EUROPEAN HEART RHYTHM ASSOCIATION

A Branch of the ESC

EHRA Patients Survey “Living with an ICD”

Coordinating centre:

Scientific Initiatives Committee (SIC) of the European Heart Rhythm Association (EHRA),

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Objectives

The European Heart Rhythm Association (EHRA) Scientific Initiatives Committee (SIC) will conduct a patient survey entitled “Living with an ICD”. The major aim of this survey is to assess the knowledge and quality of life in the ICD recipients. We are going to explore patients’ attitude towards life with an ICD and end of life issues. This survey is expected to establish the current needs of ICD patients in terms of information about the device. Study results should help physicians in providing specific counseling in ICD population.

Design and methods with inclusion and exclusion criteria

This is prospective, multicentre survey of contemporary ICD patients at centres which are located in countries-members of the ESC. A letter will be sent to participating countries’ Arrhythmia working groups to ask for participation. Also, groups of ICD patients will be targeted directly at their support groups/alliance.

Patients with ICD will be offered to participate in this survey by anonymously answering the questionnaire (attached) posted on an electronic platform and available via the Internet or in the paper form. The questionnaire contains 26 questions in the patients’ native language. Patients will be asked to submit their replies via the Internet or in the paper form, either without any help or with technical guidance from medical staff or family members. The paper forms will be uploaded online by the SIC. Data will be collected anonymously. No follow-up is planned.

Inclusion criteria: all patients with any type of ICD (ICD-VR, ICD-DR, CRT-D, S-ICD).

Exclusion criteria: patients unwilling or unable to participate.

Duration of the study

The study will be conducted from April 2021 to June 2021. There will be no follow-up of enrolled patients.

Ethical consideration

Data (excluding personal data) will be entered by the patient on the Internet using an online platform. The data can also be collected and entered on the online platform by a healthcare worker through a completer paper questionnaire. Data will therefore be collected anonymously by the ESC, through the online platform. Then, only the assigned SIC members will have access to the anonymised results. There will be no storage of clinical data outside the data collection instrument, which will be a secure, web-based form at The European Heart House. The main database will be secured according to current standards to ensure both ethical and integrity requirements of the data. If required by a local policy, the approval of local Bioethic Committees will be obtained by the investigators.

Publication

Publications of results are planned for the EP Europace Journal

Data Protection Policy

The ESC complies with the General Data Protection Regulation (GDPR) 2016/679 and the

data protection laws in France. The ESC therefore takes all reasonable care and action to

prevent any unauthorised access to the centres' and patients' personal data. Please refer to the dedicated GDPR webpage if needed.