Resource Utilisation and Healthcare Costs Among Patients With Major Depression And Active Suicidal Ideation With Intent In Italy: Initial Findings From The ARIANNA Observational Substudy

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Carmen Sansone [1], Marina Adami [1], Riccardo Cipelli [2], Andrea Franchi [1], Silvia Maffezzoli [1], Barbara Roncari [3], Dario Delmonte [1]

(1) Janssen-Cilag SpA, Department of Medical Affairs - Neuroscience, Cologno Monzese, Italy. (2) IQVIA Solutions Srl, Milan, Italy. (3) MediNeos Observational Research - an IQVIA company, Modena, Italy.

INTRODUCTION

- Major Depressive Disorder (MDD) with suicidal ideation, intent, or behavior, is a psychiatric emergency. These patients show more severe depressive symptoms, higher patient burden, and greater healthcare resource utilization than those without suicidal thoughts [Pilon et al. *J. Clin. Psychiatry* 2022; *83 (3); 21m14090*; Benson et al. *Neuropsychiatr. Dis. Treat.* 2021;17:111-23].

- Although patients with MDD and active suicidality represent a population with a high unmet medical need [Voelker et al. . *JAffect. Disord. Rep.* 2021; 5:100172; Zhdanava et al. *J. Affect. Disord.* 2022; 303–310], little evidence is currently available both on Healthcare Resource Utilization (HRU) and the economic burden of this condition, especially in Italy.

Primary objective

- To describe a subset of patients from the larger ARIANNA prospective study and to estimate secondary care resource use and associated costs both before and after diagnosis of MDD with active suicidality ideation.

METHODS

Study design

- ARIANNA is an Italian multicentre, non-interventional, prospective cohort study where patients aged 18-74 years old diagnosed with a moderate-to-severe Major Depressive Episode (MDE) and active suicidal ideation with intent were recruited between August 2020 and July 2021 in 24 centers.

- For a subset of 5 centers, primary data collected at investigating sites were deterministically linked at patient level with Claims data from Local Health Units (LHU) at the end of the enrolment period (**Figure 1**).

- The retrospective analysis collected data from the date of enrolment of the patient in the main study (Visit 1) to the prior 3 years; while prospective data allowed to calculate resource use in a follow-up period of 90 days after enrolment (**Figure 1**).

- Eligible patients signed a dedicated Informed Consent Form (ICF) allowing Claims data collection in accordance with Italian requirements. This hybrid study design was approved by Ethics Committees at each institution.

- Claims data included information on HRU and costs of hospitalizations, pharmacological treatment dispensed, Emergency Department (ED) access, outpatient visits, and laboratory tests. Reason for hospitalizations and ED access in Claims data were coded through the International Classification of Diseases (ICD-9) classification.

- Primary data collected at investigating sites during follow-up included hospitalizations, access to EDs, outpatient visits, and laboratory tests.

ACKNOWLEDGMENTS

Figure 1 – ARIANNA Substudy design
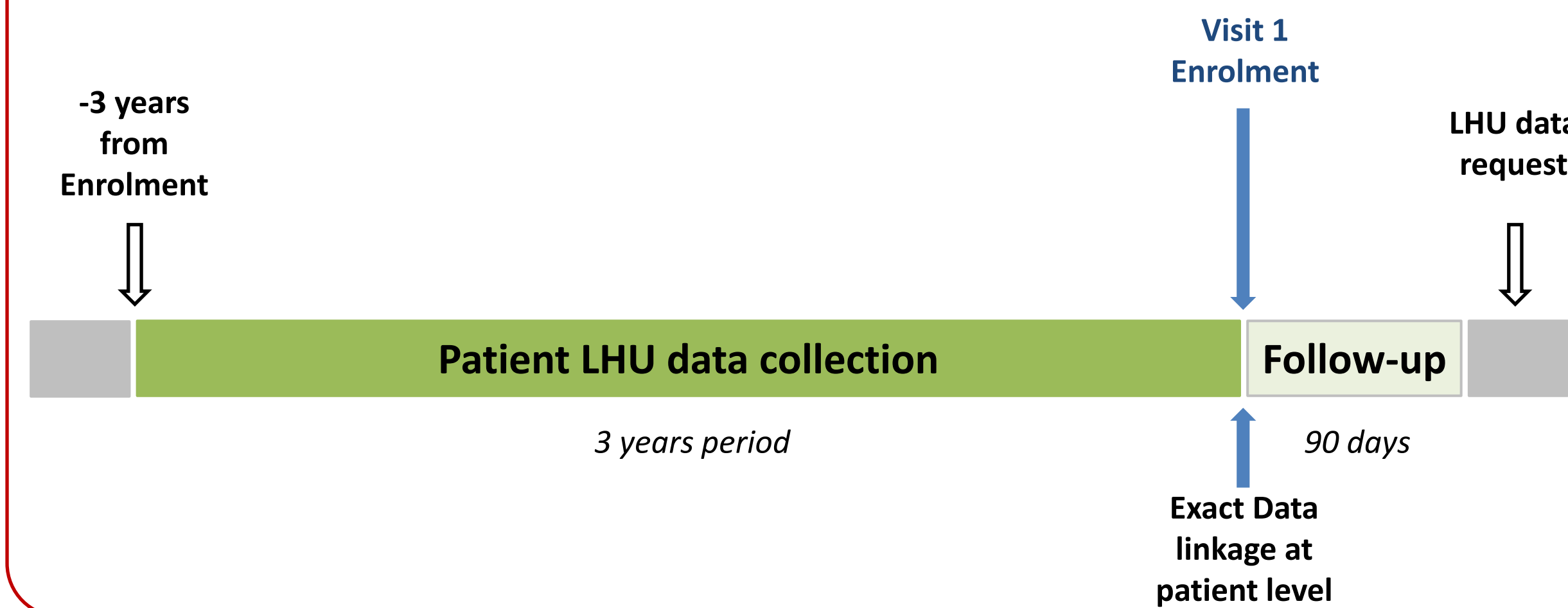
Table 1 – Diagnoses associated with hospitalisation before enrolment

Patients enrolled in the substudy, n	41
Patients with ≥1 hospitalization in the 3 years before enrolment:	
Related to all causes, n (%)	40 (97.6)
Related to Psychiatric Disorders (ICD-9: 290 to 319), n (%)	38 (92.7)
Related to MDD (ICD-9: 296.2; 296.3; 311; 296.9), n (%)	25 (61.0)
Most common diagnoses (ICD-9) associated with hospitalizations:	
Unspecified Personality Disorder (301.9), n (%)	10 (24.4)
Major Depressive Affective Disorder Recurrent Ep. (296.32), n (%)	6 (14.6)
Major Depressive Affective Disorder Recurrent Ep. (296.3), n (%)	4 (9.8)
Major Depressive Affective Disorder Single Episode (296.22), n (%)	4 (9.8)

MDD= Major Depressive Disorder

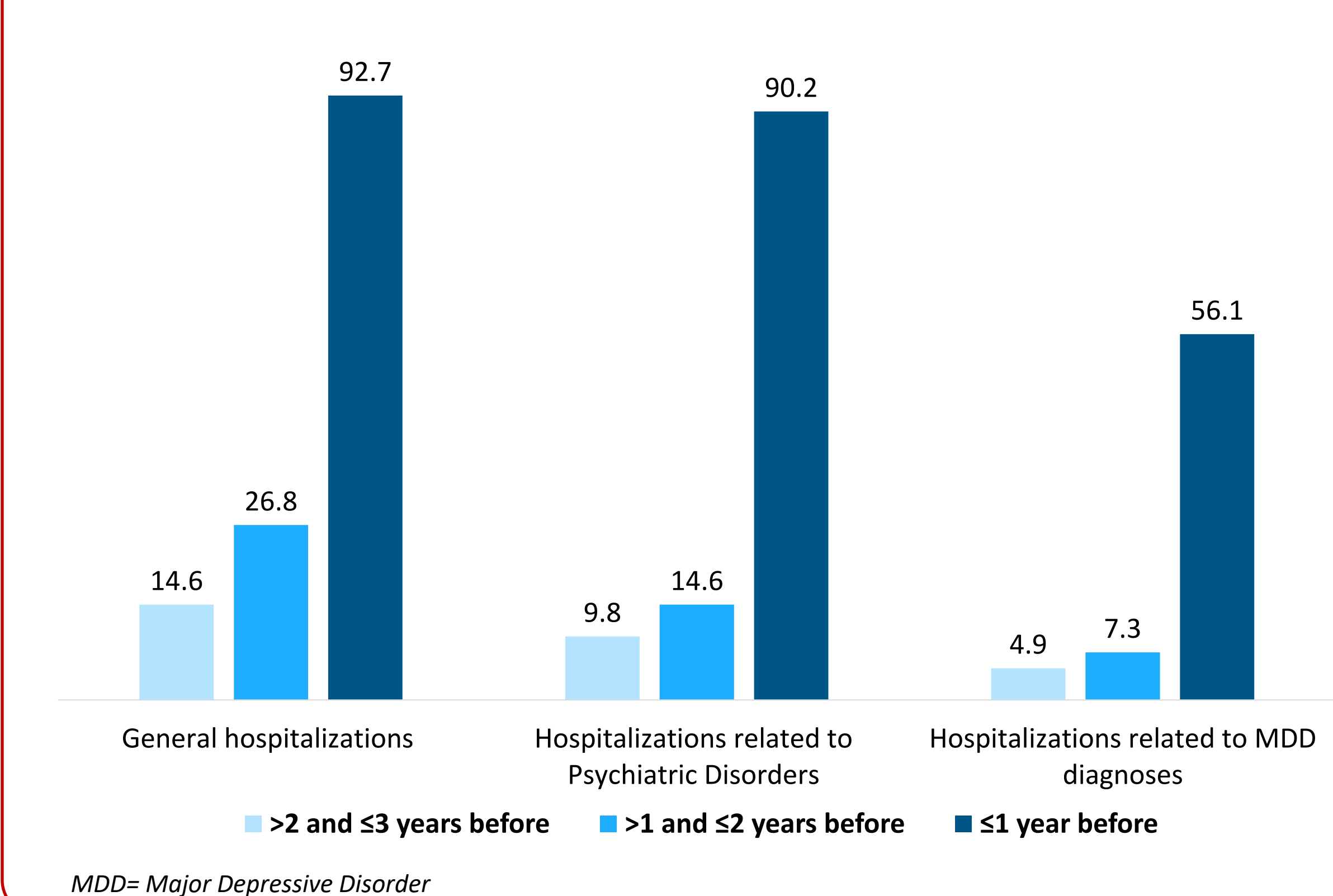### Figure 2 – Patients (%) stratified by year and reason for hospitalization

MDD= Major Depressive Disorder

Figure 3 – Patients (%) treated with ADs, AEDs or AAPs before enrolment

ADs = antidepressants; AEDs = antiepileptics ; AAPs= antipsychotics
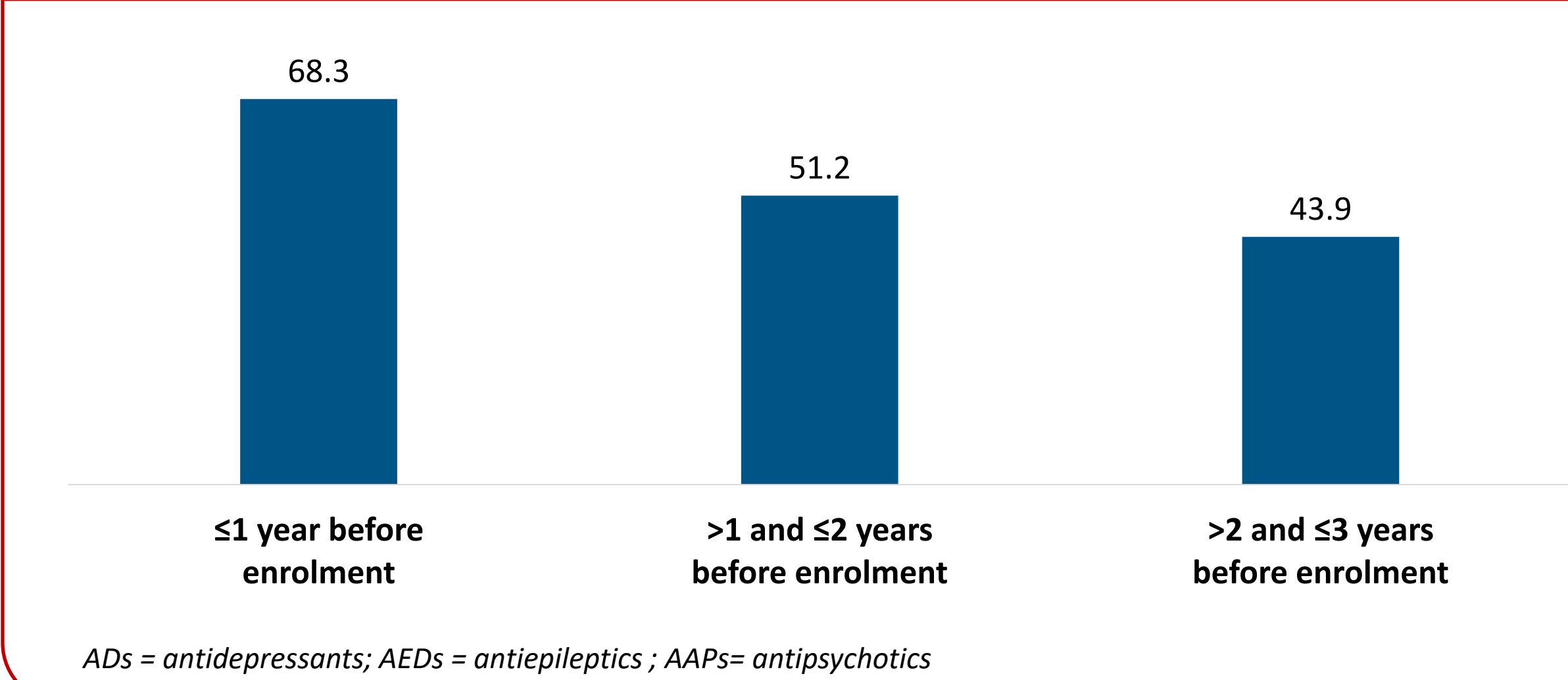
Figure 4 – Mean costs per patient in the period before enrolment

■ ≤1 year before the enrolment ■ >1 and ≤3 years before the enrolment

Mean (SD) costs per patient in the 3 years before enrolment was 6,072 € (5,881 €)
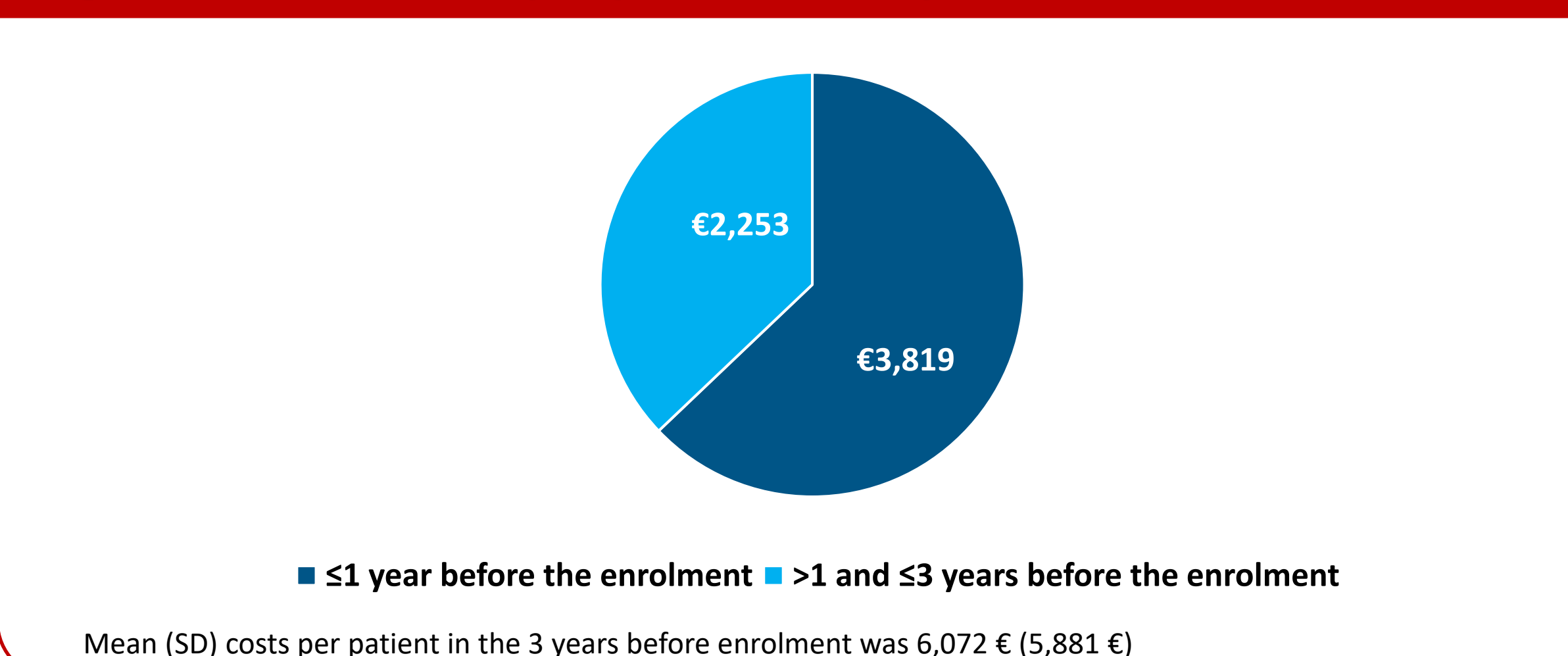
RESULTS

Baseline Characteristics

- Out of 42 enrolled patients who signed the ICF for the substudy, 41 (97.6%) were eligible for analysis and identified in the LHU databases: females were 24 (58.5%); mean age (SD) was 46.8 (16.9) years; the level of education was 'High school or higher' for 24 (58.5%) patients; while the episode of MDD at visit 1 was diagnosed as 'treatment-resistant depression' in 2 (4.9%) cases.

History of Hospitalizations & Comorbidities

- In this cohort, mean (SD) number of admissions to hospital per patient in the 3 years before enrolment was 2.2 (2.6).

- Most patients (n=38, 92.7%) had at least one hospitalization classified with an ICD-9 code for psychiatric disorders (290 to 319) in the same period (**Table 1**). Average (SD) length of stay for these hospitalizations was 16.4 (27.5) days. Unspecified Personality Disorder was the most common diagnosis recorded (**Table 1**).

- As reported in **Figure 2**, most patients were hospitalized in the 12 months leading to study enrolment. However, 26.8% of patients in the cohort were also hospitalized in the period between 12 and 24 months before enrolment.

- During follow-up (90 days), the cohort recorded an additional 24 hospitalizations overall.

Other Healthcare Resource Utilization (HRU)

- Before enrolment, 29 (70.7%) patients received at least 1 dispensation of antidepressant (ADs), antiepileptic (AEDs) or antipsychotic (AAPs) treatment for a combined total of 1084 dispensations in the 3 years period. Results stratified by year are presented in **Figure 3**.

- ED accesses were common in the 3-year period: mean (SD) number per patient was 2.9 (3.2).

Associated Costs

- In addition to resource utilization, we also estimated the costs associated to HRU. Overall, mean (SD) cost per patient was 3,819 € (3,399 €) in the 12 months leading to study enrolment, which accounted for 62.9% of the mean (SD) costs per patient, 6,072 € (5,881 €), calculated over the 3-year period (**Figure 4**).

- During the 90-day follow-up, mean (SD) cost per patient was estimated at 1,264 € (1,290 €) with hospitalizations being the most relevant cost item.

CONCLUSIONS

- **To the best of our knowledge, the ARIANNA study represents the first Italian study to combine primary data collected from investigating sites with secondary administrative Claims data to produce a complete patient profile.**

- **Using multiple data sources, we documented that patient with MDD and suicidal ideation had multiple hospitalizations and accesses to emergency both before and after this diagnosis, quantifying a relevant and increasing economic impact over different period of time**