia)
- Davor Milicic (Croatia)
- Przemyslaw Mitkowski (Poland)
- Ljilja Music (Montenegro)
- Ali Oto (Turkey)
- Yulia Persidskikh (Belarus)
- Alessandro Proclemer (Italy)
- Amiran Revishvili (Russia)
- Mária Sélleiné Márki (Hungary)
- Milos Taborsky (Czech Republic)
- Panos Vardas (Greece)
- Radu Vatasescu (Romania)
- Jüri Voitk (Estonia)
- Dmitrij Volkov (Ukraine)
- Frans Van de Werf (Belgium)
- Christian Wolpert (Germany)

Summary Statement

EHRA Summit 2010 with the Participation of Central-Eastern European Countries: "ICD for Life" Initiative –Fighting against Sudden Cardiac Death in Emerging Economies

Venue and date: Budapest, Hotel Zara, 26-27th November 2010

The main topic of the conference: "Implantable Cardioverter Defibrillator for Life" Initiative – Fighting against Sudden Cardiac Death in Emerging Economies". The event was jointly organized by the European Heart Rhythm Association and the Hungarian Society of Cardiology.

The aim of the summit was to demonstrate the benefit and efficacy of the prevention of sudden cardiac death (SCD), as at an annual level SCD is responsible for a significant part of the deceases and it is the leading cause of death in industrial countries. Many arrhythmias could be treated by device therapy and this would also reduce the death rates. The target of the summit was to build bridges between the medical, political and industrial sectors so as to procure greater political and economical care and support for the primary and secondary prevention of sudden cardiac death, heart failure and arrhythmias.

The acceptance and the efficacy of implantable devices in the treatment of heart failure and heart rhythm disturbances, especially that of ICD has increased enormously in recent years and therefore, we apply them in a wide range. In spite of this, many patients with high risk of SCD cannot receive these anti-arrhythmic treatments partly because of the low availability of the devices, and partly because of the lack of properly qualified specialists. Implantation does not simply depend on budget, financing and GDP but it also requires deep professional knowledge. As the conference emphasized both the theoretical background of device therapy – professional recommendations, choice of implantable devices, programming and problem solution- and the practical education of implantation methods are important for the increase of implantation numbers. The paradox of the effort to reduce SCD is that besides the proper risk stratification and the supply of primary illnesses, the implantation numbers of the applied devices in primary and secondary prevention – primarily that of ICD-s – have not reached the case numbers of SCD yet in the economies in transition.

The summit tried to reflect on the regional disparities, their political, economical, financial and last but not least, their educational background through a series of lectures held by the representatives of countries with low, medium and high implantation numbers. However, it also underlined the importance of patient organizations which have a crucial role in the improvement of patients' quality of life and in the risk reduction and prevention of SCD in the European population. At the end of the four sessions Central-Eastern European cardiologists, health-economists, politicians and journalists discussed the reasons and the possible solutions of the regional differences in the round table discussions. Acknowledging the importance, the timeliness and the message of the topic, Pál Schmitt, President of the Hungarian Republic and Miklós Réthelyi, Minister of the Ministry of National Resources undertook the main patronage and the patronage of the event.

Written invitation had been sent to the presidents of all Cardiologist Societies and Arrhythmia Working Groups in the member states of ESC and also to all the decision-makers of EHRA (Board Members and Committee Members). Finally, 197 registered participants from 31 countries arrived.

The program of the Summit of 2010 was all-important and concise and it was arranged on the basis of the feedbacks of the participants; even a teleconference with the leadership of EHRA was organized to discuss the program. The Faculty was composed of 55 renowned cardiologist-arrhythmologists, health economical and political experts who represented 27 countries (Armenia, Belarus, Belgium, Croatia, Czech Republic, Estonia, F.Y.R.O. Macedonia, Georgia, Germany, Greece, Hungary, Israel, Italy, Latvia, Lebanon, Lithuania, Montenegro, Poland, Romania, Russia, Serbia, Slovakia, Slovenia, Switzerland, Turkey, UK, Ukraine) and acted as invited chairs and speakers in the different sessions.

The event was preceded by a press conference in which Prof. Panos Vardas, Prof. Béla Merkely, Prof. Christian Wolpert, Prof. Goran Mlasić and Prof. Péter Józán participated. Based on the number of the participants on the part of the media and on the later media appearances, the press conference can be said extremely successful.

In the first session the event was opened by such persons of distinction as Prof. Panos Vardas, the president of EHRA and the president-elect of ESC, Prof. Béla Merkely, the president of the Hungarian Society of Cardiology and the Co-chairman of the National Societies Board of EHRA and Mária Séllei-Mári, the director general of the National Health Insurance Fund of Hungary and then, the lecturers detailed the health care and health economical differences of the European member states. Prof. Péter Józán spoke about the cardiovascular epidemiological differences, Dr. Péter Gál explained the health economical difficulties of the treatment of sudden cardiac death, Prof. Stefan Kaab held a lecture on the epidemiology of SCD and then Prof. Miran Kenda summarized in his lecture the relation of diabetes and SCD. The session closing speech was held by Prof. Christian Wolpert. He talked about the concept, the birth and the development of the EHRA White Book which is the annual publication of the association representing electrophysiological data of the member states.

The second session was about the possible device therapy for the primary and secondary prevention of SCD. The speeches of Dr. Zoltán Csanádi, Prof. Robert Hatala and Prof. Andrzej Lubinski also covered the guidelines for the possibilities of ICD treatments for conventional pacemaker, primary and secondary prevention. Prof. Milos Taborsky presented the results of the previous EHRA- Eastern Initiative Meeting held in Pitzen. His lecture was followed by a round table discussion.

In the third session about cardiac resynchronization therapy Prof. Béla Merkely summarized the latest evidences of efficacy of CRT treatment. On behalf of the National Health Insurance Fund of Hungary, Dr. József Gajdócsi explained the health economical background and the financial model of this special, expensive, but cost-effective treatment. He presented the algorithms for decision making in Hungary and pointed out the possibilities of the system.

In the fourth session Prof. Frans Van de Werf explained the process of establishment

and the implementation of international guidelines, mentioning the difficulties of the implementation as well. Then the lectures of Prof. John Camm and Prof. Michael Glikson followed. They talked about the costs of ICD treatment which proved to be the most cost-effective method of prevention and treatment of SCD and explained how the expenditure of the treatment influences the number of patients actually receiving it. As proper education also belongs to the cost-effective treatment, in his speech Prof. Josef Kautzner focused on the education and training systems and described the policy of EHRA regarding the Central-Eastern European education in arrhythmology.

In the next session Prof. Davor Milicic and Prof. George Andrei Dan occupied with such complex questions of the treatment of SCD as the screening of patients with high risk factors, the establishment of proper predictive factors and the application of this in practice. Prof. Alessandro Proclemer introduced in a separate lecture the Italian Pacemaker / ICD registry, worthy of copying in case of the follow-up of patients already wearing devices. As we learned from Prof. Amir Reishvili's lecture ventricular tachycardia ablation had become a widely accepted method of treatment in case of patients with ICD, having recurrent and frequent ventricular arrhythmias.

The lectures of the last session dealt with the management of patients already having device protection. Dr. Roland Dieckmann, Ms. Pavla Kristofova and Ms. Trudie Lobban presented the system and the achievements of the German, the Czech and the British model. The story, the importance, the goal and the planned future of the Eastern Initiative was summarized by Prof. Goran Milasinovic. Prof. Karl-Heinz Kuck projected the future perspectives of the treatment of SCD.

At the end of the second, the third, the fourth and the fifth sections in the frame of thirty minutes long round table discussions the participants had the possibility to introduce the practice and the data of their own countries, and to reflect on the political-economical background of these in a few minutes. Following this, the participants discussed the opening possibilities and pointed out the lack of homogeneity, all the invited speakers agreed that it is a problem to be solved in any case. All the round table discussions were followed by the presentation of a vision of the future and the policy of the given treatment, previously discussed in the section.

In its entirety EHRA Summit reached its goal; beside the professional talks there had been place for the presentation of the political and economical effects as well and the conclusion was also favourably received by the national and international media. Hungary had been chosen by the European Society of Cardiology as the site of the latest EHRA Summit for the reason that Hungary belongs to those countries where the number of the implanted cardiac rhythm management devices equals the healthcare demands. Hungary is part of the "green region" which means that the number of the implanted devices grows at an adequate rate and the development can be maintained. By receiving the opportunity of organizing the summit, the Hungarian Society of Cardiology could introduce its decennial work, exemplary in the region.

The fundamental message of EHRA Summit was that for the prevention of sudden cardiac death the professional collaboration does not suffice to remain within the

country borders. The collaboration has to cross borders so as to develop a common international professional, health economical and health political strategy and union. Therefore, the summit came to the consensus of creating a working board in the frame of EHRA, the "Working Board of Eastern Initiative" (WBEA) in order to delegate individual persons for specific tasks. As Christian Wolpert and Panos Vardas also supported the idea, the WBEA had been formed at the end of the summit. The members of the working board are Christian Wolpert, Béla Merkely, Josef Kautzner, Goran Milasinovic, Robert Hatala, George Andrei Dan, Milos Taborsky and Zoltán Csanádi. (Further members can be involved in the work of the board, if needed.)

First of all, the regional differences are to be investigated in full details. Based on personal communication with the cardiologist and arrhythmologist leaders of the specific region, Goran Milasinovic will define and analyze the specific regional problems and obstacles in each country. The analysis will detail the problems to be solved so as to improve the efficacy of the prevention of SCD (e.g. lack of well-trained experts and sufficient knowledge, lack of referrals, lack of infrastructural background and reimbursement). The report will be sent to WBEA in order that the working board would set the targets for the next three years to ensure the solving of the most urgent problems in each country.

Second, WBEA is responsible for the definition of proper education and the establishment of new training centers in the Eastern-European countries. Since besides the financial background and political acceptance, both short-term and long-term theoretical and practical education is needed for the development.

From WBEA Josef Kautzner was appointed to create a plan of education for all regions and to define the rules and minimal requirements that have to be fulfilled by those Eastern European high volume centres (centres of high case numbers) which with the endorsement of EHRA, proctorship and training centres can be in different issues (conventional pacemaker-, CRT-, ICD- therapies, electrophysiological studies, ablation, AF Ablation etc.). (The so-called "proctorship" programmes are programmes of 8-12 weeks, whereas the EHRA fellowship programmes are one year long educational programmes.)

The development of an international educational network, the accreditation of the training centres and the training plans and the trainees distribution according to centres and training programmes are all the competence of EHRA. On the other hand, it is the task of the industrial sector to provide financial support for these programmes. For making the public acquainted with arrhythmias, the importance of publicity has to be also emphasized. This can be realized, for example, by the permanent presence of national and international arrhythmia organizations (such as the EHRA) in the media. In addition to this, it is crucial to establish properly organized and advertised, active national and international patient organizations, similar to Arrhythmia Alliance.

Last but not least, the ICD penetration has to be improved even in those countries who have not implanted any so far. WBEA and EHRA will help to find a solution even in those countries who already have well-trained specialists (eg. those having participated in an EHRA fellowship program), have infrastructural base and referred

patients for ICD implantations but do have a lack of ICD devices. In their case, the cooperation with the industrial sector can mean the solution.

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EHRA Summit 2010, Budapest

5 Sessions dealing with

- **Device Therapy, Primary and Secondary Prevention of Sudden Cardiac Death**
- **Heart Failure: Cardiac Resynchronisation Therapy**
- **Cooperation in the Training and the Cost-effective Medical Care**
- **The Complexity of Sudden Cardiac Death**
- **The Role of Patient Organizations and The Eastern Initiative**

EHRA Summit 2010, Budapest Achievements

The establishment of the “**Working Board of Eastern Initiative**,, → to delegate individual persons for specific tasks:

- ❖ definition and analysis of the specific regional problems
- ❖ suggestion of specific education policy
- ❖ establishment of training centers in the Eastern-European countries
- ❖ creation of a plan of education for all regions
- ❖ definition of the rules and minimal requirements that have to be fulfilled by Eastern European training centres
- ❖ increase of public awareness of SCD → EHRA will help to organize lectures at national cardiology and arrhythmology meetings in the region and promote foundation of patient organizations
- ❖ to find the way to support the above educational activities in Eastern Europe

















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