

Hypertrophic Cardiomyopathy (HCM)

Demographics of patients and societal burden of obstructive hypertrophic cardiomyopathy: Results from a real-world survey in Italy and Spain

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Background and objectives

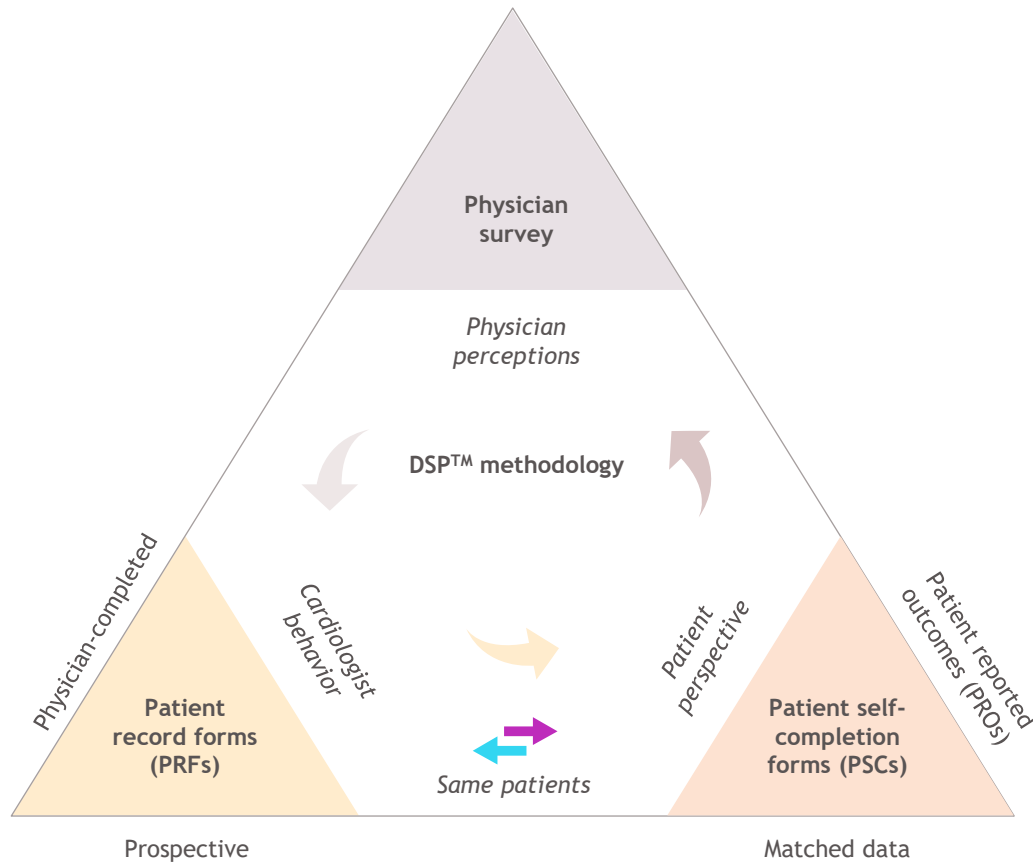
Background:

- Obstructive hypertrophic cardiomyopathy (HCM) is a chronic, progressive condition, characterized by hypercontractility, hypertrophy and left ventricular outflow tract obstruction.
- Symptom burden can be significant and may include shortness of breath, fatigue, arrhythmias, chest pain, and syncope
- The prevalence of diagnosed obstructive HCM in the UK is estimated at 2.84 per 10,000¹
- There is a paucity of data exploring patients' perspectives on the symptoms and day-to-day limitations they experience as a result of obstructive HCM.² A better understanding of the factors that contribute to poor outcomes and the life-long disease burden is needed

Objective:

- To describe the clinical characteristics, burden of illness, productivity, and caregiver support needs of patients with symptomatic obstructive HCM in Italy and Spain

Disease Specific Programme (DSP)TM Methodology



Data were drawn from the Adelphi Real World HCM Disease Specific Programme (DSP)TM, a real-world, cross-sectional survey with retrospective data collection comprising:

1. An online physician-completed patient record form (PRF), reporting data on patient demographics, disease severity, treatment and financial/societal burden.
2. A pencil and paper patient self-completion form (PSC), in which patients for whom physicians had completed a PRF were asked to voluntarily complete a survey capturing work productivity, work/activity impairment and patient need for assistance

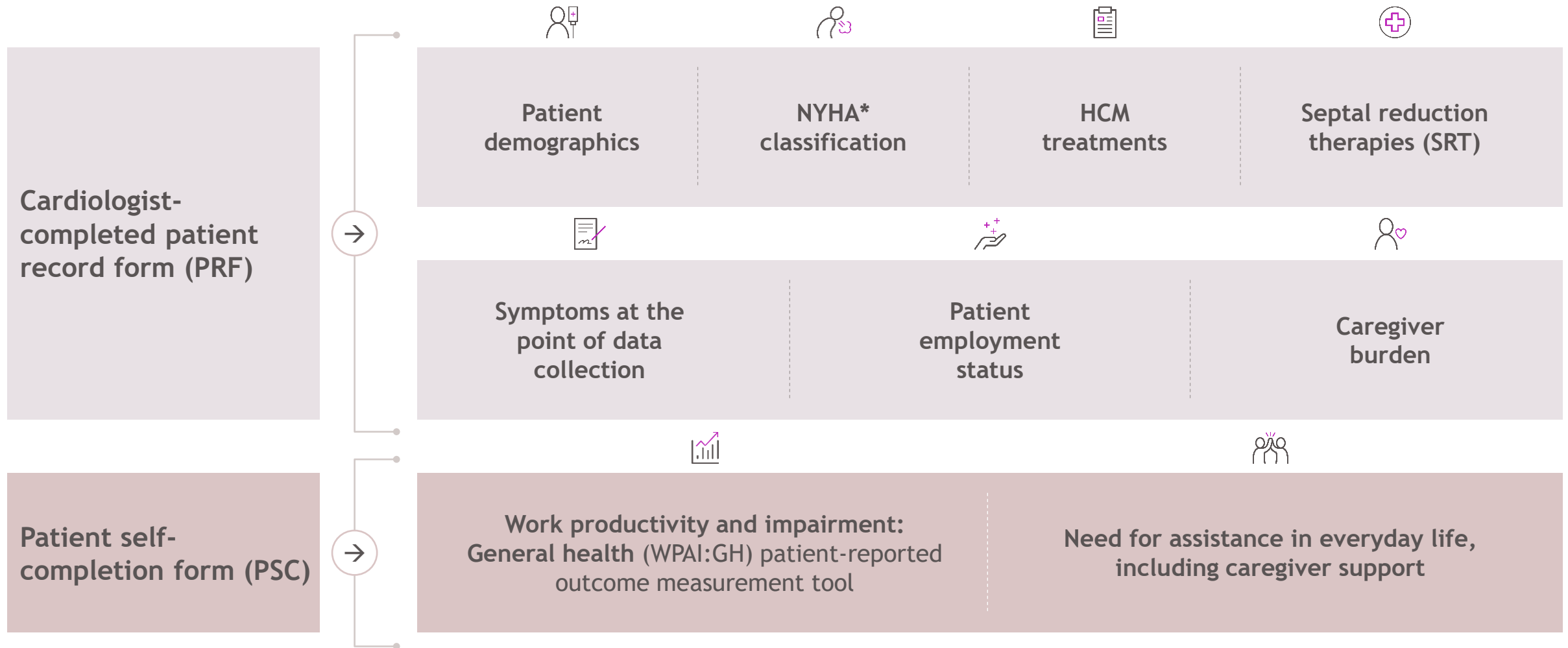
The DSP methodology has been previously published and validated (Anderson et al, 2008)¹⁻³

Methods: Inclusion criteria, data collection and analyses

- **Cardiologists were eligible** for inclusion if they were responsible for the treatment and management of a minimum of 5 patients with HCM per month
- **Patients were eligible** for inclusion if they were over the age of 18 years, had a physician-confirmed diagnosis of obstructive HCM and were symptomatic (minimum New York Heart Association (NYHA) Class II) at the time of enrollment
- Data were collected in line with a pre-specified protocol where:
 - Cardiologists were identified by local fieldwork agents using physician panels and publicly available lists
 - A **geographically diverse** sample was recruited across Spain and Italy
 - Cardiologists provided data for up to **10 consecutively consulting patients**
 - All data were **de-identified and anonymized** before receipt by Adelphi Real World
 - All data collection materials were developed in English and translated into the local language, where applicable
- **Analyses were descriptive** and completed using UNICOM Intelligence Reporter v7.5¹

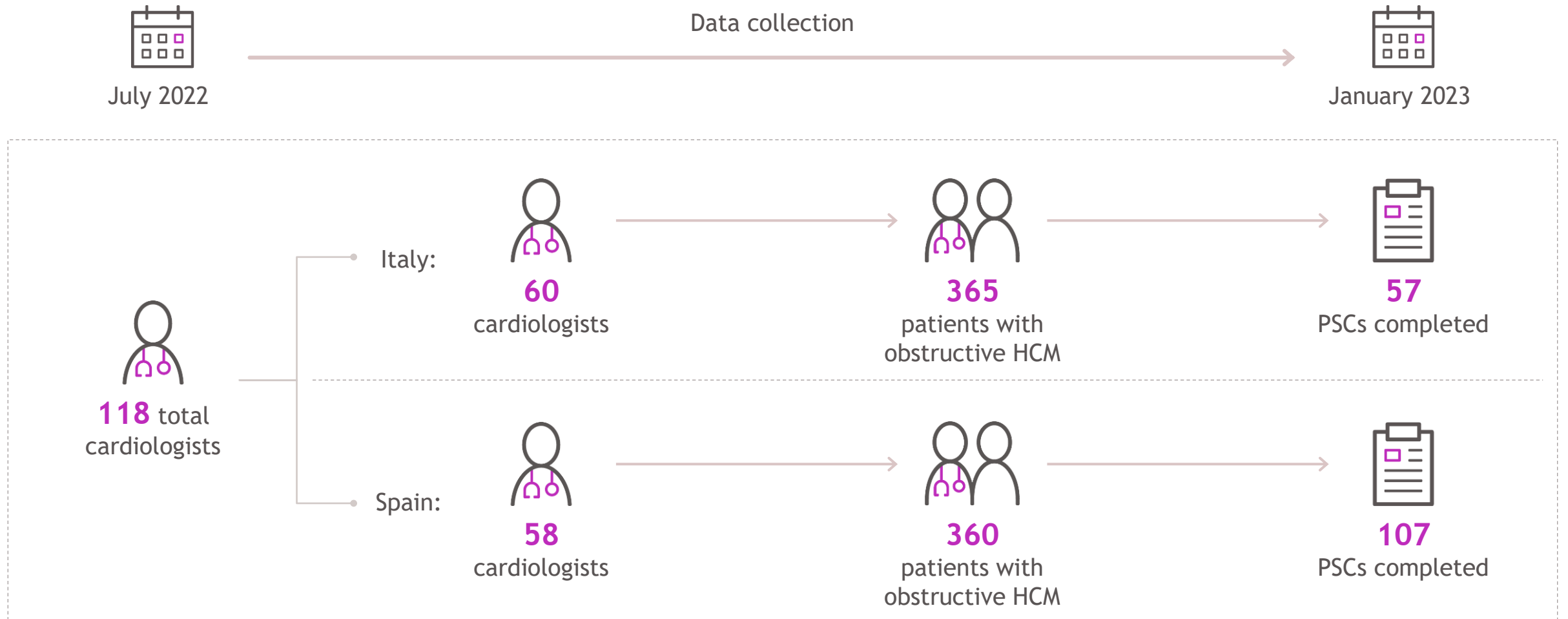


Methods: Data collected in PRF and PSC forms



*NYHA is a clinician-rated classification system widely used to categorize an individual according to the severity of symptoms while performing physical activity; worse symptoms are indicated by higher NYHA classes
HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association; PRF, patient record form; PRO, patient-reported outcome; PSC, patient self-completion form; SRT, surgical reduction therapy

Included Participants



Demographics and clinical characteristics of obstructive HCM patients

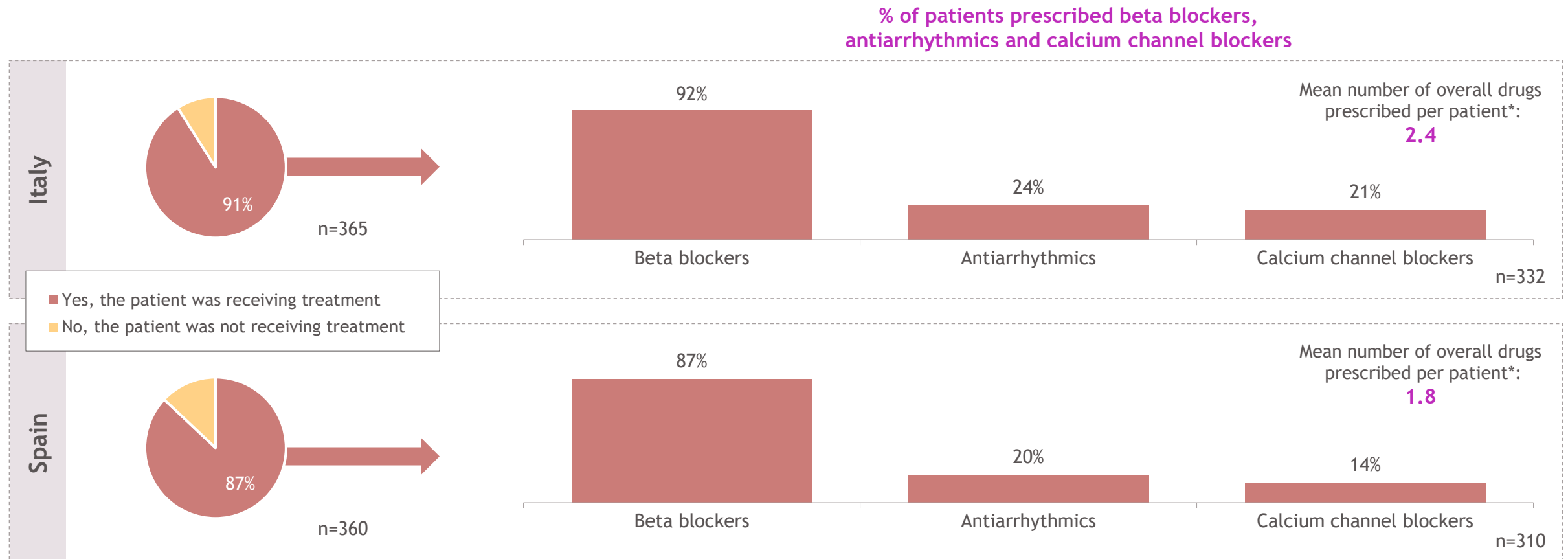
	Italy	Spain
n	365	360
Age, years [SD]	55.7 [13.0]	58.2 [15.9]
Sex, n (%)		
Male	240 (65.8)	217 (60.3)
Female	125 (34.2)	143 (39.7)
BMI, kg/m ² mean [SD]	25.8 [3.6]	27.7 [4.3]
Time since Diagnosis, years, mean [SD]	2.4 [3.3]	3.6 [4.5]
NYHA class*, n (%)		
NYHA II	277 (75.9)	317 (88.1)
NYHA III	80 (21.9)	42 (11.7)
NYHA IV	8 (2.2)	1 (0.3)

*At point of data collection

BMI, body mass index; HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association; SD, standard deviation

Current treatment prescribed for obstructive HCM

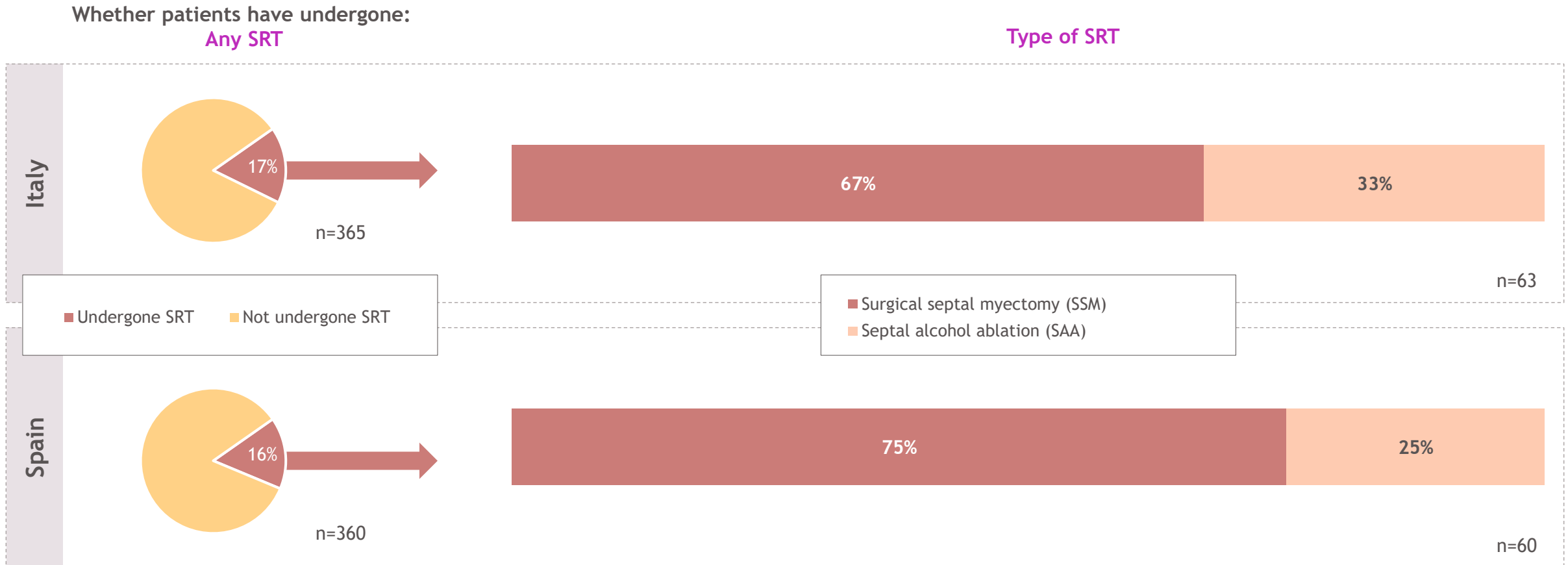
The majority of patients were prescribed beta blockers, usually in combination with another drug class



*At point of data collection
HCM, hypertrophic cardiomyopathy

Previous septal reduction therapy

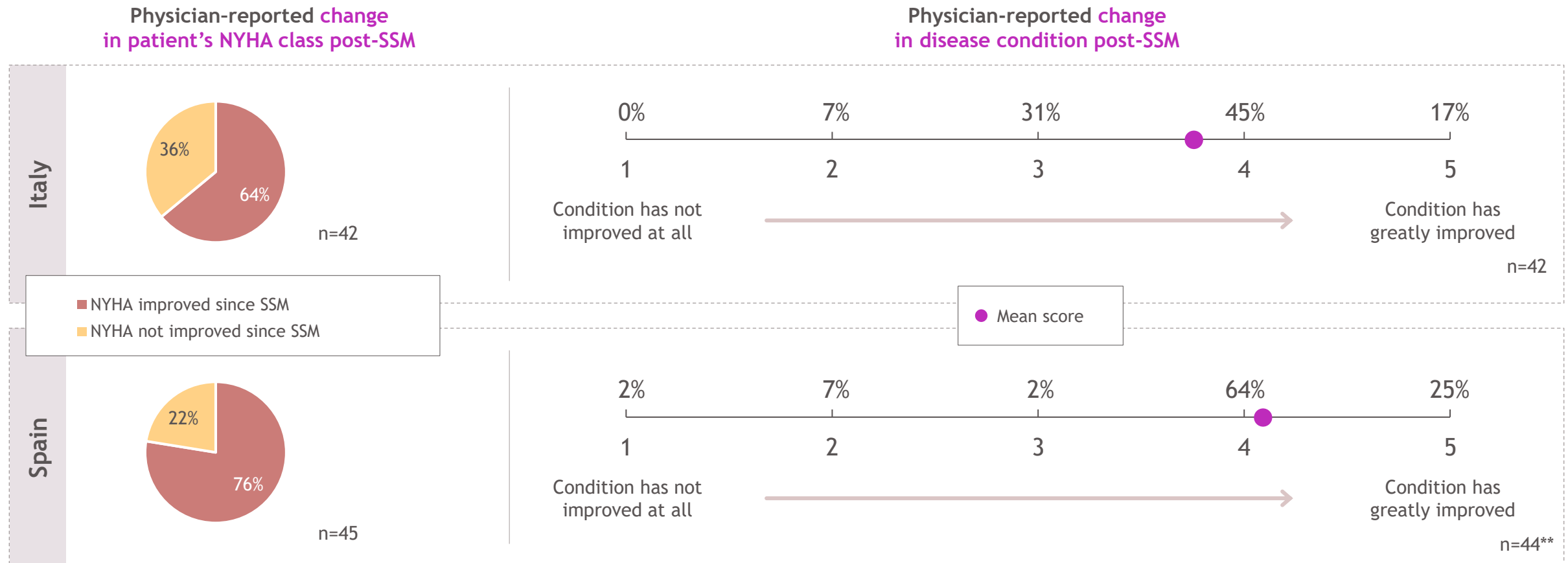
Less than a fifth of patients in both Italy and Spain had undergone SRT, with the majority undergoing septal myectomy



Note: Septal reduction therapies (SRT) are performed to relieve obstruction in the heart and improve the symptoms of obstructive HCM. There are two types of SRTs- surgical septal myectomy (SSM) and septal alcohol ablation (SAA). SAA, septal alcohol ablation; SRT, septal reduction therapy; SSM, surgical septal myectomy

Change in condition following surgical septal myectomy

Physicians reported that following Surgical Septal Myectomy over two thirds of patients in Italy, and three quarters in Spain, had an improvement in their NYHA classification



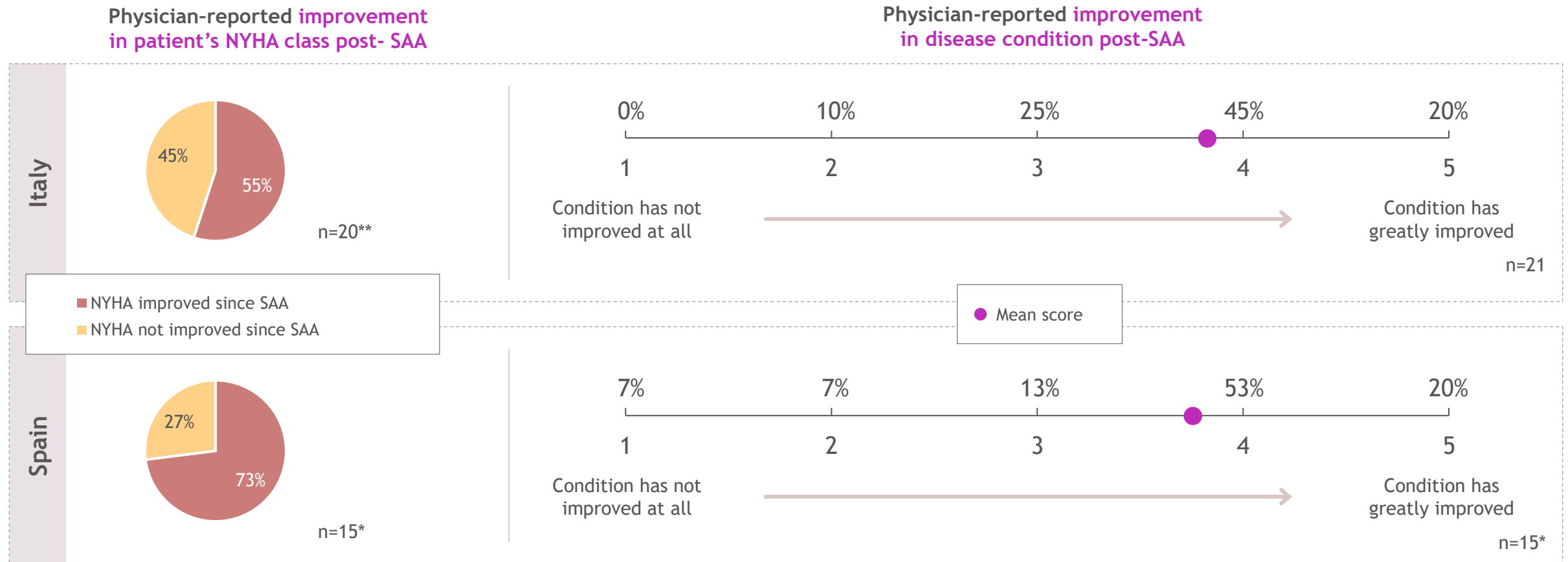
- Mean (SD) time since SSM from point of data collection was 2.3 (2.4) years in Italy (n=34) and 3.2 (3.1) years in Spain (n=41)

*Low sample size **Don't know responses were excluded

NYHA, New York Heart Association; SAA, septal alcohol ablation; SD, standard deviation; SRT, septal reduction therapy; SSM, surgical septal myectomy

Change in condition following septal alcohol ablation

Physicians reported that following Septal Alcohol Ablation just over half of patients in Italy, and under a three quarters in Spain had an improvement in their NYHA classification



- Mean (SD) time since SAA from point of data collection was 1.9 (1.3) years in Italy (n=17*) and 2.7 (3.2) years in Spain (n=14*)

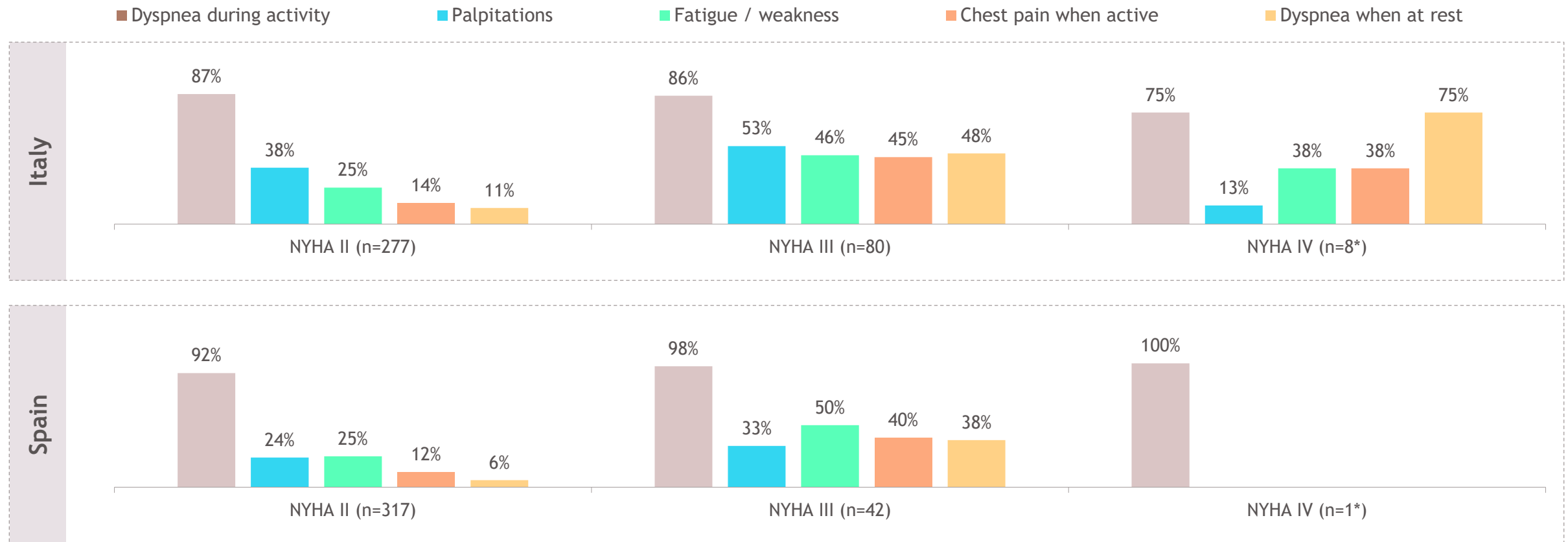
*Low sample size **Don't know responses were excluded

NYHA, New York Heart Association; SRT, septal reduction therapy; SSM, surgical septal myectomy; SAA, septal alcohol ablation

Symptomatic burden by NYHA

Dyspnea during activity was the most commonly reported symptom present at the time of data collection, followed by palpitations and fatigue

Percentage of patients with obstructive HCM which experienced the following symptoms:

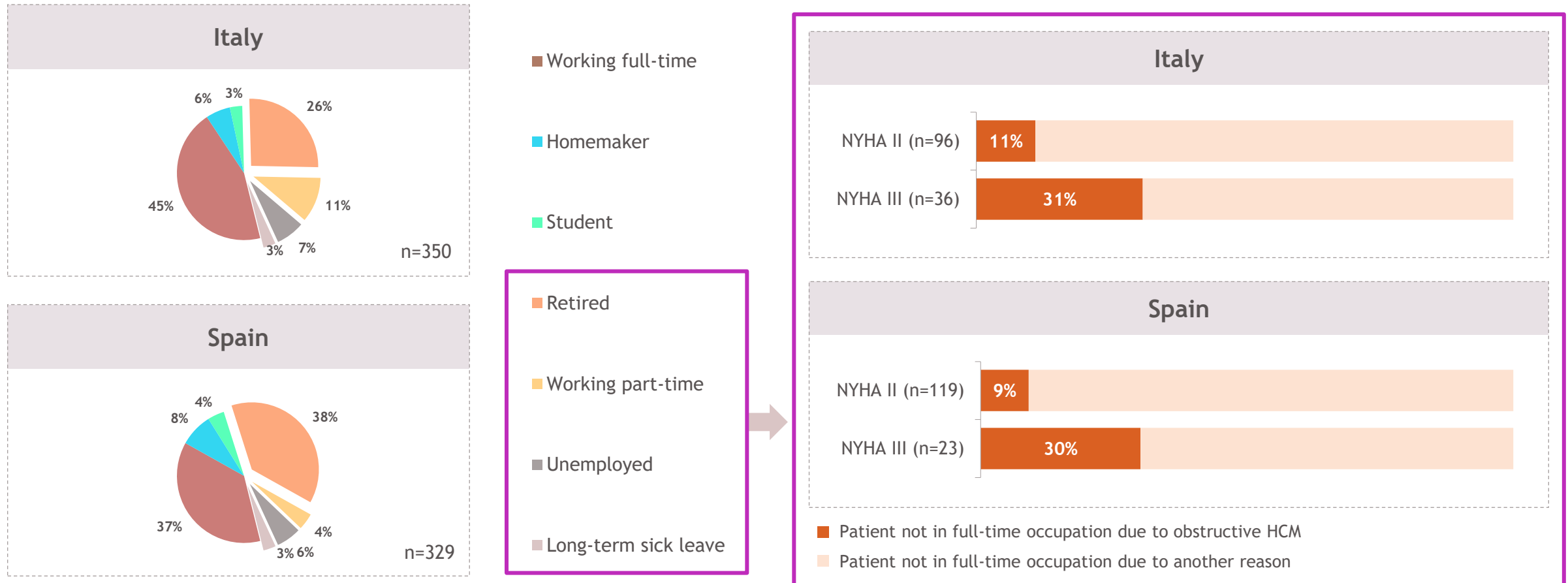


*Low sample size

HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association

Impact of obstructive HCM on employment

In Italy and Spain respectively, 11% and 9% of NYHA II patients, and 31% and 30% of NYHA III patients were not in a full-time occupation due to their obstructive HCM



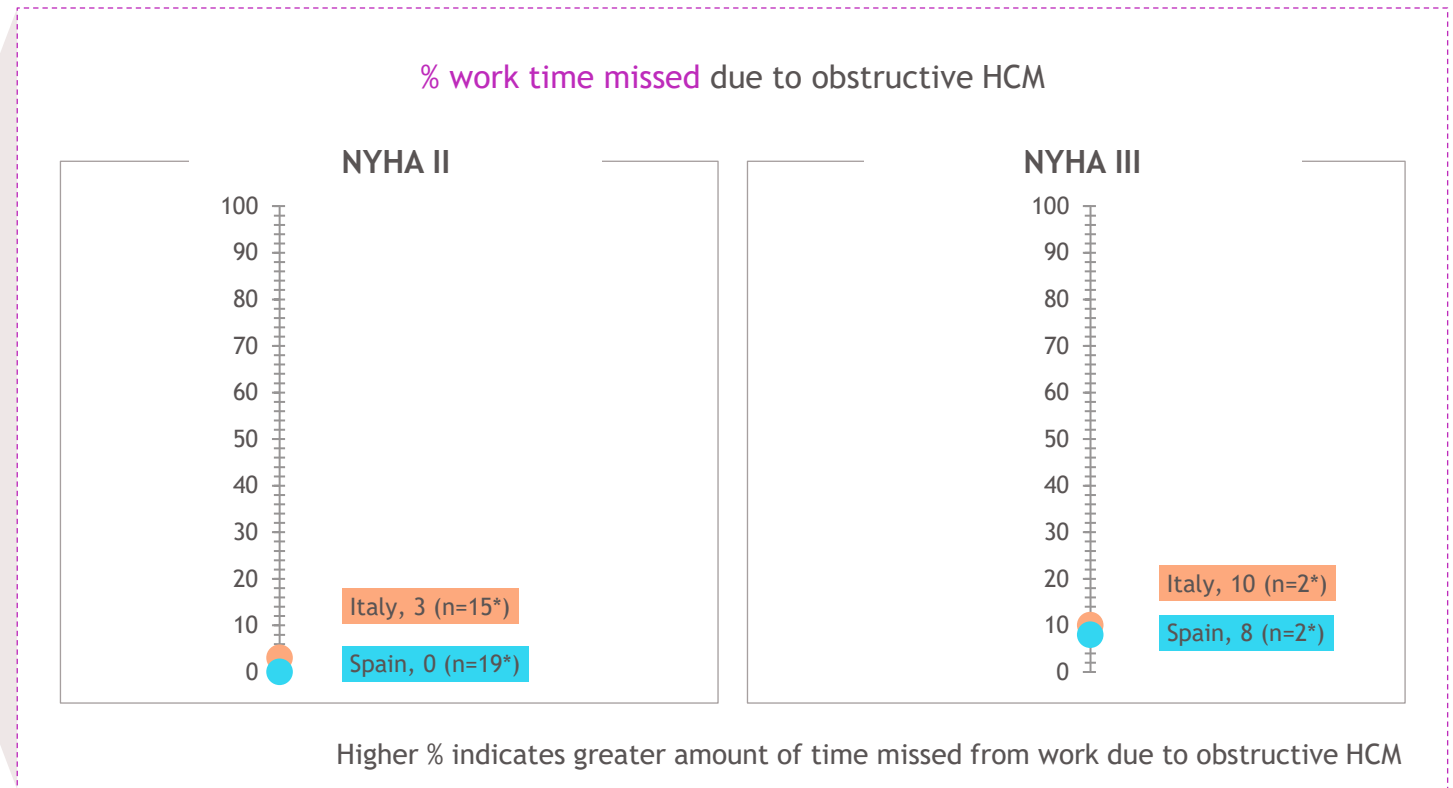
Patients who were NYHA IV not included due to low base size; **Don't know excluded
HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association

WPAI Domain: Absenteeism

Overall percentage of time missed from work ranged from 3% in Italy and 0% in Spain for NYHA II patients to 10% and 8% for NYHA III patients

Percentage work time missed due to obstructive HCM is calculated using the questions:

2. During the past 7 days, how many hours did you miss off work due to your HCM?
4. During the past 7 days, how many hours did you actually work?



No data available for patients who were NYHA IV

*Low sample size

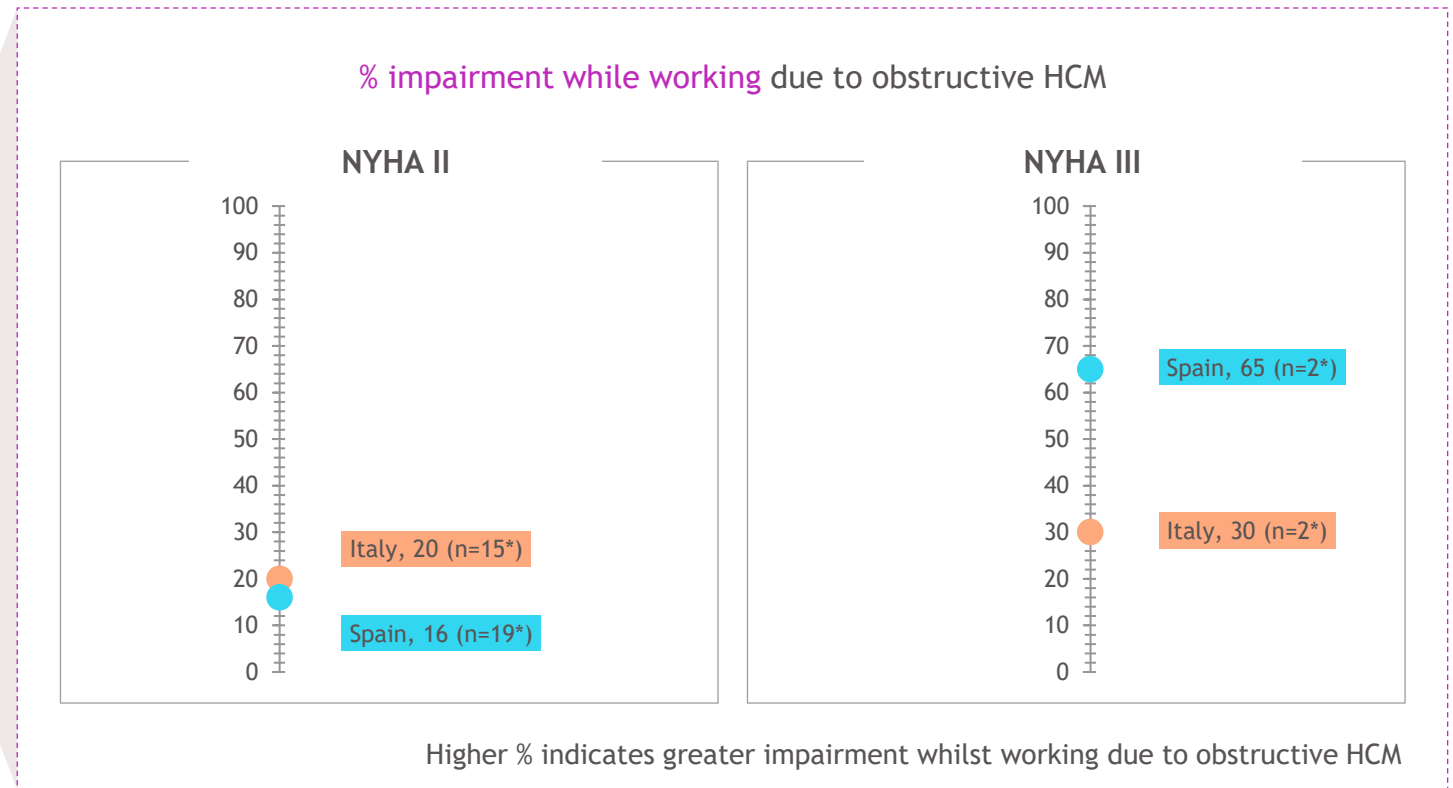
HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association; WPAI, Work Productivity and Activity Impairment

WPAI Domain: Presenteeism

Overall impairment whilst working ranged from 20% in Italy and 16% in Spain for NYHA II patients to 30% and 65%, respectively, for NYHA III patients

Percentage impairment whilst working is calculated using the question:

5. During the past 7 days, how much did HCM affect your productivity whilst you were working?



No data available for patients who were NYHA IV

*Low sample size

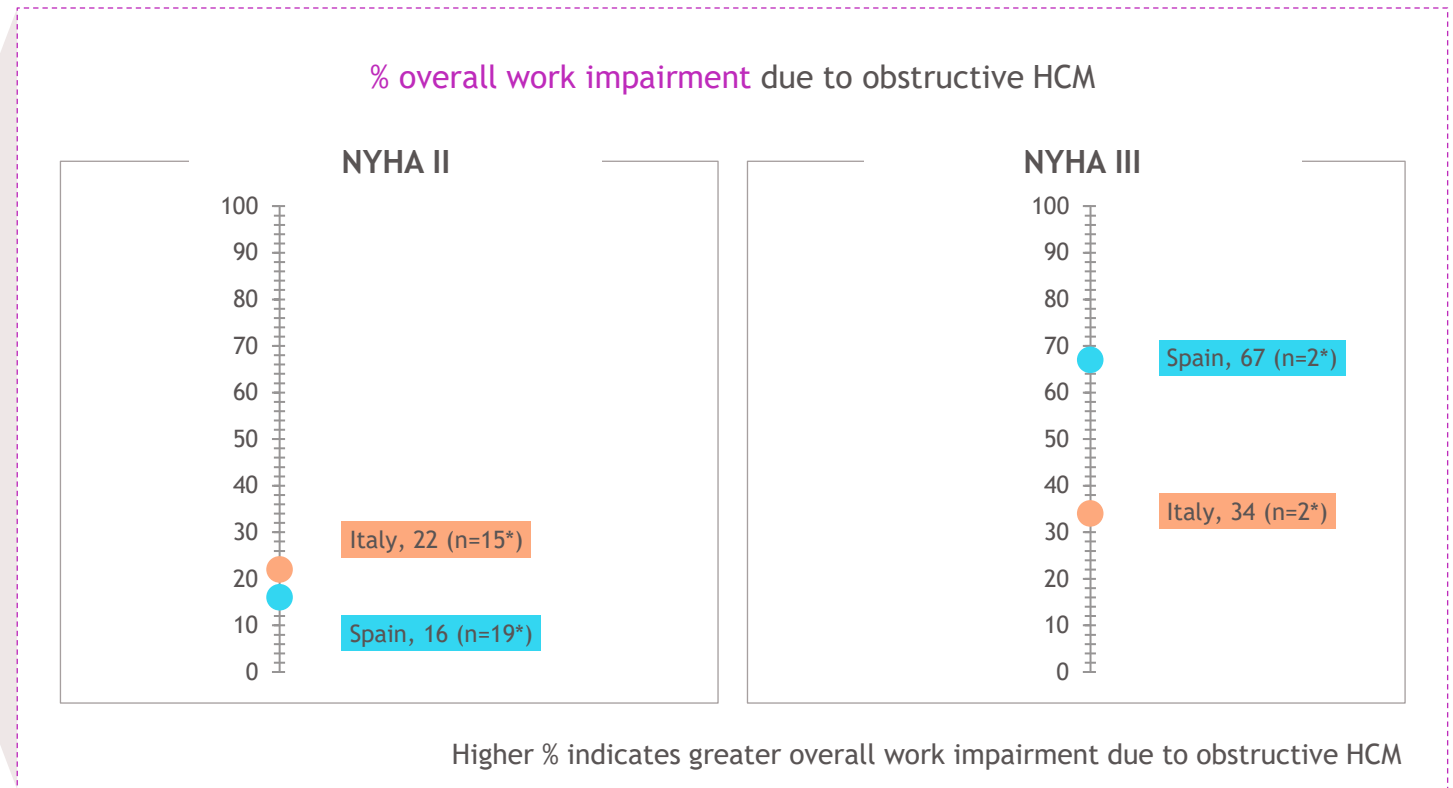
HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association; WPAI, Work Productivity and Activity Impairment

WPAI Domain: Work Productivity Lost

Overall work impairment score ranged from 22% in Italy and 16% in Spain for NYHA II patients to 34% and 67%, respectively, for NYHA III patients

Percentage overall work impairment is calculated using the questions:

2. During the past 7 days, how many hours did you miss off work due to your HCM?
4. During the past 7 days, how many hours did you actually work?
5. During the past 7 days, how much did HCM affect your productivity whilst you were working?



No data available for patients who were NYHA IV

*Low sample size

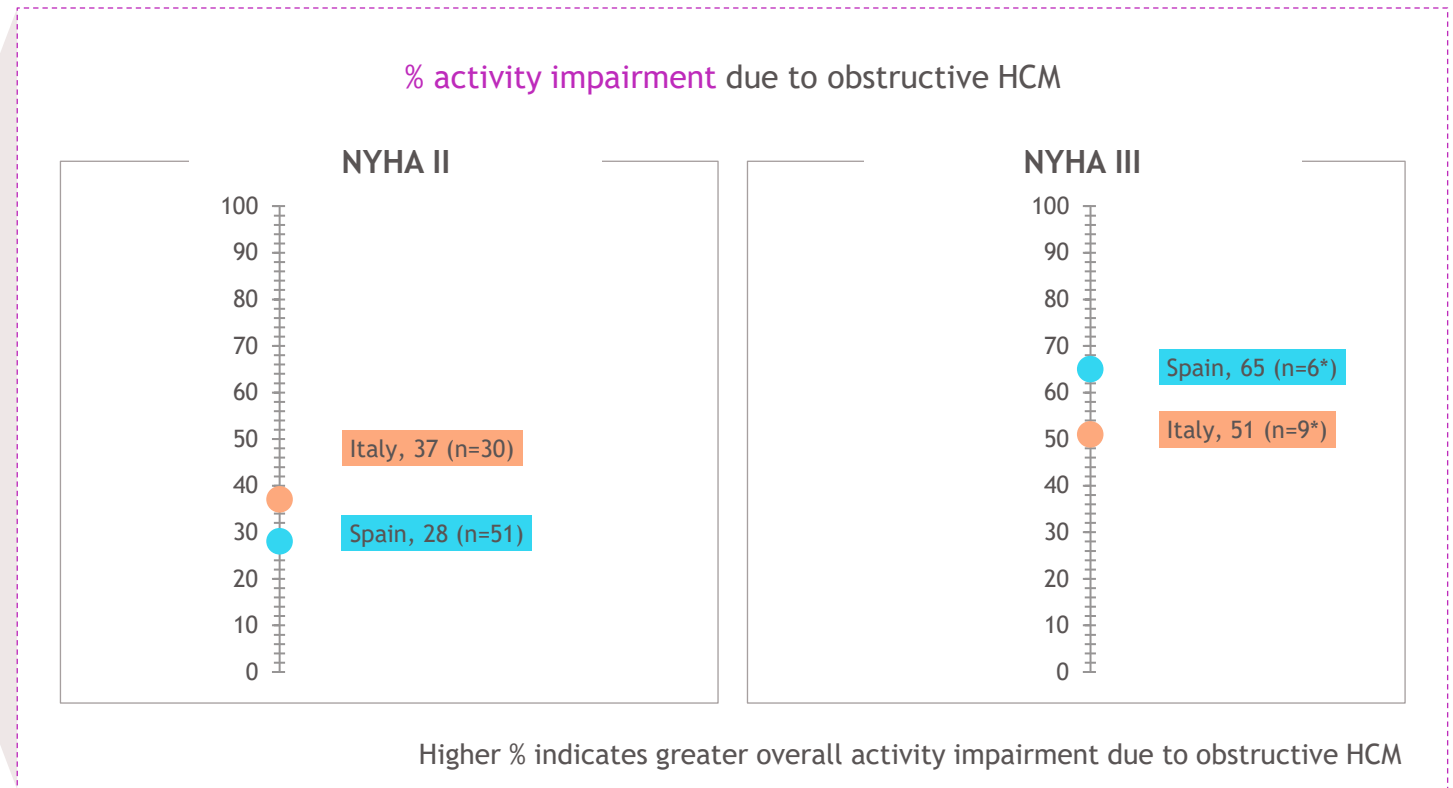
HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association; WPAI, Work Productivity and Activity Impairment

WPAI Domain: General Activity Impairment

Overall activity impairment ranged from 37% in Italy and 28% in Spain for NYHA II patients to 51% and 65% for NYHA III patients

Percentage activity impairment is calculated using the question:

6. During the past 7 days, how much did your HCM affect your ability to do your regular daily activities, other than work at your job?



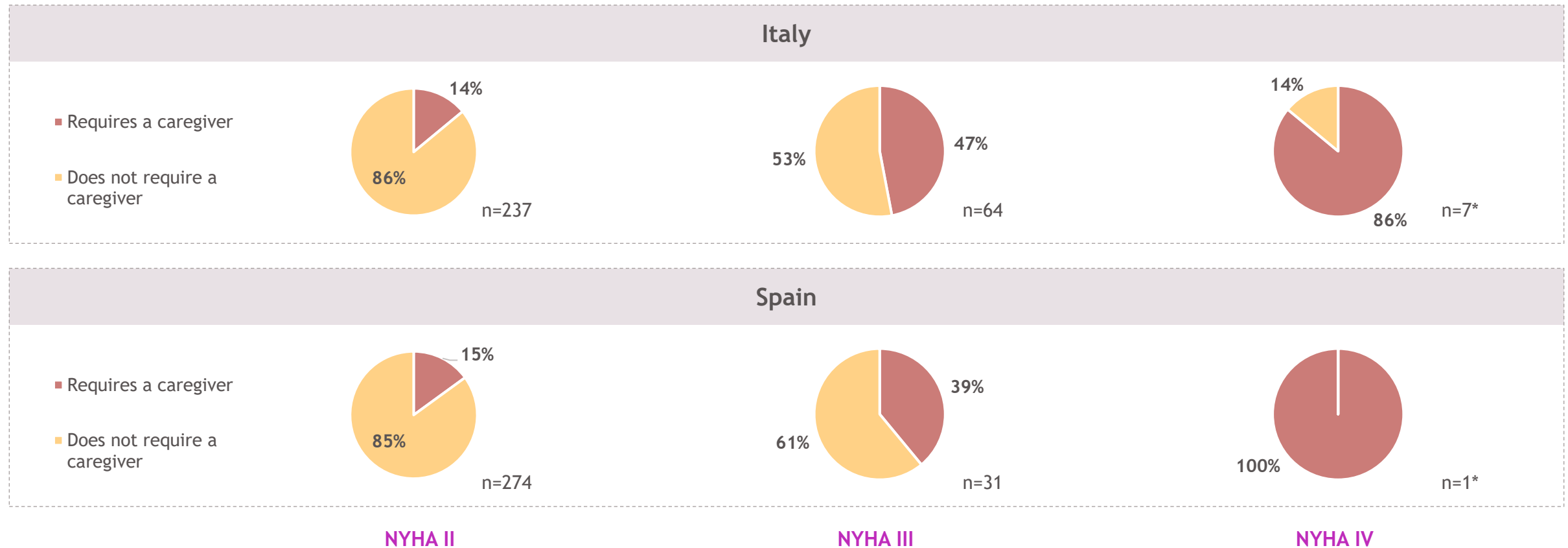
No data available for patients who were NYHA IV

*Low sample size

HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association; WPAI, Work Productivity and Activity Impairment

Need for caregivers

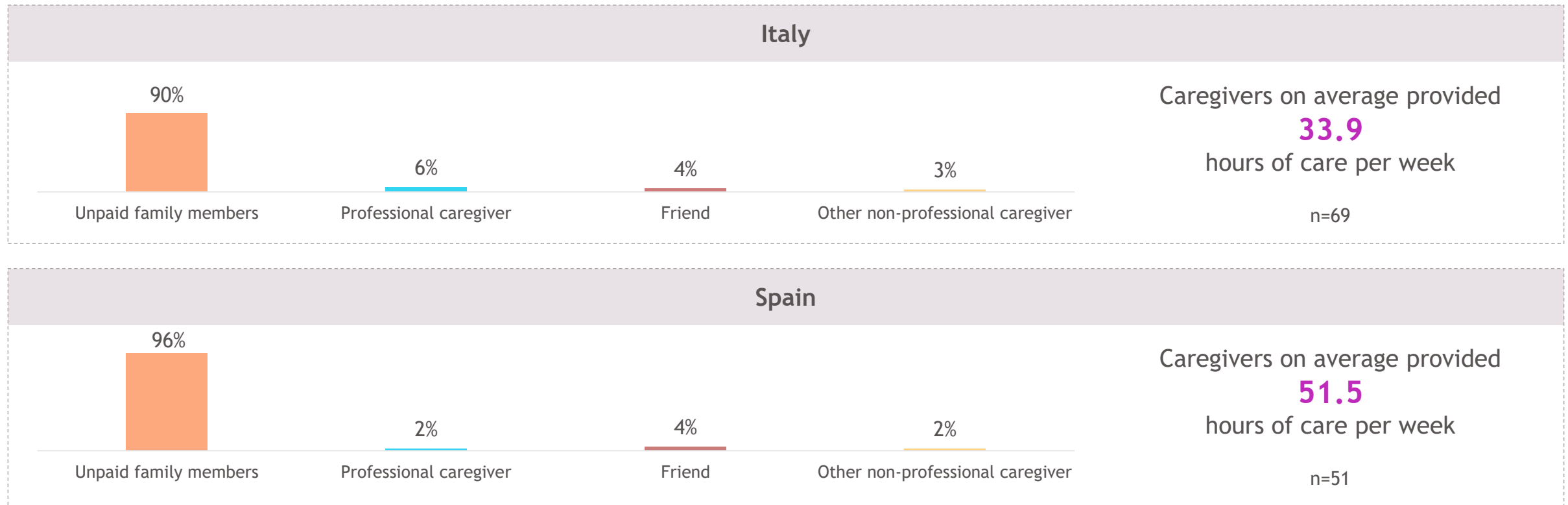
The proportion of patients who required a caregiver ranged from 14% in Italy and 15% in Spain for NYHA II patients to 86% and 100%, respectively, for NYHA IV patients



*Low sample size
NYHA, New York Heart Association

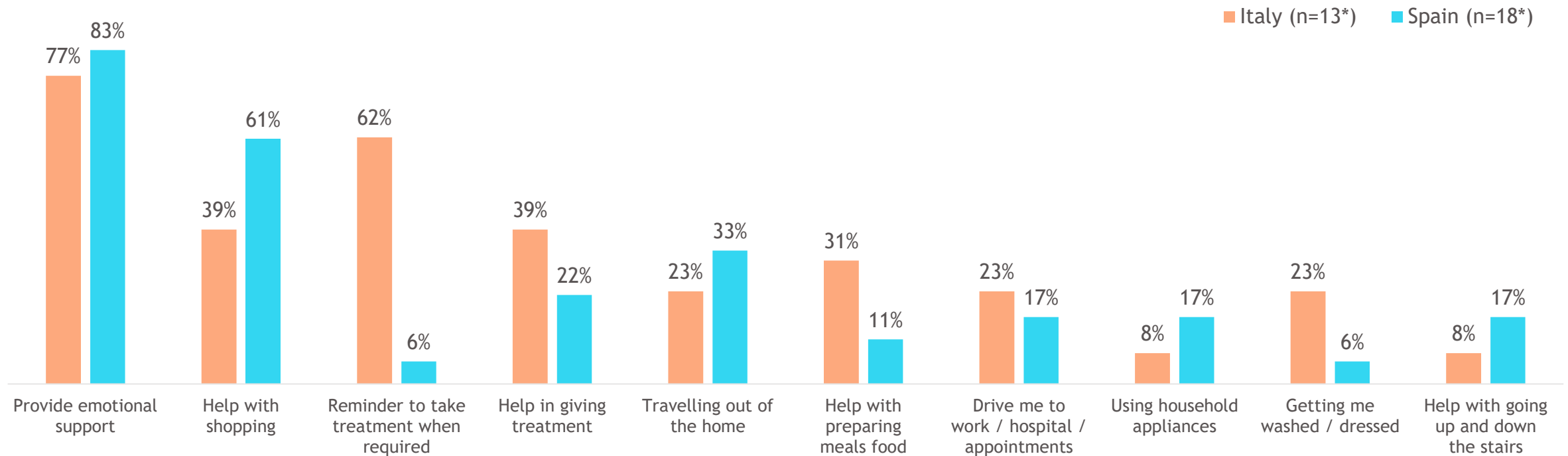
Caregiver support

The majority of caregivers were unpaid family members and spent an average of 33.9 hours in Italy and 51.5 hours in Spain caring for their family member with obstructive HCM



Caregiver assistance with activities

Patients with obstructive HCM reported that their caregivers provided a wide range of assistance. Emotional support and help with shopping were commonly reported



Note: The data on this slide was taken from the voluntary patient completed form, and as such the base consists of only those patients who opted to provide an answer

*Low sample size

HCM, hypertrophic cardiomyopathy

Limitations

- PSC sample sizes were small (voluntary completion) and therefore may not be nationally representative in both Spain and Italy
- Patients who were consulted by video or telephone were included in this study, which may have impacted PSC completion rates due to the PSC being in paper format
- Participating patients may not reflect the general obstructive HCM population since the DSP only includes patients who are consulting with their physician. This means that patients who consult more frequently have a higher likelihood of being included
- The DSP is based on a pseudo-random sample of physicians. While minimal inclusion criteria governed the selection of participating physicians, participation was influenced by their willingness to complete the survey



Conclusions

- Obstructive HCM is associated with substantial clinical and societal burden in both Italy and Spain
- As NYHA increases, patient productivity tended to decrease and need for carer support tended to increase
- The majority of caregivers for patients with obstructive HCM were unpaid and spent between 33.9 hours in Italy and 51.5 hours in Spain per week providing care. This suggests both a financial and personal impact to caregivers, and suggests that further support for caregivers of patients with obstructive HCM may be needed
- Less than a fifth of patients in both Italy and Spain had undergone any SRT, with the majority of patients undergoing septal myectomy
- Despite current treatment, a large symptom burden remains, suggesting the need for alternative treatment options



Acknowledgments, disclosures and contact details

Acknowledgments

- This study was supported by Bristol Myers Squibb
- Bristol Myers Squibb did not influence the original methodology of the DSP. The analysis described here used data from the Adelphi Real World HCM DSP. The DSP is a wholly owned Adelphi Real World product. Bristol Myers Squibb is one of multiple subscribers to the DSP
- All authors contributed to and approved the presentation; writing support was provided by Adelphi Real World and editorial assistance was provided by Grant Womack of Oxford PharmaGenesis, Oxford UK, funded by Bristol Myers Squibb

Disclosures

- Mollie Lowe, James Jackson, Kathryn Tebbs and Sophie Barlow are employees of Adelphi Real World. Yue Zhong, Marta Contente and Taryn Krause are employees of Bristol Myers Squibb and may own stock in Bristol Myers Squibb

For more information, please contact Taryn Krause (Taryn.Krause@bms.com)