Economic burden of obstructive hypertrophic cardiomyopathy in France

Poster number: EE155

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Introduction

- Hypertrophic cardiomyopathy (HCM) is a commonly inherited cardiovascular disease and is defined by left ventricular hypertrophy that cannot be explained by an abnormal loading condition. This chronic, progressive myocardial disease occurs as obstructive or non-obstructive subtypes[1,2]
- Previous studies, primarily US-based, have shown that obstructive HCM, if not well-controlled, is associated with increased risks of downstream cardiovascular (CV) conditions, increased risk of symptoms, and impaired quality of life, and can result in substantial economic burden.[3,4] The relationship between New York Heart Association (NYHA) class and related economic burden has been poorly studied

Objectives

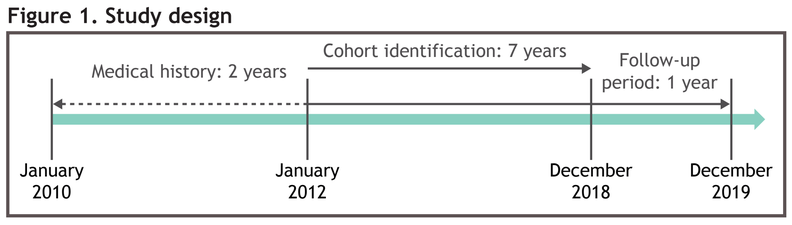
- The aim of the study was to estimate the economic burden of the disease as captured by healthcare resource utilization (HCRU) among patients with obstructive HCM and with consideration of disease severity as measured by NYHA class

Methods

Data source

- This study used data from the French National Health Data System (Système National des Données de Santé; SNDS) belonging to the Caisse nationale de l'assurance maladie (CNAM)
- The SNDS contains individual-level data for health expenditure billing and reimbursement purposes for outpatient and private healthcare facilities (DCIR [outpatient healthcare consumption data]), linked to the hospitalization database (PMSI [hospital discharge database]) with a unique, anonymous identifier. SNDS encompasses all healthcare claims for more than 99% of the population residing in France, regardless of the patient's insurance scheme (almost 65 million people)[5]

Figure 1. Study design



Study population

- All adult (≥ 18 years) patients with at least 1 hospital stay or long-term disease status (affection longue durée; ALD) related to HCM code (International Classification of Diseases, 10th Revision [ICD-10] codes I42.1, I42.2, or I42.9 associated with septal reduction therapy [SRT]) between 2012 and 2018 were included (**Figure 1**)
- Patients with less than 1 year of follow-up data available and patients with amyloidosis, aortic stenosis, hypertensive heart disease, or storage disease were excluded
- The obstructive HCM population was identified as:
  - at least 1 diagnosis code for obstructive HCM (ICD-10 code I42.1) **or**
  - at least 1 diagnosis code for HCM (ICD-10 code I42.2 and/or I42.9) and at least 1 code for SRT
- Patients with obstructive HCM were further categorized by NYHA class based on a baseline and time-varying algorithm that was developed based on treatments and symptoms

Analysis procedure

- Baseline patient characteristics, including demographics, comorbidities, and current treatments, were identified
- Health outcomes, HCRU, and costs were analyzed for the obstructive HCM study population and for the subgroups
- Results were attributed to the subgroup that the patient was in at the time of the documented outcome
- To account for differences in patient follow-up times, costs were annualized based on patient-year (PY)

Cost evaluation

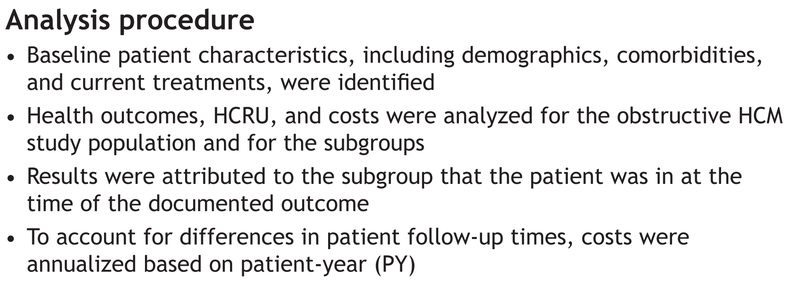
- Hospital costs are determined from the perspective of CNAM in 2022 EUR
- Hospital costs are attributed from official French national disease-related group (DRG) tariffs for years 2020–2021 and expressed in 2022 EUR.[6] Supplements, additional costs related to drugs and medical devices, and additional costs for hospitalization in an intensive care unit were also considered

Results

Patient population

- Between 2012 and 2018, 20,111 adult patients met the eligibility criteria (**Figure 2**)
- 4571 of the patients had obstructive HCM as their first HCM diagnosis during the study period. An additional 2252 patients initially had non-obstructive HCM and later developed obstructive HCM, for a total of 6823 patients with obstructive HCM during the study period (34%)

Figure 2. Study population selection



[a]Patients with aortic stenosis, hypertensive heart disease, storage disease, or amyloidosis; [b]Includes 2252 patients whose first diagnosis during the study period was non-obstructive HCM followed by a subsequent diagnosis of obstructive HCM.

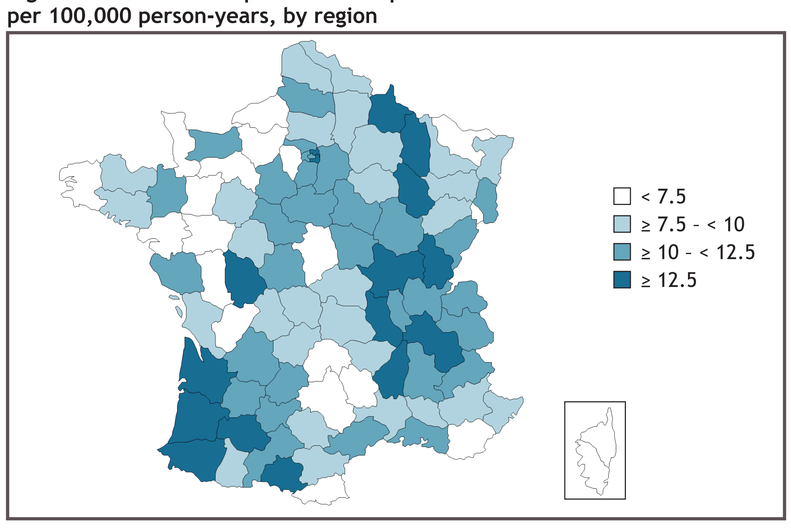
- Of the total obstructive HCM group (n = 6823), 45% were female, the mean age was 66.2 years (standard deviation [SD]: 16.7 years), and mean follow-up was 4.4 years (SD: 2.5 years) (**Table 1**)
- Patients in higher NYHA classes at baseline had higher comorbidity burden based on Charlson Comorbidity Index (CCI) score as well as a greater percentage having other cardiovascular comorbidities at index date, in particular hypertension, heart failure, and atrial fibrillation/flutter
- Prevalence of obstructive HCM varied by region (**Figure 3**)

Table 1. Baseline characteristics of patients with obstructive HCM, by NYHA class

Baseline characteristics	NYHA class I (n = 294)	NYHA class II (n = 2150)	NYHA class III (n = 4102)	NYHA class IV (n = 277)	Total (n = 6823)
Age, mean (SD)	56.9 (21.8)	59.6 (16.8)	70.3 (14.7)	67.2 (15.8)	66.2 (16.7)
Female, %	41	40	49	43	45
CCI score, mean (SD)	2.67 (2.39)	2.76 (2.12)	4.45 (2.19)	4.55 (2.08)	3.84 (2.32)
Comorbidities, %					
Atrial fibrillation/flutter	6	13	36	37	28
Coronary artery disease	7	15	18	26	17
Depression	13	15	17	13	16
Diabetes	10	13	22	27	19
Heart failure	5	9	31	63	25
Hypertension (primary)	21	81	93	96	86
Previous events, %					
DVT/PE	2	2	2	2	2
Myocardial infarction	8	7	8	9	8
SRT	< 1	< 1	< 1	< 1	< 1
Stroke/TIA	5	5	7	5	6

DVT, deep vein thrombosis; PE, pulmonary embolism; SD, standard deviation; TIA, transient ischemic attack.

Figure 3. Standardized prevalence of patients with obstructive HCM per 100,000 person-years, by region



Costs

- The annual cost per patient with obstructive HCM that was reimbursed by CNAM was €12,824 with cost increasing with higher (worse) NYHA class, ranging from €8881 for NYHA class I to €22,818 for NYHA class IV (**Table 2**)
- Patients with obstructive HCM were mainly in NYHA class II and III throughout the study and cost in excess of €101 million and €251 million, respectively (**Table 2** and **Figure 4**)
- Although very few patients in NYHA class IV throughout the study contributed to lower the overall costs (**Figure 4**), the cost per PY was the highest among all NYHA classes (**Table 2**)
- Costs were driven by hospitalizations, with HCM-related hospital costs comprising the majority of all hospital costs (**Table 2**, **Figures 4** and **5**)
- Indirect costs, including sick leave, disability pension costs, and days of sick leave, generally increased with higher NYHA class (**Table 3**)
- The average annual cost of care per patient varies by region, with higher costs in urban areas that had HCM specialty centers that could care for more complex cases (**Figure 6**)
- SRT is a high-cost procedure, with an average cost of €10,956 per hospitalization. There were 562 SRT procedures, with an average annual cost of care per patient of €6897 in the year before the SRT and €7484 in the year following the SRT

Table 2. Annualized cost of care by NYHA class per PY

Cost per PY (€)	NYHA class I (PY = 857)	NYHA class II (PY = 11,104)	NYHA class III (PY = 17,484)	NYHA class IV (PY = 783)	Total (PY = 30,228)
Drugs	949	1192	1673	2446	1495
CV drugs	2	5	46	125	32
Medical devices	517	402	791	961	645
Outpatient consultations	172	250	340	362	303
Paramedical consultations	554	597	1423	1255	1091
Hospital consultations	193	264	294	424	283
Hospitalizations	4782	5011	7929	14,746	6944
CV-related hospitalizations	3097	3290	5629	12,764	4883
HCM-related hospitalizations	2319	2475	3534	6984	3200
CV-related hospitalizations, without coded HCM diagnosis	779	816	2095	5781	1683
Non-CV-related hospitalizations	1685	1721	2299	1982	2061
Home hospitalizations	299	44	65	24	63
Laboratory tests	104	153	277	363	229
Medical procedures	240	365	396	420	381
Transportation	482	597	835	962	741
Other	305	243	366	316	318
Total for all costs[a]	**8881**	**9535**	**14,658**	**22,818**	**12,824**

[a]Costs include sick leave and disability pension costs not shown in Table 2.

Table 3. Annualized indirect costs (sick leave and disability pension) per patient with obstructive HCM, by NYHA class, among patients 65 years of age and younger

Average annual indirect costs	NYHA class I (PY = 857)	NYHA class II (PY = 11,104)	NYHA class III (PY = 17,484)	NYHA class IV (PY = 783)	Total (PY = 30,228)
Sick leave and disability cost (€ per PY)	284	418	270	541	332
Sick leave cost (€ per PY for patients ≤ 65 years of age)	313 (PY = 610)	611 (PY = 3544)	622 (PY = 3765)	725 (PY = 233)	639 (PY = 15,542)
Length of sick leave (days per PY for patients ≤ 65 years of age)	14	25	26	42	27

Figure 4. Total costs of patients with obstructive HCM per NYHA class throughout the study

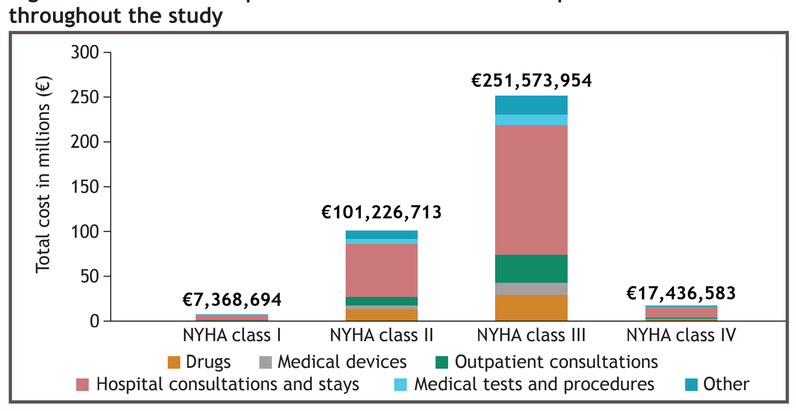
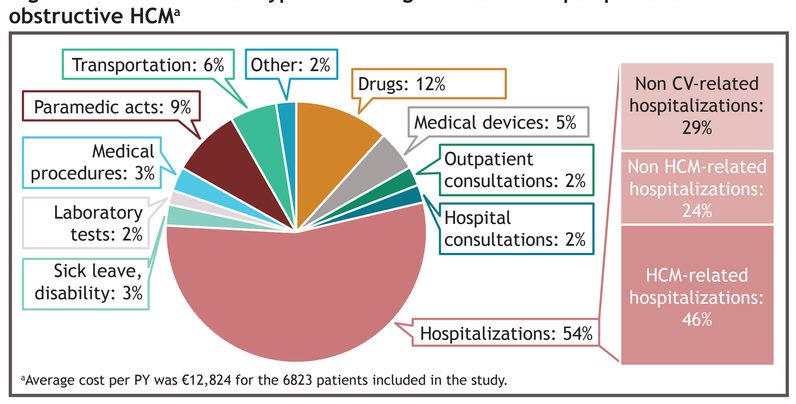
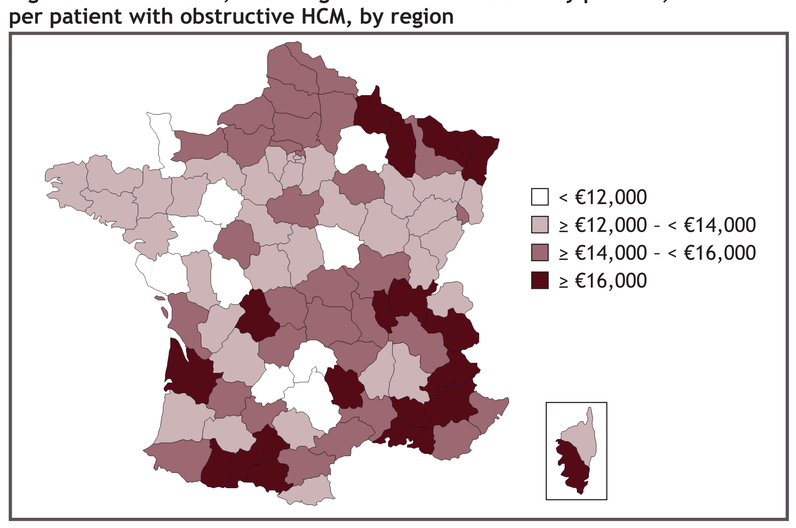


Figure 5. Distribution of types of average annual costs per patient with obstructive HCM[a]



[a]Average cost per PY was €12,824 for the 6823 patients included in the study.

Figure 6. Annual cost, including sick leave and disability pension, per patient with obstructive HCM, by region



Limitations

- The study was based on data in the French National Health Database (secondary data), the original intent for which is the reimbursement of healthcare costs. The quality of claims data are dependent on the individual completeness and quality of coding for billing purposes and on the existing classification systems; therefore, this study has all the limitations of similar studies based on administrative data
- Since only patients with a hospitalization for HCM could be identified, patients with HCM who were not hospitalized are not included. Therefore, results are not representative of all patients with HCM
- NYHA class and symptoms are not directly coded in the database and were assigned to subgroups based on an algorithm developed with clinical expert input. This algorithm should be considered a proxy for actual NYHA class and needs to be validated
- Only patients with at least 1 year of follow-up were included in this study. Thus, patients who died within 1 year following their index diagnosis were not represented in the analysis

Conclusions

- This is the first nationwide study in France to demonstrate that patients with obstructive HCM have a high economic burden
- Patients in worse NYHA classes have higher costs of medical care, especially CV-related hospitalizations, further emphasizing the financial impact associated with the severity of their condition
- In this study, patients in NYHA class II and III represent the greatest number of patients and the highest total costs to the healthcare system
- SRT is a costly procedure and does not reduce the annual cost of care for patients in the year following the procedure
- Among patients of working age, sick leave, average annual cost per patient, and number of days also increases with higher NYHA class, adding to the economic burden
- The annual cost per patient with obstructive HCM varies by region, with higher costs in those regions that have specialty centers that care for complex patients

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Acknowledgments

- The study was supported by Bristol Myers Squibb.
- All authors contributed to and approved the poster. Editorial assistance was provided by Heather Swift and Grant Womack of Oxford PharmaGenesis, Oxford, UK, funded by Bristol Myers Squibb.
- The author team would like to thank the teams of the Strategy, Studies and Statistics Department (DSES), the Data Access, Processing and Analysis Department (DATAD), and the CNAM Cell in charge of accompanying Extraction Requests (DEMEX) of the French National Health Insurance Fund (CNAM) for data extraction.

Disclosures

- Philippe Charron has received consulting fees/honoraria from Amicus, Bristol Myers Squibb, Novartis, Pfizer, and Sanofi. Carla Zema is a contractor of Bristol Myers Squibb. François-Emery Cotté, Taryn Krause, and Michael Hurst are current employees of Bristol Myers Squibb and may own Bristol Myers Squibb stock or stock options. Arthur Juban was an employee of Bristol Myers Squibb at the time of the study. Aurélie Schmidt and Julia Gonzalez are employees of HEVA, which received funding from Bristol Myers Squibb to conduct this study. Jean-Noël Trochu has received personal fees from Abbott, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, and Vifor Pharma, grants and personal fees from Novartis, and grants from Boston Scientific.

Presented at ISPOR Europe 2023; November 12–15, 2023; Copenhagen, Denmark

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