EHRA
European Heart
Rhythm Association

EUROPEAN HEART RHYTHM ASSOCIATION

A Branch of the ESC

EHRA Patients Survey "Patient's Experience in the Electrophysiology Laboratory"

Coordinating centre:

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

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Objectives

The Scientific Initiatives Committee (SIC) and Patient Coordination of the European Heart Rhythm Association (EHRA), along with the European Society of Cardiology (ESC) Patient Forum, will conduct a patient survey entitled "Patient's Experience in the Electrophysiology Laboratory". The primary aims of this survey are to evaluate patients' experience undergoing device implantation, an electrophysiology study or an ablation procedure and to improve the quality of care. This questionnaire is expected to determine the current standard of care in the Electrophysiology Laboratory. The survey results are intended for quality care assessment and improvement.

Design and methods with inclusion and exclusion criteria

This will be a prospective, multicenter survey of patients undergoing device implantation, an electrophysiology study or an ablation procedure. Patients will be targeted at the hospitals located in the countries-members of the ESC. A letter will be sent to the participating countries' Arrhythmia working groups to ask for participation.

Patients who have had a device implanted, an electrophysiology study or an ablation procedure will be invited to participate in this survey. Patient participation will be voluntary. The patients willing to participate will anonymously answer the questionnaire (attached) at the hospital discharge after the intervention. The survey will be posted on an electronic platform and accessible via the Internet or in paper form. When the paper form questionnaire is filled, it will then be uploaded on the electronic platform. Patients will be asked to submit their responses without assistance

or with technical assistance from family members. There are 25 questions in the patients' native language. EHRA SIC members will translate the questionnaire into different languages with the help of the EHRA Young EP Committee members. Each center will only have access to data from its center without comparing the centers. If justified, the use of data by country or region will be allowed. Data will be collected anonymously. There will be no follow-up.

Inclusion criteria: patients undergoing device implantation, an electrophysiology study or an ablation procedure.

Exclusion criteria: patients unwilling or unable to participate.

Statistical analysis will be done using SPSS (version 25.0, SPSS Inc., Chicago, IL, USA). Survey results will be expressed as numbers and percentages. Test for normality will be performed using the Kolmogorov–Smirnov test. Comparison will be made by Pearson and Fisher's exact test, as appropriate.

Duration of the study

The study will be conducted from June 2023 to July 2023. There will be no follow-up of enrolled patients.

Before the final launch of the questionnaire, the conduction of a pilot questionnaire for one month (from 1st of May to 30th of May 2023) is planned in several centers selected by the EHRA SIC Committee. The pilot questionnaire aims to check the feasibility of the questionnaire per protocol. The protocol will be revised if any problem is reported in implementing the protocol.

Ethical consideration

The patient will enter data (excluding personal data) using an online platform. The data can also be collected and entered online by a healthcare worker through a completed 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 anonymized results. There will be no clinical data storage 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 the ethical and integrity requirements of the data. If required by a local policy, the investigators will obtain the approval of local Bioethics Committees.

Publication

Results are planned to be published in the EP Europace Journal as open access. Participating centers will inform patients about the results of the survey after the publication of the results.

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