Clinical and Economic Burden in NYHA Class I vs II–IV Hypertrophic Cardiomyopathy: Real-World Survey Data From the United States of America

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INTRODUCTION

- Hypertrophic cardiomyopathy (HCM) is a chronic, progressive disease characterized by left ventricular hypertrophy.[1,2]
- Studies have reported that HCM is associated with substantial symptoms that can significantly impact quality of life (QoL).[3,4]
- Studies examining the clinical and economic burden of patients with symptomatic vs asymptomatic HCM remain limited.

OBJECTIVE

- Characterize and compare the clinical and economic outcomes in patients with HCM and New York Heart Association (NYHA) functional class I vs NYHA II–IV in the United States.

METHODS

Study Design

- Data were drawn from the Adelphi Real World HCM Disease Specific Programme™ (DSP™), a multinational, cross-sectional survey conducted between May 2024 and October 2024 in the United States.
- The DSP methodology details were previously described, validated, and demonstrated to be representative and consistent over time.[5-7]
- Briefly, cardiologists completed questionnaires on demographic and clinical characteristics, symptoms, and healthcare resource utilization (HCRU) for their patients with HCM, and patients completed EQ-5D-5L and EQ-VAS questionnaires.

Statistical Analysis

- Clinical and economic outcomes were compared between NYHA I and II–IV groups using Mann-Whitney U tests for ordered categorical, Fisher's exact for nominal categorical, or t-tests for continuous outcomes (P<0.05 considered significant).

Outcomes

- Clinical outcomes, including symptoms and cardiovascular (CV) comorbidities, were collected.
- HCRU (ie, hospitalizations, emergency room [ER] visits, day visits, caregiver support) and QoL assessed by EQ-5D-5L and EQ-VAS were measured.
- Mean (SD) was reported for utilization and QoL (EQ-5D-5L; US value set); symptoms and comorbidities with prevalence >5% were summarized as percentages.

RESULTS

Patient Population

- Demographics and characteristics for all patients (N=701) and of the NYHA II–IV and NYHA I groups are shown in **Table 1**.
- Of 701 patients, mean age was 56.27 years and 56.06% were male.
- Overall, 77.60% of patients were in NYHA class II–IV.
- 77.46% received beta-blockers, for a mean duration of 1.63 years.

Clinical Outcomes

- Compared with NYHA I, the NYHA II–IV group had a higher symptom burden, including dyspnea when active, fatigue/weakness, palpitations, and dizziness (P<0.05 for all) (**Table 2**).
- CV comorbidities were also more prevalent in the NYHA II–IV group vs NYHA I group, including hypertension (49.26% vs 36.31%; P=0.0048), atrial fibrillation/atrial flutter (21.14% vs 8.92%; P=0.0003), whereas structural change (left atrial dilation) and heart failure events did not differ between the groups.

HCRU and QoL

- In the prior 12 months, there was a higher proportion of patients in the NYHA II–IV group experiencing ≥1 HCRU event vs those in the NYHA I group (27.78% vs 18.33% P=0.0505).
- HCRU was also higher in the NYHA II–IV group, with more ER visits, day visits, and caregiver support in hours per week (all P<0.05) (**Figure 1**).
- Furthermore, patients with NYHA II–IV vs NYHA I reported lower QoL, as measured by EQ-5D-5L and EQ-VAS scores (P<0.05 for both) (**Figure 2**).

Table 1: Patient demographics and characteristics

	Total HCM N=701	NYHA I n=157	NYHA II–IV n=544
Age, years	**n=701**	**n=157**	**n=544**
Mean (SD)	56.27 (14.78)	52.51 (14.61)	57.35 (14.66)
Time since first onset of symptoms, years	**n=427**	**n=107**	**n=320**
Mean (SD)	2.97 (3.23)	2.50 (2.98)	3.13 (3.29)
Time since HCM diagnosis, years	**n=625**	**n=145**	**n=480**
Mean (SD)	2.62 (3.12)	2.18 (3.75)	2.76 (2.89)
Biologic sex	**n=701**	**n=157**	**n=544**
Male	393 (56.06)	91 (57.96)	302 (55.51)
Female	308 (43.94)	66 (42.04)	242 (44.49)
Current HCM Treatment	**n=701**	**n=157**	**n=544**
Beta-blockers	543 (77.46)	107 (68.15)	436 (80.15)
Calcium channel blockers	336 (47.93)	64 (40.76)	272 (50.00)
Diuretics	143 (20.40)	32 (20.38)	111 (20.40)
ACE inhibitors	126 (17.97)	11 (7.01)	115 (21.14)
Cardiac myosin ATPase inhibitor	111 (15.83)	28 (17.83)	83 (15.26)
ARBs	101 (14.41)	20 (12.74)	81 (14.89)
Antiarrhythmics (including disopyramide)	63 (8.99)	14 (8.92)	49 (9.01)
MRAs	35 (4.99)	8 (5.10)	27 (4.96)
Other	10 (1.43)	3 (1.91)	7 (1.29)
None	75 (10.70)	34 (21.66)	41 (7.54)
Duration of current treatment, years	**n=701**	**n=157**	**n=544**
Mean (SD)	1.63 (1.29)	1.47 (1.20)	1.68 (1.31)

All data are n (%) unless otherwise indicated.
ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blockers; CV, cardiovascular; HCM, hypertrophic cardiomyopathy; MRA, Mineral receptor antagonists; NYHA, New York Heart Association.

Table 2: Clinical outcomes (HCM symptoms and CV comorbidities)

	Total HCM N=701	NYHA I n=157	NYHA II–IV n=544	*P* value
Proportion of patients currently experiencing symptoms	**n=701**	**n=157**	**n=544**	
Currently experiencing symptoms	627 (89.44)	115 (73.25)	512 (94.12)	<0.0001
Not currently experiencing symptoms	74 (10.56)	42 (26.75)	32 (5.88)	
Current symptoms[a]	**n=627**	**n=115**	**n=512**	
Dyspnea when active	498 (79.43)	75 (65.22)	423 (82.62)	<0.0001
Fatigue/weakness	307 (48.96)	35 (30.43)	272 (53.12)	<0.0001
Chest pain when active	161 (25.68)	22 (19.13)	139 (27.15)	0.0776
Palpitations	138 (22.01)	16 (13.91)	122 (23.83)	0.0244
Dizziness	113 (18.02)	13 (11.30)	100 (19.53)	0.0435
Dyspnea when at rest	52 (8.29)	11 (9.57)	41 (8.01)	0.5761
Edema	45 (7.18)	9 (7.83)	36 (7.03)	0.6943
Total number of top 5 symptoms experienced[b]	**n=701**	**n=157**	**n=544**	
0 (no symptoms experienced)	92 (13.12)	53 (33.76)	39 (7.17)	<0.0001
1	206 (29.39)	63 (40.13)	143 (26.29)	
2	239 (34.09)	28 (17.83)	211 (38.79)	
3	130 (18.54)	10 (6.37)	120 (22.06)	
4	27 (3.85)	3 (1.91)	24 (4.41)	
5 (all symptoms experienced)	7 (1.00)	0 (0.00)	7 (1.29)	
CV comorbidities[a]	**n=701**	**n=157**	**n=544**	
Hypertension	325 (46.36)	57 (36.31)	268 (49.26)	0.0048
Atrial fibrillation / atrial flutter	129 (18.40)	14 (8.92)	115 (21.14)	0.0003
Heart failure	70 (9.99)	10 (6.37)	60 (11.03)	0.0969
Left atrial dilation	69 (9.84)	15 (9.55)	54 (9.93)	1.0000

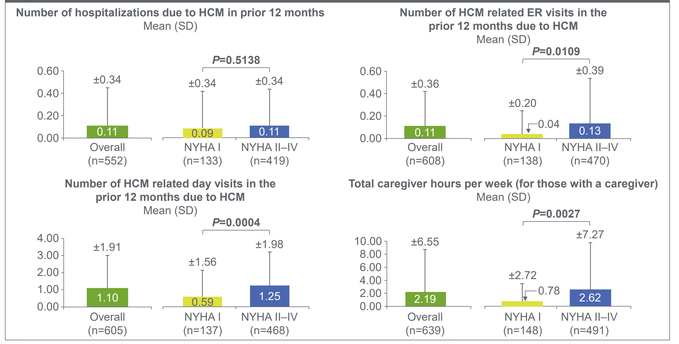
All data are n (%) unless otherwise indicated.
[a] Reported for >5% of the population.
[b] Top 5 symptoms include dyspnea when active, fatigue/weakness, palpitations, chest pain when active, and dizziness.
CV, cardiovascular; HCM, hypertrophic cardiomyopathy; NYHA, New York Heart Association.

Table 3: Economic outcomes (HCRU and QoL)

	Total HCM N=701	NYHA-I n=157	NYHA II–IV n=544	*P* value
Number of HCM-related hospitalizations in the last 12 months	**n=552**	**n=133**	**n=419**	
Mean (SD)	0.11 (0.34)	0.09 (0.34)	0.11 (0.34)	0.5138
Number of HCM-related ER visits in the last 12 months	**n=608**	**n=138**	**n=470**	
Mean (SD)	0.11 (0.36)	0.04 (0.20)	0.13 (0.39)	0.0109
Number of HCM-related day visits in the last 12 months	**n=605**	**n=137**	**n=468**	
Mean (SD)	1.10 (1.91)	0.59 (1.56)	1.25 (1.98)	0.0004
Total caregiver hours per week (for those with a caregiver)	**n=639**	**n=148**	**n=491**	
Mean (SD)	2.19 (6.55)	0.78 (2.72)	2.62 (7.27)	0.0027
HCRU in the last 12 months[a]	**n=462**	**n=120**	**n=342**	
HCRU use	117 (25.32)	22 (18.33)	95 (27.78)	0.0505
No HCRU use	345 (74.68)	98 (81.67)	247 (72.22)	
EQ-5D-5L (US value set)	**n=118**	**n=31**	**n=87**	<0.0001
Mean (SD)	0.83 (0.15)	0.92 (0.15)	0.80 (0.13)	
EQ-VAS	**n=115**	**n=30**	**n=85**	
Mean (SD)	77.81 (11.77)	83.10 (11.74)	75.94 (11.27)	0.0038

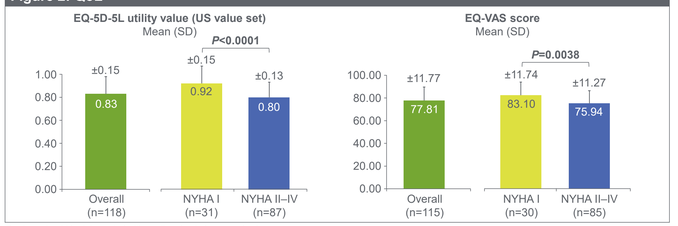
All data are n (%) unless otherwise indicated.
[a] HCRU in the last 12 months is defined as the proportion of patients who have/have not experienced any of the following HCRU events in the last 12 months: HCM-related hospitalizations, HCM-related ER visits, HCM-related day visits, and hours of care >0.
ER, emergency room; EQ-5D-5L, EuroQol 5-Dimension 5-Level; HCM, hypertrophic cardiomyopathy; HCRU, healthcare resource utilization; NYHA, New York Heart Association; QoL, quality of life; VAS, visual analog scale.

Figure 1: HCRU



HCRU in the last 12 months is defined as the proportion of patients who have/have not experienced any of the following HCRU events in the last 12 months: HCM-related hospitalizations, HCM-related ER visits, HCM-related day visits, and hours of care >0.
ER, emergency room; HCM, hypertrophic cardiomyopathy; HCRU, healthcare resource utilization; NYHA, New York Heart Association.

Figure 2: QoL



P values should be interpreted with caution due to low sample sizes.
EQ-5D-5L, EuroQol 5-Dimension 5-Level; NYHA, New York Heart Association; VAS, visual analog scale.

Limitations

- Data from the survey were cross-sectional, with limited information about individual patient journeys or disease trajectory.
- Participation is affected by the willingness to complete the survey and may not reflect a random sample of cardiologists or patients with HCM.
- There could be heterogeneity within the NYHAII–IV group; further analysis is warranted to explore and address this.

CONCLUSIONS

- Over three quarters of US patients with HCM are symptomatic (NYHA II–IV) and experienced greater clinical burden and HCRU compared with NYHA I.
- Notably, despite these differences, patients with NYHA I were still experiencing clinical symptoms and required medical interactions impacting HCRU and QoL.
- These findings demonstrate the need for HCM therapies that address the underlying mechanisms of disease and effectively and safely improve HCM symptoms and patient quality of life.

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Disclosures

PG, JB, MB, SS, PD: Employees of and hold stock in Cytokinetics, Incorporated; **JJ, LH, SB, LL:** Employees of Adelphi Real World.

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