CRT Survey

a Joint initiative of the Heart Failure Association (HFA) of the ESC and the European Heart Rhythm Association (EHRA)

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PROTOCOL

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To improve quality of life and longevity, through better prevention, diagnosis and treatment of heart failure, including the establishment of networks for its management, education and research.
EHRA Mission
To improve the quality of life of the European population by reducing the impact of cardiac arrhythmias.

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1. CRT Survey Summary

The European CRT survey represents a joint initiative between two ESC associations; the Heart Failure Association and the European Heart Rhythm Association. The survey will be performed in collaboration with The Institut für Herzinfarktforschung in Ludwigshafen which will handle the data collection and data analysis.

2. Background and rationale of the CRT Survey

The 2005 and 2008 ESC Heart Failure Guidelines [1,2] and the ESC/EHRA Guidelines for Cardiac Pacing [3] provide cardiac resynchronisation therapy (CRT) with a class 1 recommendation with evidence level A for treatment of patients with symptomatic heart failure despite optimal medical therapy and a QRS duration >120 msecs both to improve survival and reduce morbidity.

Published meta-analyses of randomised clinical trials confirm substantial clinical benefit [4,5,6,7] and the European Guidelines essentially harmonise with the ACC/AHA heart failure guidelines [8,9]. Despite these clear guidelines, implementation rates have only increased modestly [10].

Although convincing evidence has recently been provided demonstrating efficacy, the target population most likely to profit from intervention has not adequately been identified[4]. No consensus exists among investigators and clinicians describing the precise measurements from various investigations that would best serve to identify likely responders from the population representing potential candidates for CRT implantation[11,12].

There is a need to precisely quantify both the extent of clinical improvement and adverse experience associated with implantation in daily practice. Implantation techniques and recommendations for fine-tuning device programming are also rapidly evolving. The recommendation to include an ICD in the device (CRT-D) is often a difficult clinical decision and practice varies widely. Appropriate patient selection, the implantation process and follow-up requires close cooperation between heart failure physicians, echocardiographers and electrophysiologists. Invasive cardiologists and cardiovascular nurses are frequently involved. Management of these patients requires a multidisciplinary approach.

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3. Objectives of the CRT Survey

The primary objective of this survey is to describe current European practice based on a representative sampling in 13 countries.

The Survey will capture data from patients receiving CRT-P/CRT-D devices:

- Demographics and clinical characteristics
- Diagnostic criteria assessed prior to implantation
- Pharmacological therapy at baseline and follow-up
- Implantation procedure and techniques
- Device programming
- Short and long-term outcomes
- Adverse experience and hospitalisation
- Economic analyses
- Adherence to guidelines

These data should also provide information contrasting practice between centres and countries and adherence to guideline recommendations. Participating centres will be able to benchmark online with national and international practice and participation enables quality assurance assessment.

4. Participating countries and investigators

The two Associations HFA and EHRA will invite investigators from the following 13 European Countries to participate in the survey: **Austria, Belgium, France, Germany, Spain, Ireland, Israel, Italy, the Netherlands, Norway, Sweden, Switzerland and UK. It is estimated that these countries are responsible for over 90% of the implants in Europe. We have identified 807 potential implanting centres. The Survey establishes an infrastructure for networking among cardiologists managing these patients and provides a potential for cooperation in clinical trials.**

Physicians involved in selecting appropriate patients and performing CRT/CRT-D implantation invest considerable effort into learning the technique, assessing the patient and performing the procedure. Similarly to PCI interventionalists, responsible physicians should be willing to make

the extra effort to enter data into a streamlined electronic CRF. The participation guarantees benchmarking reports to the participating centres and is free of charge.

5. Study population

All consecutive patients receiving a CRT-P/CRT-D device at a participating centre are eligible for inclusion. There are no exclusion criteria except for battery replacements. The procedure itself identifies the patient as a survey candidate and the survey should provide a large sample size that accurately reflects current European practice. With a conservative estimate of response from 1/3 -1/2 of the approached centres with in 6 months of recruitment period, the approximate number of included patients will be 4000-6000.

6. Structure of the CRT Survey

The survey is a joint enterprise of HFA and EHRA and will be conducted in close collaboration with the Institut für Herzinfarktforschung in Ludwigshafen and ESC. The Scientific Committee consists of persons chosen among cardiologists with expert knowledge in this field and includes members from HFA, EHRA and EAE.

7. Enrolment and Follow-up

Two national coordinators are selected from each of the 13 participating countries, one each from the fields of Heart Failure and Electrophysiology. An active secretariat composed of Tessa Baak and Tobias Limbourg will actively recruit and motivate centres to assure rapid inclusion and successful follow-up. The national coordinators will motivate sites and assist the secretariat in obtaining IRB approval and administrating the Survey in an effective manner. A cardiology fellow and PhD candidate Nigussie Bogale (Norway), is attached to this initiative with organisational and scientific responsibilities.

8. Electronic Case Report Form (eCRF)

Data will be collected using online, user-friendly internet data entry. The case report form is streamlined yet collects essential details. The database will be administrated by the data management centre in Ludwigshafen.
Specific parameters to be captured are demographics, etiology of heart failure, past medical history, preimplant clinical evaluation, ECG and echocardiography, procedural details, complications, post implantation assessment, medication before and after implantation, discharge status and follow-up data.

9. Data Analysis and Management

The database will be constructed, maintained and interrogated at the data management centre in **The Institut für Herzinfarktforschung in Ludwigshafen** under the direction of Anselm Gitt which will also perform data analyses for publications.

10. Benchmarking reports

The Institut für Herzinfarktforschung in Ludwigshafen will provide reports of all collected data to every participating centre on a regular basis. The data of the participating centre will be displayed against the data of its country and against the overall data of Europe. No data from any participating centre will be released to any other participating hospital or medical institution. This benchmarking system will offer the participating centre a tool for internal quality control to check for adherence to the ESC practice guidelines. Sponsors will have the right to interrogate the database. All requests for analyses will be approved by the Scientific Committee.

11. Ethical approval

The data of all enrolled patients will be transferred to the central database without any patient identification. In some of the participating countries there is no need to apply for ethical approval for anonymous data collection and transfer. In the majority of countries ethical approval has to be applied for to the appropriate Institutional Review Board. The National Coordinators will make application and the secretariat will provide appropriate documentations (eCRF, Protocol, Patient Information and Consent Form). All patients receiving a CRT device will be approached by the primary investigator at each site and, if necessary, based on local standards - written informed consent to participate in the survey will be obtained.

12. Data ownership and publication policy

The database is the intellectual property HFA and EHRA of the ESC and the Scientific Committee. The individual investigators will have access to the database and participate in the publication process. Sponsors will have the right to interrogate the database through requests channelled to the Scientific Committee. All National Coordinators maintain the right to publish on their national data. The ground rules for the publication process have been developed by the Scientific Committee and are available in a separate document.

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13. Timelines

We target 1 November 2008 as a start date for recruitment with a 6 months recruitment period. The follow-up visit will be at 1 year with a flexible window to schedule patients between 9 and 15 months. We intend to complete the Survey by 30 June 2009.

Prof. Kenneth Dickstein

Prof. Silvia Priori

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[11] Naguesh et al. Mechanical dyssynchrony in congestive heart failure: diagnostic and therapeutic implications. J Am Coll Cardiol 2008;51:11-22

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