

European Heart Rhythm Association Summit

Research in Arrhythmias: Institutions,
Industry and Networking needs

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Clinical research: what do we need in EP

- Clinical research in our area is mainly conducted with large international clinical trials (mainly planned and conducted in the USA) and research at individual centers.
- Less attention is paid to the collection of solid epidemiological data and surveys.

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Surveys, Registries, Data bases, Clinical Observatories....

**Why do we need them at the
time of clinical mega-trials?**

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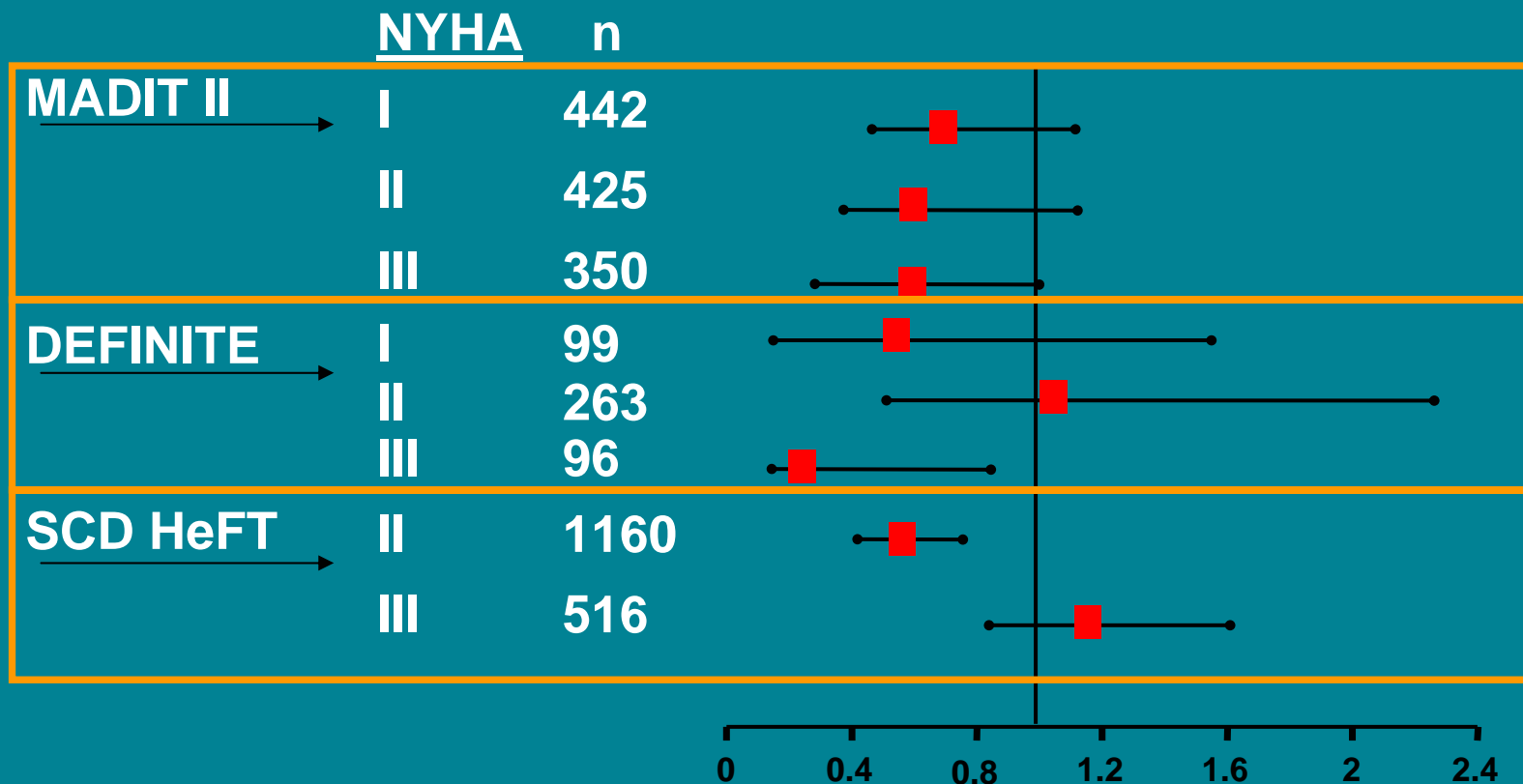


The gaps of the trials

- Patients enrolled in clinical trials are:
 - limited in numbers
 - selected to ensure compliance to protocol
 - better treated
 - followed at tertiary centers
-
- DATA FROM REAL LIFE ARE IMPORTANT

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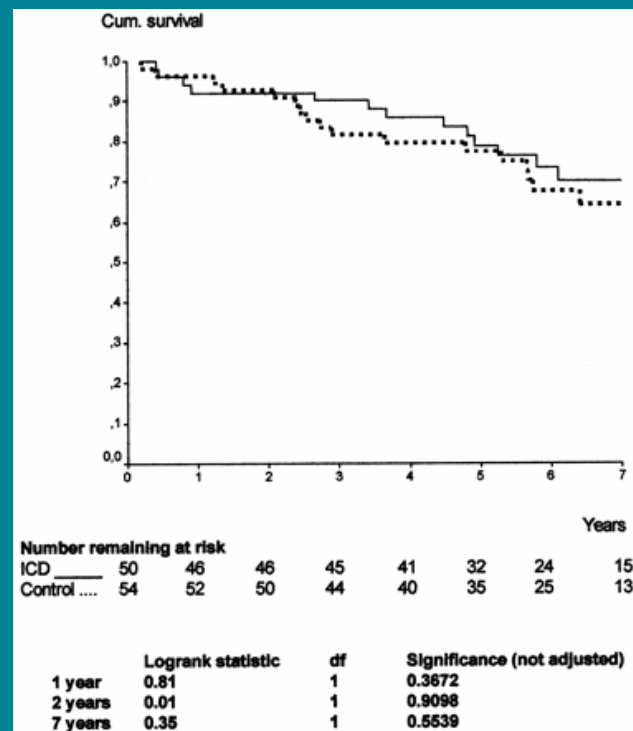


Epidemiological data in Europe

- We lack epidemiological data in Europe
- In the context of the preparation of Guidelines on prevention of SCD the writing committee realized that there are no solid figures of the incidence of SCD in Europe.
- National data are not collected in a uniform way to allow easy pooling.

Epidemiological data

- CAT Trial designed on assumption of mortality of 30% at first year. Mortality was 5% at first year!



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Clinical trials/ Registries/Data bases/Clinical Observatories

- Test the results of trials in the unselected population of clinical practice.
- Broad geographic distribution
- Representation of medical centers
- More realistic compliance to therapy and followup

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The infrastructure for networking

- In Europe thanks to the strenght of established Societies and WG in EP there is already a capillary infrastructure that can develop EUROPEAN sinergies for research.

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WHAT EHRA CAN DO

- EHRA can promote synergies among EP societies and WGs to gather resources to merge national Registries and Observatories.
- EHRA members can act at the national level to encourage the creation of local data bases and observatories that can be joined to provide a european view.

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Implementation of Guidelines

- Projects like the Euro Heart Survey provide a structure to monitor at the European level adherence of practice to clinical guidelines.
- EHRA can facilitate networking to develop this type of activities.

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Hurdles to Clinical Research

- Lack of attractiveness for the professional figure of the physician-scientist
- Tighter control of health-care resources has limited the opening of positions for academic medicine
- Progressive reduction of European Funding for research
- Increasing cost of clinical research and of clinical trials

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Hurdles to Clinical Research: the financial aspect

- Lack or paucity of financial support for investigating topics unrelated to drug / device development
- Lack of resources for creating registries to collect data with uniform methodology on unselected & consecutive patients in different European countries.

Translational research

- The commitment of EHRA in promoting research should include promotion of **BASIC SCIENCE**.
 - Education
 - Promote the figure of the MD/PhD in EP
 - Facilitate and encourage interaction with the Basic EP community (WG cellular EP)
 - Develop a training program (fellowship) for clinician/scientists

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What EHRA is doing

- EHRA has the largest training fellowship program of the ESC (larger than that of the ESC itself)
- 42 applications for EP fellowships for 10 awards (5 basic training 5 advanced training)
- 14 applications for EP training centers
- Promote international exchange, cross-fertilization, collaboration environment.

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WHAT EHRA CAN DO

- Promote programs to support training of research scientists.
- Give credibility and value to the professional profile of the research scientist.
- Promote the development of professional incentives/ recognition for clinicians with a reserach training.

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Industry: a most important partner for the medical community

- Development of new therapeutic agents / devices and diagnostic procedures is based on the interaction between science and technology and can only be achieved by an interaction between the academia and the industry.

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Industry: a most important partner for the medical community

- R&D groups within the industry are abandoning Europe and concentrating in the USA: this is a negative trend that is market-driven and should be attenuated by creating incentives for maintaining R&D activities in Europe.
- EHRA can play an important role in requesting involvement of European in EP in R&D initiatives.

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The need for funding independent research

- If clinical trials are organized **predominantly** by the industry, the medical community has to face several dilemmas:
 - The study design may be planned to achieve selected objectives i.e. maximize the probability of positive outcomes
 - Positive trials are unlikely to be repeated
 - The selection of the study population may be targeted to cost containment

The example of women enrollment in cardiovascular trials

- Because the base-line rate of cardiovascular disease is so much lower in women than in men **40,000** women had to enter the Women's Health Study versus **22,000** men in the Physicians' Health Study to test a very similar hypothesis
- Obviously this means that it is more expensive to conduct a trial in cardiovascular medicine including women with a lower event rate.

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The need for independent trials

- EHRA can play an important role in promoting the need for independent trials that allow to address issues that are not of interest to the Industry.
- EHRA should act at European level to promote funds for clinical trials in EP

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Conclusions

- EHRA THROUGH NATIONAL SOCIETIES AND WORKING GROUPS IN EP CAN:
- Support the development of networks for clinical trials/observatories/registries/surveys in Europe
- Promote education on science, clinical research and translational research by creating programs that encourage young doctors to engage in research.
- Increase the interaction between basic scientists and clinicians in order to maximize the application of novel developments into the clinical arena
- Attract the Industry to invest in translational research in Europe

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