Rationale, objectives, and design of the HEart failuRe ObsErvational Study of the Polish Cardiac Society (HEROES)

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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 in Poland have HF, 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 HF patients in both outpatient and hospital settings 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, the European HF Registry [4] has introduced novel methods of treatment. The HEROES database allowed not only the examination of the impact of those novel methods on prognosis but also exploration of current topics in modern HF management (i.e., frailty).

METHODS

This was a prospective, multi-center, observational study, which was designed to describe the clinical status of HF patients in a representative national sample. The study design and selection of centers were based on the Long-term Registry on Patients with Heart Failure endorsed by the European Society of Cardiology and overseen 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 HEart failuRe ObsErvational Study of the Polish Cardiac Society (No.RNN/316/20/KE with the amendment KE/762/23). The study received funding from the Polish Cardiac Society (contract No.CRU0120-KCKB-2023).

Scientific Committee

The Scientific Committee included the authors of this article. The current President of the Polish Cardiac Society and the National Consultant for Cardiology were added to the team.

Centers

The centers applying for the HEROES were analyzed in terms of geographical representation and their 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 varizus levels of specialist facilities:
   — 25% of centers with on-site cardiac surgery,
   — 25% of centers with a hemodynamics laboratory but without cardiac surgery,
   — 50% of centers without hemodynamics or cardiac surgery;
3. consent from 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. The 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 handling remained compliant with applicable regulations on the protection of data and sensitive data (including the GDPR).

The eCRF was used 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 examina-

tion 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 was obtained from all participants. In the case of hospitalized patients, the range of the data was supplemented on discharge. The analysis of the current condition of the patients could be carried out based on data from ambulatory or hospital records.

Follow-up

Data on overall mortality during the follow-up, provided in accordance with the GDPR, 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 the 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 underwent 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 specialists responsible proper functioning of the eCRF and the principal investigator in a given center.

The planned statistical analysis of gathered data will include methods of descriptive statistics. Categorical variables will be presented as numbers and corresponding percentages, while quantitative variables as means (with standard deviations) or medians (with interquartile ranges) depending on data distribution. For comparisons of subgroups, tests of independence and 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 will be precisely described in each manuscript.

Completion and first results of the study

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

The project was launched on April 2, 2022, and patient recruitment was completed on March 27, 2024, which allowed obtaining clinical and survival data on all 1422 patients (no patients 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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Study URL: https://heroes.umed.pl

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