Effect of Roxadustat on Heart Failure Patients with Anaemia and Moderate-to-Severe Chronic Kidney Disease

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Objective

Previous clinical observations of potential benefit from Roxadustat in this complex patient population prompted this investigation Therefore, the investigators designed this retrospective, observational study to thoroughly investigate the effects of Roxadustat on heart failure treatment and ventricular remodelling in this specific patient population, aiming to provide new insights for patients' management.

Design

This single-centre, retrospective, observational study was designed to evaluate the role of Roxadustat in improving or delaying the progression of heart failure and ventricular remodelling in heart failure patients with renal insufficiency and anaemia.

Inclusion Criteria: Eligible patients met the following criteria:

- aged 18-85 years, regardless of gender;
- fulfilled the diagnostic criteria for heart failure and chronic kidney disease;
- haemoglobin level <130 g/L for men or <120 g/L for women at baseline;
- had regularly received Roxadustat for over one year;
- possessed complete clinical data, including information from pre-specified time points.

Exclusion Criteria: Patients were excluded for any of the following:

- comorbid myelodysplastic syndromes, multiple myeloma, hereditary hematologic diseases (e.g., thalassemia, sickle cell anaemia, pure red cell aplasia), hemosiderosis, hemochromatosis, or other disorders confirmed to cause anaemia due to erythrocyte destruction and/or abnormal hematopoietic function;
- haemoglobin level ≤45 g/L on two or more blood tests, a history of major bleeding within one year, or a history of anaemia corrected by blood transfusion;
- bilateral nephrectomy, kidney transplantation within ≤6 months, or congenital kidney diseases (e.g., polycystic kidney disease);
- hypertrophic obstructive cardiomyopathy or congenital heart disease with right-to-left shunt;
- comorbid malignancy with an investigator-assessed life expectancy of less than 12 months;
- pregnancy or lactation;
- known allergy to the study drug (active ingredient or excipients);
- participation in a drug clinical trial within one year.

This study was approved by the Ethics Committee of Zhongda Hospital Affiliated to Southeast University (Ethics approval number: 2025ZDSYLL380-P01).

Study population

This study retrospectively reviewed the baseline characteristics, changes in relevant parameters, and clinical events during one year of regular Roxadustat treatment in eligible patients.

Using the electronic medical record system and the Jiangsu Provincial Medical Platform, we initially identified all inpatients at Zhongda Hospital Affiliated with Southeast University between January 2022 and December 2023 who were diagnosed

with ("chronic renal insufficiency" OR "chronic kidney disease") AND "anaemia" AND "heart failure." Subsequent screening excluded duplicate entries and patients with incomplete clinical data. Following a review and joint confirmation by two independent investigators to ensure that all inclusion criteria were met and no exclusion criteria applied, and that all patients had received optimal medical therapy for heart failure.

Outcome variables

The primary outcome variables in this study included B-type natriuretic peptide (BNP) levels, NYHA functional classification, and echocardiographic measurements of left ventricular structure and function—specifically, left ventricular ejection fraction (LVEF), left ventricular end-diastolic dimension (LVEDD), interventricular septal thickness (IVS), and left ventricular posterior wall thickness (LVPW). Major Adverse Cardiovascular Events (MACE) and a composite endpoint were also evaluated.

MACE was defined as the occurrence of any of the following: all-cause mortality, hospitalization for unstable angina or coronary revascularization, heart failure rehospitalization, or ischemic stroke.

Statistical analysis

Continuous variables are presented as mean ± standard deviation or median with interquartile range, as appropriate based on their distribution. Comparisons of continuous variables between groups were performed using the t-test, analysis of variance (ANOVA), or the Mann-Whitney U test. Categorical variables are expressed as percentages and were compared using the Chi-square test or the Mann-Whitney U test.

For the analysis of follow-up data within the same group, the paired t-test or the Wilcoxon signed-rank test was applied. To analyse outcomes based on the occurrence of Major Adverse Cardiovascular Events (MACE), patients were dichotomized into two groups (MACE vs. no MACE). Univariable analyses were then conducted to assess differences in baseline characteristics and treatment profiles between these groups.

All statistical analyses were performed at Zhongda Hospital Affiliated with Southeast University. The SPSS statistical software (version 26.0.0, SPSS Inc., an IBM Company), R statistical software (version 4.5.1, R Core Team), and GraphPad Prism (version 10.0.0, GraphPad Software Inc.) were used for data analysis and graph generation. A two-sided P-value of less than 0.05 was considered statistically significant.