

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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INTRODUCTION

- Major Depressive Disorder (MDD) with suicidal ideation, intent, or behavior, is a complex, multifaceted psychiatric condition characterized by a variety of symptoms. 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. *J. Affect. Disord. Rep.* 2021, 5:100172; Zhdanova et al. *J. Affect. Disord.* 2022, 303-310] especially because there is no specific approved medication for its treatments, little evidence is currently available both on Healthcare Resource Utilization (HRU) and its economic burden.

Primary objective

- To describe a subset of Italian 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 multicenter observational prospective study involving both a primary data collection and secondary use of data. 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 Aug 2020 and Jul 2021 in 24 centres (**main study**).
- For a subset of 5 centres (**substudy**), 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**).
- Eligible patients signed a dedicated Informed Consent Form (ICF) for the substudy. This hybrid study design was approved by Ethics Committees at each institution.
- Primary data collection allowed to calculate HRU from the date of enrolment of the patient (Visit 1) until 90 days after enrolment (Follow-up) for both main study and substudy patients; while retrospective Claims data allowed to calculate HRU and costs in the 3 years prior to Visit 1 (**Figure 1**) in the substudy. Retrospective analysis did not consider HRU and costs associated to Visit 1.

Costs calculations

- Costs were associated to HRU primary data collected during follow-up through standardized costs and literature references [Mattoni, *Min. Salute* 2007, 23; Remunerazione prestazioni di assistenza ospedaliera [...] *Gazz. Ufficiale* 2013, 23; Accordo interregionale per la compensazione della mobilità sanitaria *Conferenza Stato Regioni* 2020].
- Claims data included information on costs of hospitalizations, drug treatments, Emergency Department (ED) access, and outpatient visits related to psychiatric disorders.

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Figure 1 – ARIANNA Substudy design

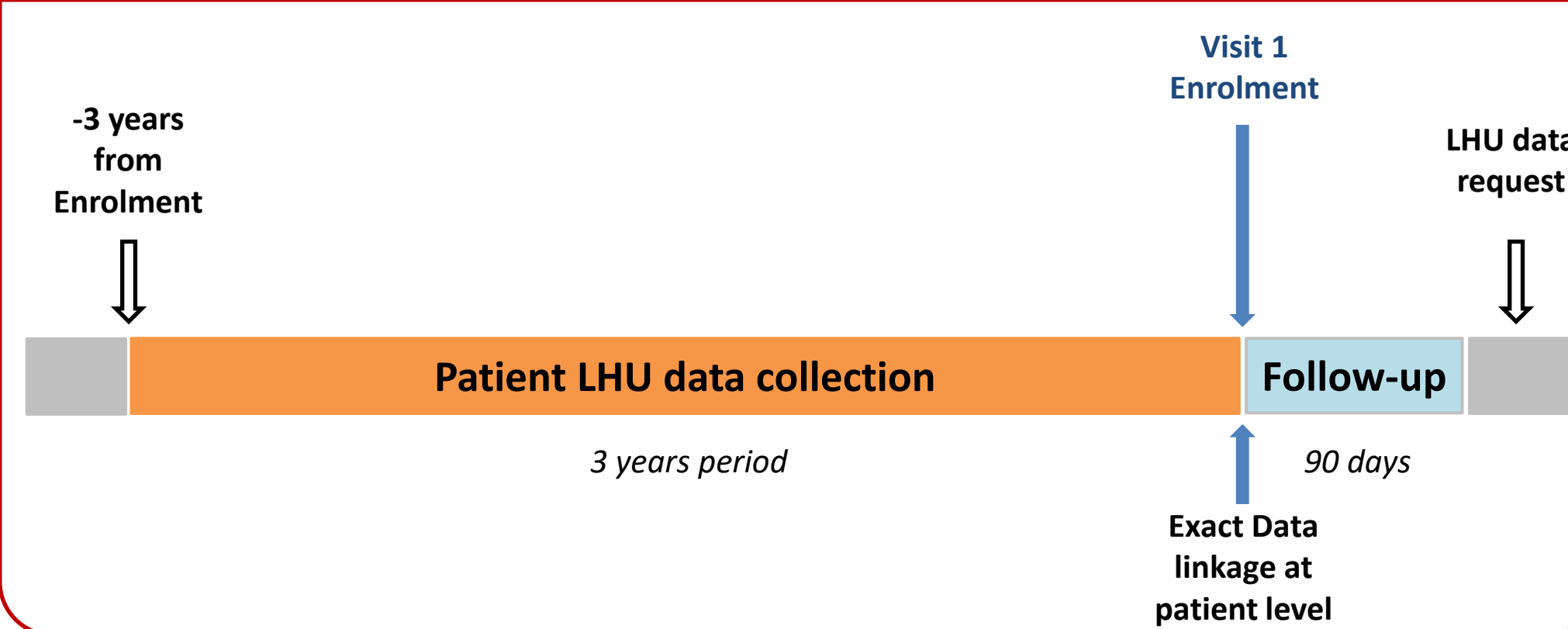


Figure 2 – Mean costs per patient over the entire study period

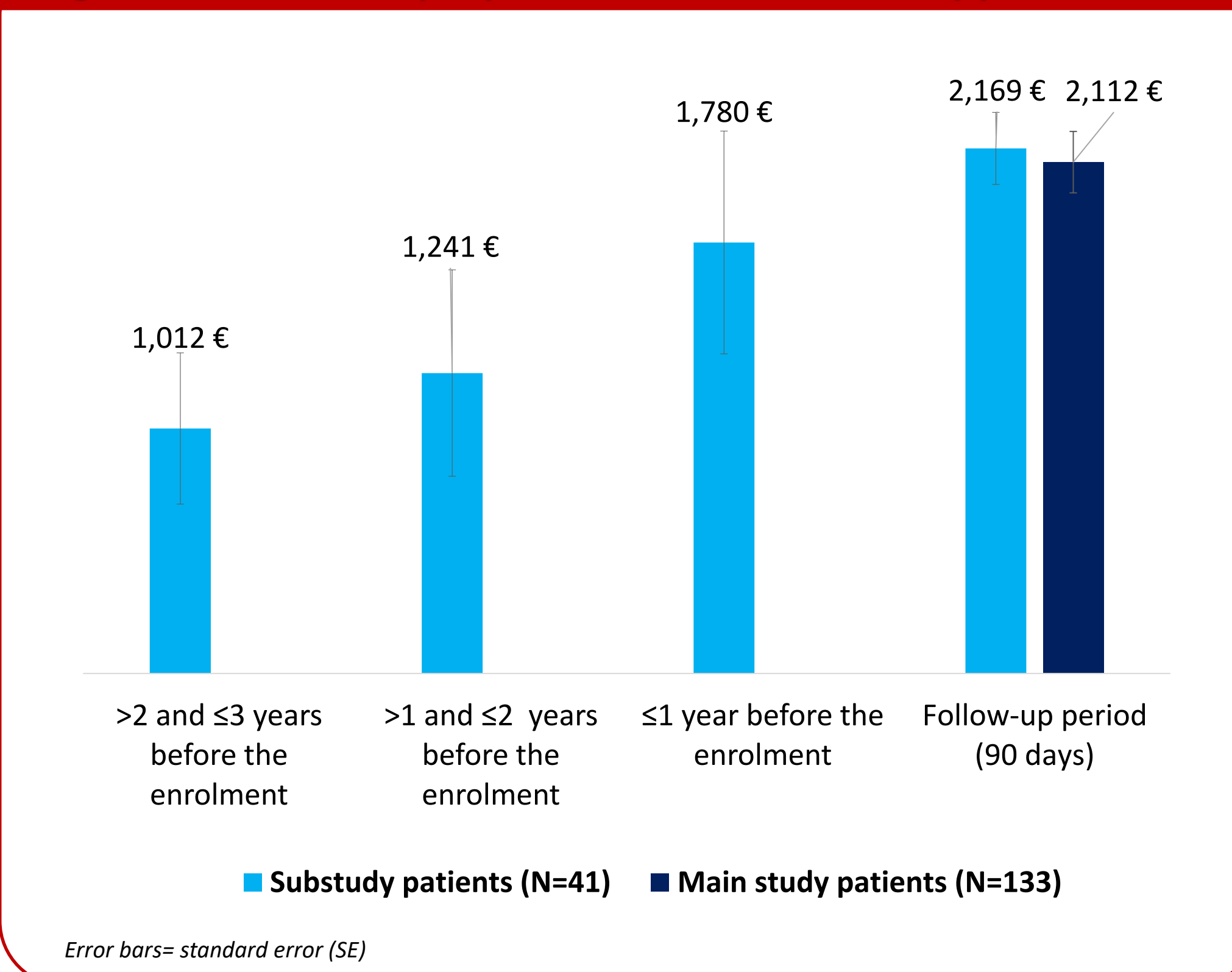


Figure 3 – Mean costs per patient in the period before enrolment

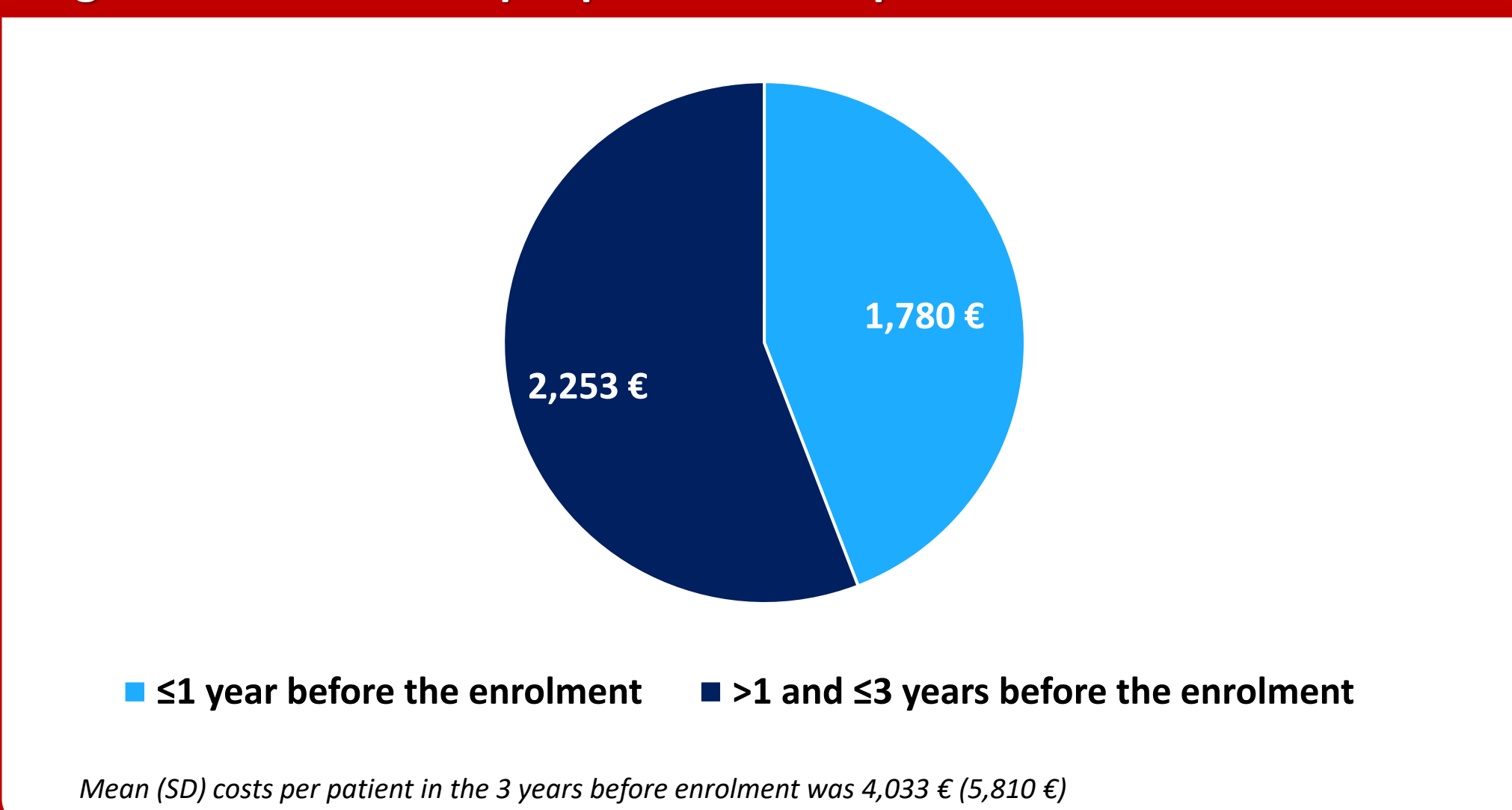
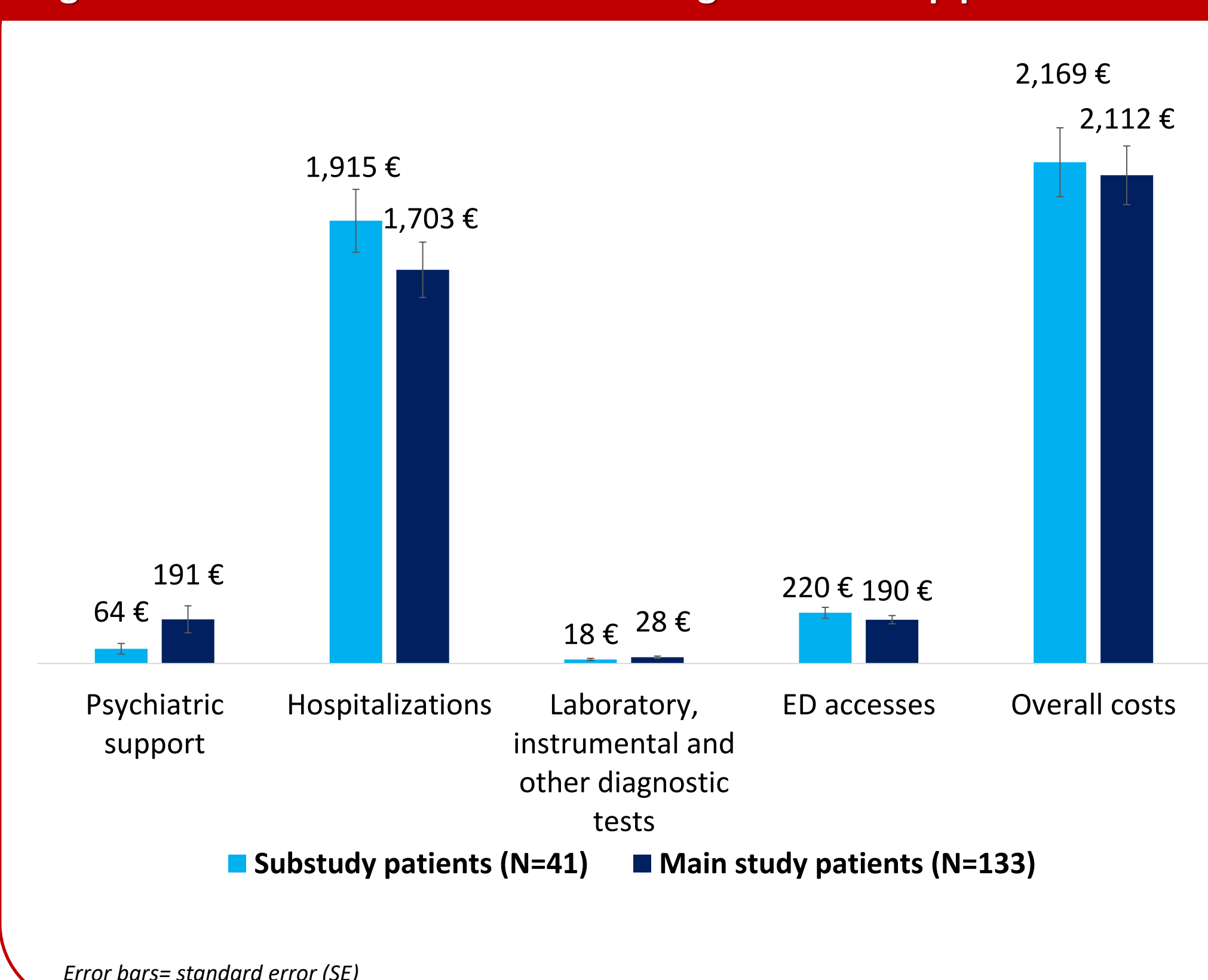


Figure 4 – Healthcare related costs during the follow-up period



RESULTS

Baseline Characteristics

- Out of the 133 eligible patients, a higher proportion of subjects were female (68.4%) than male; with a median (25th-75th percentile) age of 47.0 (29-56 years) years. The level of education was 'High school or higher' for 81 (61%) patients.
- 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.

Healthcare Costs – Before enrolment

- Considering the 3 years period before enrolment (**Figure 2**), there was an increasing trend in the mean cost per patient during the retrospective period leading to Visit 1. A higher average cost per patient was recorded in the year before Visit 1: mean (SD) was 1,708 € (2,947 €). On the other hand, in the second and third year before enrolment, patients included in the substudy recorded less health care costs related to psychiatric disorders. In particular, a mean (SD) cost per patient of 1,012 € (2,001 €) was recorded in the third year (**Figure 2**).
- Overall, the mean cost per patient in the 12 months leading to study enrolment accounted for 44.1% of the mean (SD) costs per patient, 4,033 € (5,810 €), calculated over the 3-year period (**Figure 3**).

Healthcare Costs – Follow-up period

- In the substudy cohort, the increasing trend that was seen before enrolment was confirmed when considering also the follow-up period of 90 days (**Figure 2**).
- In addition, healthcare costs were similar when measured in the substudy (N=41) and the main study cohorts (N=133): mean (SD) cost per patients were 2,169 € (953 €) and 2,112 € (1,461 €), respectively (**Figure 2 and 4**).
- When we analysed the single cost items (**Figure 4**), Hospital Admissions were the most relevant factor influencing overall costs during follow-up. No particular difference emerged between the single cost items when measured in the substudy or main study cohorts (**Figure 4**).

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 recorded multiple HRU both before and after the diagnosis, quantifying a relevant and increasing economic impact over different period of time.
- Considering the lapse of time before the suicidal ideation, it resulted that costs tended to increase as time elapsed.

DISCLOSURES

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