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Short title: The HEart failuRe ObsErvational Study (HEROES): Study rationale

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INTRODUCTION

Heart failure (HF), has become one of the most important contemporary medical challenges. A report from the Polish Cardiac Society states that 1.2 million people have HF in Poland, characterized by a 40% 5-year mortality rate, annual treatment costs of PLN 1.7 billion, and a total expenditure of PLN 6.2 billion on direct costs [1].

There is a lack of up-to-date data on risk factors, clinical symptoms, pharmacotherapy, use of devices, as well as the clinical indicators of re-exacerbations and prognosis [2]. Therefore, through the Scientific Platform of the Polish Cardiac Society, we conducted an observational study, the HEart failuRe ObsErvational Study of the Polish Cardiac Society (HEROES).

The main objective of the HEROES was to obtain comprehensive and contemporary clinical data in a representative population of Polish patients with HF, both outpatient and hospitalized in cardiology and internal medicine departments. One of the most important aims of the study was to describe current treatment, including adherence to the latest European and Polish HF guidelines [3]. Moreover, since the conduction of the European HF Registry [4] novel methods of treatment were introduced. The HEROES database will allow not only to examine the impact of those novel methods on prognosis, but also to explore current topics in modern HF management (i.e., frailty).

METHODS

This a prospective, multi-center, observational study which was designed to describe the clinical status of patients with HF in a representative national sample. The design of the study and selection of centers, was based on the Long-term Registry on Patients with Heart Failure endorsed by European Society of Cardiology and guided by 25 national societies of cardiology including the Polish Cardiac Society [4–6]. The acquired data were the basis for more than 30 publications [7–15].

The Bioethical Committee at the Medical University of Lodz approved the implementation of the HEart failuRe ObsErvational Study of the Polish Cardiac Society — No.RNN/316/20/KE with the update KE/762/23. Funding — Polish Cardiac Society contract No.CRU0120-KCKB-2023.

Scientific Committee

Scientific Committee consists of the authors of this article. The team composition was automatically supplemented by the current President of the Polish Cardiac Society and the National Consultant for Cardiology.

Centers

Centers applying for the HEROES were analyzed in terms of geographical representation and its equipment in accordance with the principles developed by the EURObservational Research Program of the European Society of Cardiology:

1. representation of all areas of Poland;
2. representation of centers with various levels of specialists facilities, as follows:
    a. 25% of centers with on-site cardiac surgery,
    b. 25% of centers with a hemodynamics laboratory but without cardiac surgery,

c. 50% of centers without a hemodynamics nor cardiac surgery;

3. consent of the center to share unmodified full profile of clinical data.

Forty one centers were approved for the HEROES, including 32% with on-site cardiac surgery, 22% with a cath-lab but without cardiac surgery and 46% without a cath-lab or cardiac surgery.

Data collection

To facilitate consecutive enrollment, patients were enrolled in the registry on a one-day-per-week basis. Detailed inclusion and exclusion criteria and the objectives of the data collection are presented in Supplementary material, *Appendix 2*.

Clinical data sheet

The electronic case report form (eCRF) was developed by the Scientific Committee. The eCRF was supplemented by the investigator's brochure, which contained descriptions of procedures and definitions necessary to properly conduct the study and complete the form. Patient data remained compliant with applicable regulations on the protection of personal data and sensitive data (including the provisions of the GDPR).

The eCRF was dedicated to collect complete and qualitatively valuable clinical data. Its scope depended only on the availability of routine diagnostic and therapeutic tests. None of the elements of eCRF required any examination or treatment other than those related to the individual decision of the attending physician based on the current clinical situation. Each diagnostic or therapeutic item in the eCRF contained the option of stating "Not performed". The most important clinical variables collected in the eCRF are presented in Supplementary material, *Appendix 3*.

Signed written informed consent were obtained from all participants. In the case of patients treated in a hospital, the range of the data were supplemented at the time of the discharge. The analysis of the current condition of the patient could be carried out based on data from ambulatory or hospital databases.

Follow-up

Data on overall mortality during the follow-up period, provided in accordance with RODO regulations, were sourced from the Polish Ministry of Digital Affairs and included only the exact date of death from all causes. The document was dated May 21, 2024, which was established as the fixed "end of follow-up date" for HEROES database. There were no follow-up visits planned according to the protocol and no other endpoints than all-cause death were estimated.

Statistical analysis and data publications

All data reported by the centers will be subject to professional statistical analysis. The published results of the analyzes will not apply to any center or their subgroup other than those of equipment facilities in accordance with the description listed above in the subsection „Centers". Clinical data will be the only criteria used to subgroup patients.

No individual data of specific patients and selected data of a specific center will be made available to any party other than the strict group of informatics responsible for the proper functioning of the eCRF and the principal investigator of a given center.

Planned statistical analysis of gathered data will include methods of descriptive statistics. Categorical variables will be presented as number and corresponding percentage, while quantitative variables — as mean (with standard deviation) or median (with interquartile range) — depending on data distribution. For comparisons of subgroups tests of independence and for risk factors identification methods of regression (linear/logistic; uni-/multivariate) will be used. Further statistical methods (i.e. survival analysis) will be performed depending on the particular sub-analysis and precisely described in each manuscript.

Completion and first result of the study

Based on the HEROES database and further sub-analysis, over 30 publications are planned, including: population characteristics, quality of life, frailty, HF with supranormal ejection fraction, patients with HF and cancer, antithrombotic treatment in HF and atrial fibrillation and others.

The project was launched on April 2, 2022, and patient inclusion completed on March 27, 2024 which allowed obtaining clinical and survival data on all 1422 patients (0% lost to follow-up). During the mean follow-up of 16 months (median: 485 days, interquartile range: 397–599 days) 246 patients died (17.3%). The annual mortality rate was 12.9%.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

Article information

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Conflict of interest: None declared.

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Study URL: https://heroes.umed.pl

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