CHARACTERIZATION OF PATIENTS PRESCRIBED WITH SACUBITRIL/VALSARTAN IN PORTUGAL: A CROSS-SECTIONAL OBSERVATIONAL STUDY (PRIME STUDY)

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BACKGROUND / OBJECTIVES

- Sacubitril/valsartan reimbursement in Portugal is conditional to a specific subgroup of patients:
  - adult patients with symptomatic chronic heart failure with reduced ejection fraction;
  - left ventricular ejection fraction (LVEF) ≤35%;
  - patients in the functional classes NYHA II and III despite treatment for at least 4 weeks with angiotensin-converting-enzyme inhibitors or angiotensin receptor blocker plus beta-blockers, in combination with other recommended treatments (e.g. diuretics and/or aldosterone antagonists, if tolerated)[1,2].
- The aim of this study was to characterize the sociodemographic, clinical and therapeutic profile of patients being prescribed with sacubitril/valsartan in Portugal.

METHODS

- The PRiMe (sacubitril/valsartan PRescription Monitoring study) is a cross-sectional, multicenter and drug utilization study in Portuguese community pharmacies using primary and secondary data collection.
- All community pharmacies associated with the Portuguese National Association of Pharmacies (~2,500; ~85% of the total universe of pharmacies in Portugal) were invited to participate.
- Adult (≥18 years) patients or caregivers with a prescription (initial or refill) of sacubitril/valsartan, from June 2018 to July 2019, in community pharmacies were invited to participate.
- Individuals who did not give their informed consent or with any cognition impairment were excluded.
- Sociodemographic data, clinical characteristics, healthcare resource utilization and patient-reported outcomes were collected through a structured two-part questionnaire:
  1) The first part delivered by a trained pharmacist
  2) The second part (PRO) filled in by the patient
- Self-assessed NYHA was measured through a previously developed instrument and prior HF medication was filled by the patient with the assistance of a trained pharmacist[3].
- Additional data were collected through the pharmacy's software and patient's echocardiogram report (the last available before sacubitril/valsartan initiation).
- This study was approved by the competent Ethics Committee and is compliant with the General Data Protection Regulation.

RESULTS

- A total of 423 pharmacies participated in the study and, among those, 35.5% recruited at least one patient.
- Setting (urban/sub-urban/rural) distribution of participating pharmacies was similar (p=0.702) to the universe of community pharmacies in Portugal, ensuring national representativeness.
- During the study period, 285 patients were recruited in which 22.8% were recruited through their caregiver.
- The median age of patients was 72.0 years (IQR 63-80) and 65.6% were male.
- Baseline characteristics are presented in Table 1.
- Our results show that 65.6% of patients had NYHA class II or III at sacubitril/valsartan initiation, 75.4% had previous HF treatment and 53.2% had LVEF ≤35% (Figure 1).

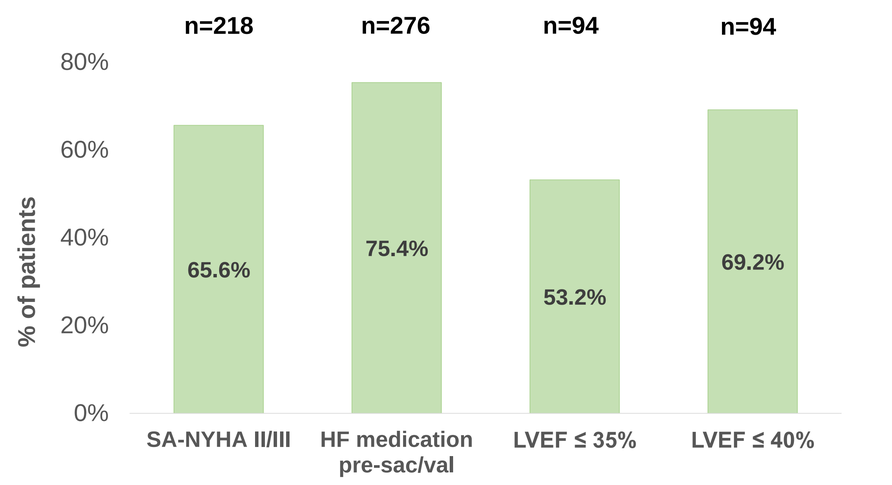
RESULTS (cont.)

Table 1. Baseline features

	Total n=285
Female, n (%)	98 (34.4)
Age, years, median (IQR)	72 (63.0-80.0)
Age classes, years, n (%)	
<65	75 (28.0)
65-74	75 (28.0)
≥75	118 (44.0)
Education level, n (%)	
None	21 (7.6)
Basic education (4 years)	139 (50.2)
Basic education (6 years)	29 (10.5)
Basic education (9 years)	28 (10.1)
Upper secondary education or equivalent (12 years)	35 (12.6)
Bachelor/ University Degree	25 (9.0)
Employment status, n (%)	
Employed	31 (10.9)
Unemployed	13 (4.6)
Retired	232 (81.4)
Other	9 (3.2)
Time since HF diagnosis, years, median (IQR)	5.0 (1.8-11.0)
Co-morbidities, n (%)	
High blood pressure	195 (68.7)
Atrial Fibrillation/flutter	157 (55.3)
High cholesterol	151 (53.2)
Sleep disorders	134 (47.2)
Anxiety	113 (39.8)
Diabetes Mellitus	112 (39.4)
Angina pectoris	44 (15.5)
Stroke	40 (14.1)
Sac/val first prescriber specialty, n (%)	
Cardiology	209 (81.3)
General Practice	25 (9.7)
Internal Medicine	20 (7.8)
Other	3 (1.2)

HF, Heart failure; IQR, interquartile range; SD, standard deviation; Sac/Val, sacubitril/valsartan. Sample size not constant due to missing data in some variables.

Figure 1. Description of predefined reimbursement characteristics



Values presented correspond to patients with available information only.

HF, Heart Failure; LVEF, Left Ventricular Ejection fraction; SA-NYHA, self-assessed New York Heart Association.

LIMITATIONS

- NYHA class was self-assessed by patients through a previous published instrument that showed correlation with some HF outcomes[3]. Additionally, it has also been reported that clinician-assigned NYHA has high intra-observer variability, showing a concordance of only around 55%[4,5].
- The LVEF data was taken from the echocardiogram reports patients had. These reports may not correspond to the one used by the clinician at the time of sacubitril/valsartan first prescription.

CONCLUSIONS

- Our population is similar to other HF populations, excepting the age that is older[6]. Nevertheless, even the older age is in line with other real-world studies with sacubitril/valsartan[7,8].
- Our findings suggest that most of the patients prescribed with sacubitril/valsartan have HFrEF with NYHA II-III and that a great proportion had previous treatment for HF. These characteristics match the defined reimbursement characteristics for sacubitril/valsartan in Portugal.
- Future work needs to focus on improving patient engagement and the exhaustiveness of clinical data in order to enhance the robustness and precision of our data.

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