SEPTAL MYECTOMY FOR OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY PATIENTS IN THE BRAZILIAN PUBLIC HEALTH SYSTEM – A REAL-WORLD STUDY

[Poster Code: EPH211]

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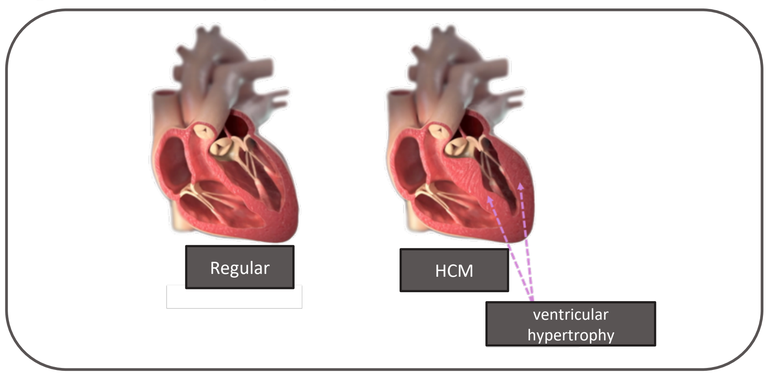
Background

- Cardiac muscle hypercontractility is a key pathophysiological abnormality in HCM, and a major determinant of dynamic left ventricular outflow tract (LVOT) obstruction as shown in Figure 1.[2]
- Hypertrophic cardiomyopathy (HCM) is often a genetic disorder characterized by left ventricular hypertrophy (LVH) without an identified cause.[1]

Figure 1. Normal versus hypertrophic Heart [12]



- HCM is a common and globally reported genetic heart disease, characterized by unexplained thickening of the left ventricular wall, typically defined as a wall thickness ≥15 mm, or >13 mm in individuals with a positive family history or pathogenic genetic variants. It can cause shortness of breath and chest pain, as well as arrhythmias that can result in strokes or even sudden death. [3,4]
- Reported prevalence in the general population varied between 1/500 or 1/200, however, only approximately 10% of affected individuals are clinically identified.[5,6,7,10,16]
- HCM can be classified into two types: obstructive HCM and non obstructive HCM. Obstructive HCM, distinguished by the presence of both myocardial hypertrophy and a left ventricular outflow tract (LVOT) gradient greater than 30 mmHg, either at rest or with provocation, may lead to blocks or reduce the blood flow from the left ventricle to the aorta.[8]
- The New York Heart Association (NYHA) is the widely used to categorize patients with heart failure into one of four classes based on their symptoms at rest and during activity, with Class I indicating no symptoms and Class IV indicating severe limitations in physical activities.[9]
- Patients with obstructive HCM experience progressively worsening symptoms and reduced exercise capacity. In patients with severe obstructive HCM refractory to maximal standard medical therapy, typically class III or class II with exertional dyspnea, septal reduction therapy (SRT) is a treatment option recommended by the Brazilian guidelines.[10]
- Septal reduction therapy, consisting of a surgical procedure (SM - septal myectomy) or a catheter-based therapy (alcohol septal ablation), has been used to treat this subset of patients. The aim of SRT is to abolish the left ventricular outflow tract obstruction and relieve the symptoms, allowing these patients with severe debilitation to return to a near-normal lifestyle.
- There are limited data evaluating patient access to SM treatment in the Brazilian public healthcare system (SUS).

Objectives

Primary Objectives

- To describe characteristics of outpatients with diagnosed obstructive HCM treated in the public health system in Brazil
- To describe the occurrence and frequency of inpatient SM in the public health system in Brazil.

Exploratory Objectives

- To describe average outpatient cost and SM cost.
- To describe the mortality percentage of SM.
- To descriptively report distribution of patients and SMs among different cities of Brazil.

Methods

Overview of Study Design

A retrospective and descriptive database study was conducted from SUS perspective using claim data from the government information system, from 2015 to 2024. All SM procedures (local procedure code 0406010323) and cases of diagnosed obstructive hypertrophic cardiomyopathy (ICD-10 I42.1) were identified.

Study Population:

- All outpatients diagnosed with obstructive HCM (ICD code I42.1) who have been treated at the SUS with available claim data in the SUS database from anytime during the period of 2015 and 2024.
- All inpatients SRT procedures performed at the SUS between 2015 and 2024.

Inclusion Criteria

- Outpatients with a diagnosis of obstructive HCM (ICD code I42.1)
- Inpatients with one or more codes for septal hypertrophy correction (SHC) procedures (local procedure code: 0406010323)
- Patients with records available in the SUS database

Exclusion Criteria

- Patients under 18 years old were excluded.

Data Source/Data Collection Process

The data source was the SIH/SUS database, a public database which contains electronic claim records for all Brazilian citizens treated in the public health system.

Data collection was conducted retrospectively for all outpatients with ICD code I42.1 treated over the past years in the public health system and all inpatient SM procedures (0406010323) which have available records in the SUS database.

Data was collected and analyzed in Python version 3.9 by one researcher and validated by a second researcher.

Results

Patients Results

The total number of outpatients diagnosed with obstructive HCM in the SUS in the study period was 1,379, of which 46% were male (n=639) with a mean age at diagnostic date of 50.11 ± 20.80 years (see Figure 2 and 3). It is noted that outpatients are concentrated in main cities of Brazil such as Belo Horizonte and São Paulo (see Table 1).

Figure 2. Outpatients diagnosed with obstructive HCM in the SUS by gender from 2015 to 2024

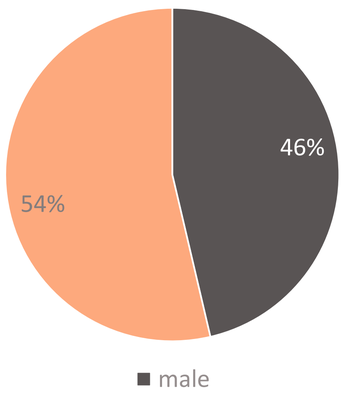


Figure 3. HCM outpatient average age (2015 to 2024)

50.11 years ± 20.8 (Standard deviation)

Patient average age

Table 1. Outpatient distribution among main cities - Top 10 cities from 2015 to 2024

# Patients	City	State
162	Belo Horizonte	Minas Gerais
148	São Paulo	São Paulo
113	Ribeirão Preto	São Paulo
56	Porto Alegre	Rio Grande do Sul
52	Brasília	Distrito Federal
49	Goiânia	Goiás
49	Rio de Janeiro	Rio de Janeiro
48	São José dos Campos	São Paulo
44	Salvador	Bahia
41	Curitiba	Paraná

Septal myectomy (SM) Results

A total of 209 inpatient SM (15.16% of patients) were performed at SUS from 2015 to 2024 with 62% of the patients being male and a mean age at the procedure time of 51.85 ± 14.64 years. Despite the predominance of female patients (54%) diagnosed with hypertrophic cardiomyopathy (HCM) in Brazil, surgical myectomy procedures were more frequently performed in male patients (62%).

The cities of São Paulo and Belo Horizonte account for the highest concentration of outpatients diagnosed with obstructive HCM, as well as the largest number of surgical procedures performed to treat the condition.

The average cost of an outpatient visit was (BRL) R$ 116.93. Septal myectomy cost during the analysed period was R$ 16,484.48, with a mortality rate (any death during the SRT procedure including hospitalization period) of 8.1% (17/209) as shown in Figure 4.

Table 2 presents the top three ICD codes associated with septal myectomy procedures performed between 2015 and 2024. Among these, the diagnosis of unspecified congenital malformation accounts for the highest number of surgeries.

Table 2. Septal myectomy from 2015 – 2024 - Top 3 ICD codes

ICD-10	ICD-10 description	# SM Procedures
Q21.9	Unspecified congenital malformation of cardiac septum	135
I42.1	Hypertrophic obstructive cardiomyopathy	32
Q24.3	Pulmonary infundibular stenosis	22

Figure 4. Septal myectomy average mortality rate and average cost

8,1%

SM mortality rate

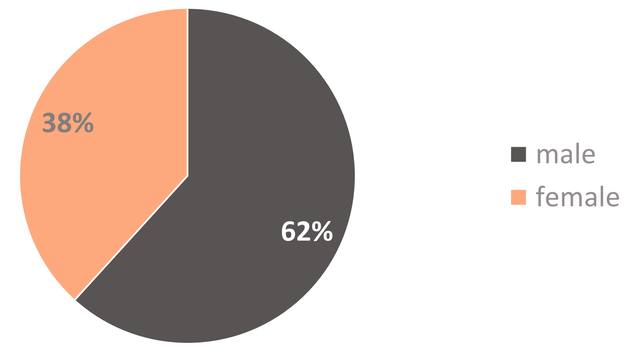
R$ 16,484.48

SM average cost

Table 3. Septal Myectomy - Top 10 cities

# Procedures	City	State
44	São Paulo	São Paulo
17	Belo Horizonte	Minas Gerais
14	Campina Grande do Sul	Paraná
11	Campinas	São Paulo
8	Arapongas	Paraná
8	Presidente Prudente	São Paulo
8	Curitiba	Paraná
6	Xanxerê	Santa Catarina
4	Porto Alegre	Rio Grande do Sul
4	São José dos Campos	São Paulo

Figure 5. Septal Myectomy by gender - Brazilian Public Health System



Discussion

In Brazil, data from the public health system (SUS) indicate that 209 surgical myectomies (SM) were performed over the past decade, with procedures predominantly concentrated in major urban centers. São Paulo leads all Brazilian cities in surgical myectomy volume, reflecting its important role for HCM care. This limited SM distribution underscores the restricted access to invasive treatments for obstructive hypertrophic cardiomyopathy within the country. Moreover, the observed mortality rate in the Brazilian cohort (8%) is substantially higher than that reported in international studies from high-volume centers. Surgical expertise plays a critical role in procedural outcomes, as evidenced by U.S. data[16] from 2010 to 2019 showing a strong correlation between annual procedural volume and in-hospital mortality. Mortality rates can vary from below 1% in hospitals performing more than 28 myectomies per year to as high as 100% in centers averaging only 2.2 procedures annually.

Unmet medical needs remain evident in Brazil, particularly given the limited accessibility and risks associated with invasive septal reduction therapies such as SM. These procedures are linked to notable complications[13-15] and high perioperative mortality rates and are only available in highly specialized centers. In this context, the evaluation of non-invasive, safe, and effective therapies, which targets the underlying pathophysiology of obstructive hypertrophic cardiomyopathy and significantly reduces the proportion of patients eligible for surgery is particularly relevant.

Study limitations/strengths

The main strength of the study is to be able to analyze almost the entire Brazil population using datasets collected in the SIHSUS database. The data are routinely collected for reimbursement purposes and not specifically for this study, meaning that the study objectives do not influence the events used as outcomes and ensuring that the findings are highly relevant to the local context. However, the study's findings are contingent upon the data stored in the database, and missing information could pose challenges. Usage of ICD-10, which may be prone to miscoding, may causing information bias. Multiple SRTs performed by the same patient will not be identified and can overestimate the percentage of patients that had undergone SRT.

Conclusion

- The real-world study using data from Brazilian Health Care System (SUS), demonstrated that SM is performed for only a small proportion of patients with obstructive HCM patients. The reasons for this limited utilization need to be further investigated and may be attributed to a combination of factors such as contraindications, patient preferences, variation in clinical practice, and limited access and availability of experienced centers and surgeons.

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