

# An innovative real world data linkage approach to evaluate the disease burden of Hidradenitis Suppurativa (HS) in Italy: initial findings from the HIDRAS Study

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## Background

Hidradenitis Suppurativa (HS) is an uncommon, but not rare, chronic inflammatory disease of the skin that causes recurrent and painful nodules, boils, abscesses, and skin lesions that occur predominantly in the axillary, inguinal, and anogenital regions<sup>1</sup>. Due to the variable signs and symptoms exhibited by patients, it remains largely unrecognized and difficult to treat, resulting in a significant diagnostic delay<sup>2</sup> and inconsistent treatment process<sup>3</sup>.

## Objective

The aim of the present study was to describe a cohort of patients with HS in terms of clinical burden of disease, Healthcare Resource Utilization (HRU) and associated direct and indirect costs.

## Methods

This was an Italian, multicenter, retrospective, cross-sectional observational study that involved adult patients with HS enrolled from September 2022 to September 2023 in four dermatology centers. In particular, this was a hybrid study, a composite design successfully implemented in previous studies<sup>4,5</sup> based on the combination of multiple data sources, where patient-level data from both primary and secondary data collection were used. Primary data collection was performed during the enrollment visit and consisted in the acquisition of demographic and medical information available for each patient, the completion of a Patient Reported Outcome (PRO) for patients' Quality of Life (QoL) assessment, namely Dermatology Life Quality Index (DLQI) questionnaire, and the conduction of a structured interview aimed at investigating out-of-pocket and indirect costs of HS during the previous 12 months. Data gathered at enrollment were then integrated with existing claims data covering the 36-month period before enrollment extracted from Local Health Units (LHUs) databases, which provided information on resource consumption due to HS and associated direct costs covered by the Italian NHS (Figure 1). Claims data are collected by LHUs for accounting and healthcare reimbursement purposes and they include all the following data: hospitalizations, outpatient visits (procedures and exams), emergency department, flow of drugs from pharmacies in the area, flow of drugs from hospitals in the area and database of patients' demographics. The integration of the different data sources was carried out through exact patient linkage: the usage of unique ID codes collected at enrollment visit allowed to identify HS patients involved in the study in the LHUs administrative databases related to the site where they were enrolled and extract all information on HRU and costs associated to them. The implementation of this innovative integrated approach allowed to provide a multifaceted overview of the HS population in Italy: specifically, primary data collection allowed to correctly identify HS patients and define a full clinical profile of HS patients otherwise difficult to obtain, while secondary data from administrative databases enabled to gather multiple and critical information on the economic burden of HS.

## Results

Out of 50 patients enrolled in the study, 48 were eligible: mean (SD) age at enrolment was 35.1 (14.7) years, 28 (58.3%) were males, while 27 (56.3%) patients had moderate or severe HS based on Hurley system (Figure 2). The median (25th – 75th percentiles) duration of HS at enrollment since first diagnosis was 4.7 (2.6 – 8.5) years. In terms of QoL, HS had a moderate to extreme impact for two-thirds of the patients (n=32, 66.7%) (Figure 3), with median DLQI total score equal to 8. Patients with moderate/severe HS were particularly impacted, with nearly half of them reporting very or extremely large effect of the disease on their QoL (n=13, 48.1%) (Figure 3). The overall mean (SD) direct costs for HS per patient in the 12 months preceding enrolment were 2,194€ (3,650€), including both direct costs covered by NHS and those sustained by the patient. Pharmacological treatments were the main contributor to direct costs covered by NHS with a mean (SD) cost per patient of 1,582€ (3,045€), while outpatient visits accounted for the remainder (Table 1). Similarly, patients incurred in many out-of-pocket expenses mainly related to the purchase of medicines, resulting in a mean (SD) cost of 307€ (521€) per patient (Table 1). As for indirect burden of HS related to productivity loss, the mean (SD) cost per patient in the 12 months preceding enrollment was 1,490€ (4,068€), whereas it was 2,435€ (5,223€) in those with moderate/severe HS (Figure 4).

## Conclusions

**This first Italian hybrid study in dermatology provided a comprehensive evaluation of the burden of HS both from a psychosocial and economic perspective, which was not available at Italian level until now. These results highlight the impact of the severity of the disease on patients' well-being and costs, underlying that there are still significant unmet needs in the management of HS. Further research on current HS treatment is warranted.**

### REFERENCES

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Figure 1. HIDRAS Study design

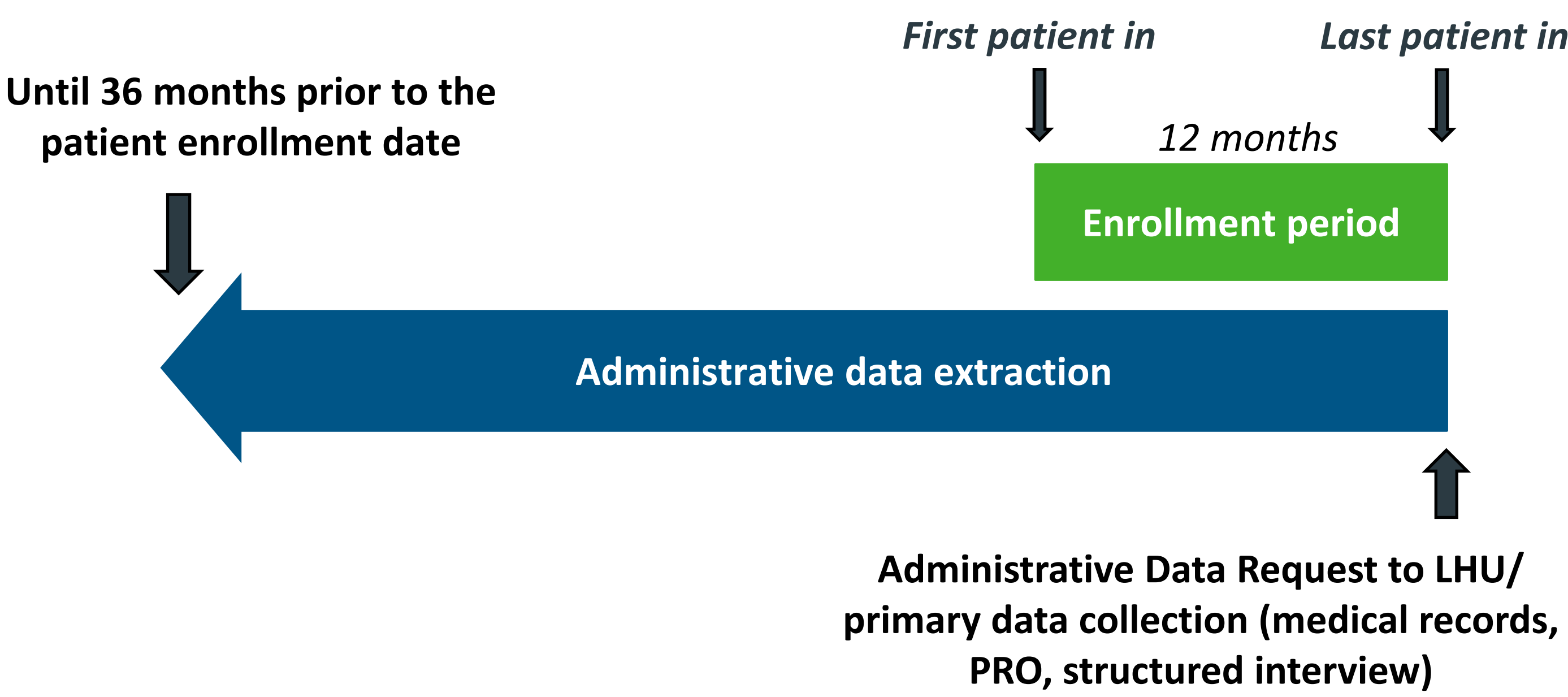


Figure 2. Proportion of patients based on HS severity recorded at enrollment

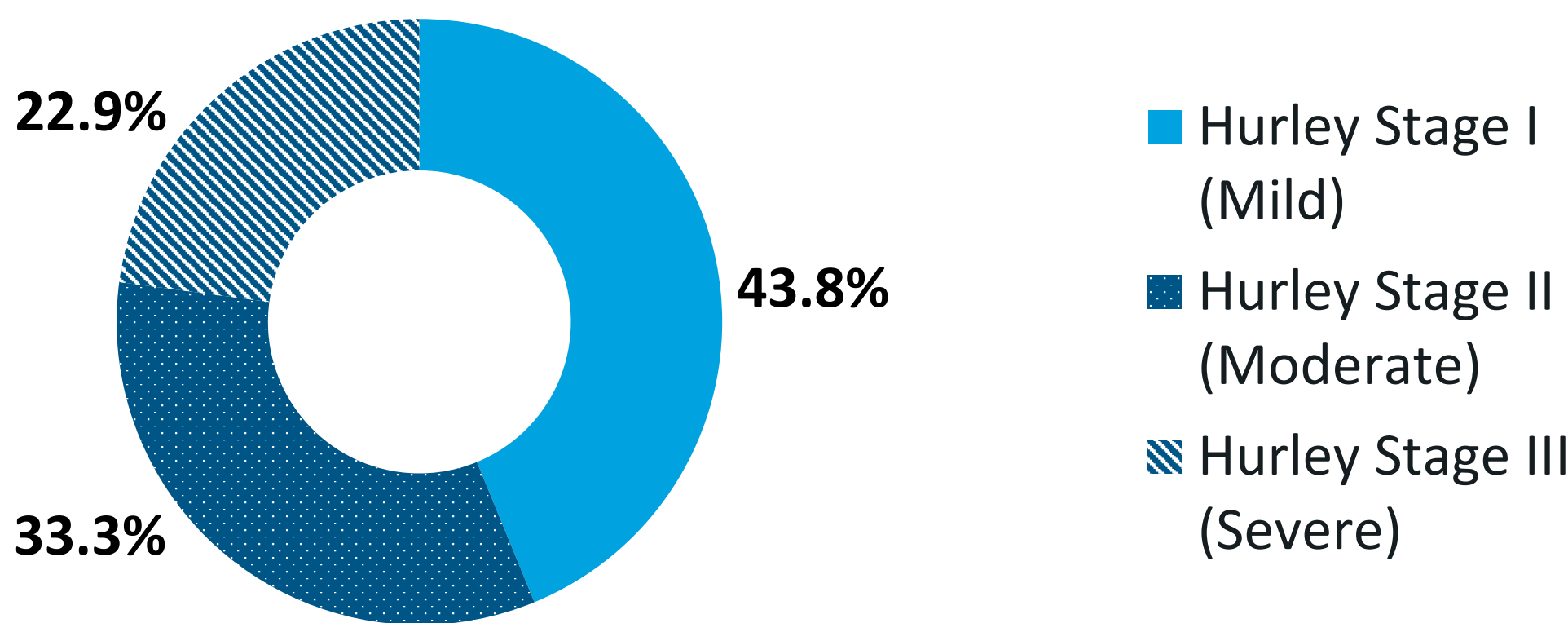


Figure 3. Distribution of patients according to DLQI total score classes by HS severity

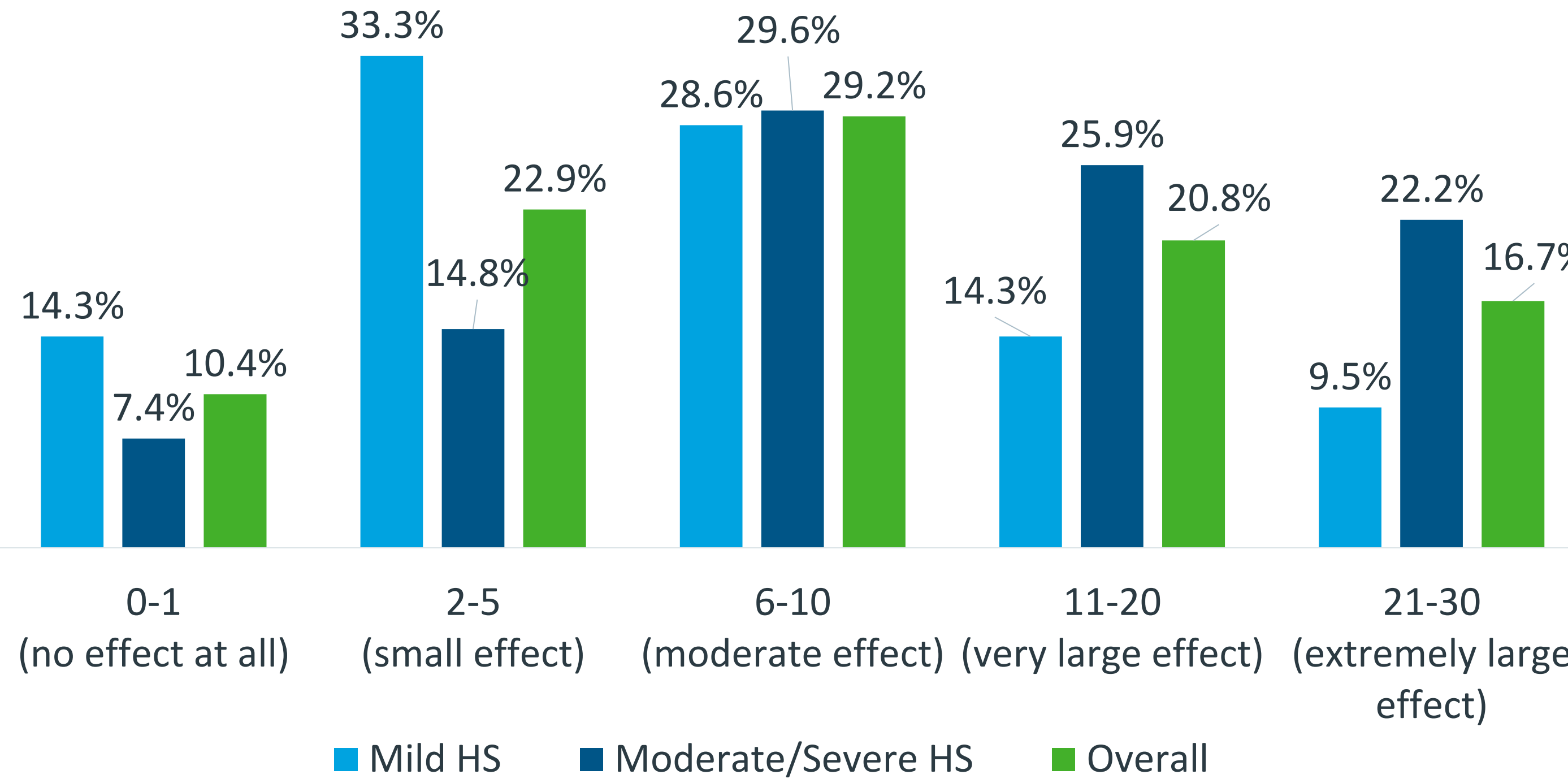


Table 1. Direct costs of HS in the 12-month period prior to enrollment by HS severity

	Mild HS (n=21)	Moderate-Severe HS (n=27)	All patients (n=48)
Direct costs covered by NHS, mean (SD)			
Pharmacological treatments related to HS	816€ (1,639€)	2,178€ (3,722€)	1,582€ (3,045€)
Specialist visits and diagnostic tests	55€ (89€)	36€ (44€)	44€ (67€)
Overall costs	873€ (1,634€)	2,214€ (3,725€)	1,627€ (3,044€)
Direct costs not covered by NHS, mean (SD)			
HS treatments*	276€ (686€)	327€ (388€)	307€ (521€)

\*excluding HS supplements, surgical interventions and psychological support

Figure 4. Mean indirect costs of HS by HS severity

