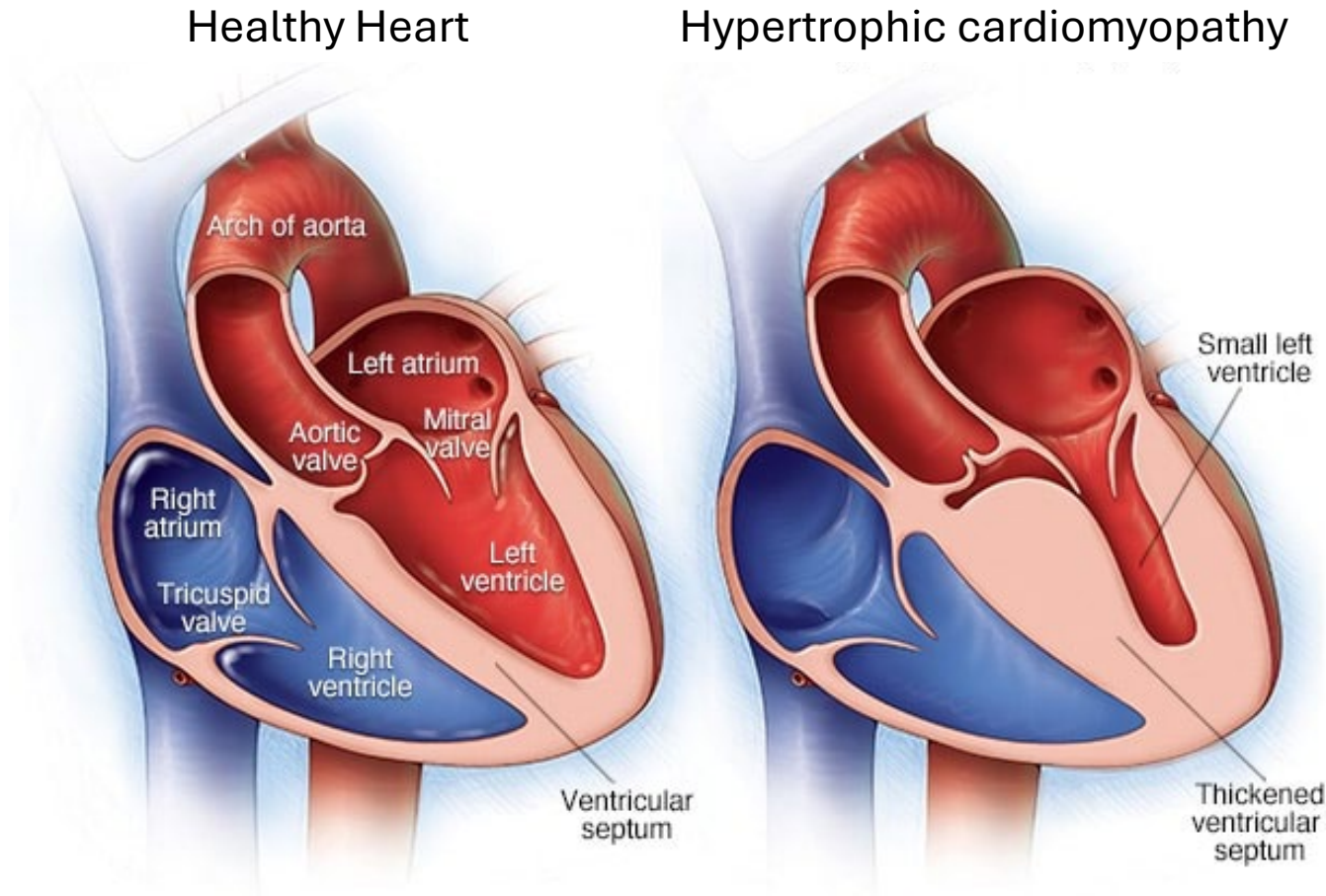


Transcatheter Division of Interventricular Myocardial Septum



ICD-10 Coordination and Maintenance Committee Update
September 2025

The Problem – Hypertrophic cardiomyopathy (HCM)



Most common inherited cardiomyopathy

Typically diagnosed around 20-40 years of age

Thickened muscle, typically septum

Obstructs LVOT (left ventricular outflow tract)

Ineffective pumping (i.e., heart failure)

Can restrict activities of daily living

Existing Treatment Options have Significant Limitations

Surgical Myectomy

Remains the gold-standard in the right hands

- High quality only available at a small number of centers in North America
- Low-volume centers have high morbidity and low clinical success rates
- Many patients are not surgical candidates
- Resource intensive

Medical Therapy (old medications)

- Negative inotropes: beta blockers, disopyramide, calcium blockers
- Economical
- Ineffective in overwhelming majority

Alcohol Septal Ablation

- Easy and simple
- High rate of permanent pacemaker
- High rate of failure
- Not all patients have the required vessel anatomy

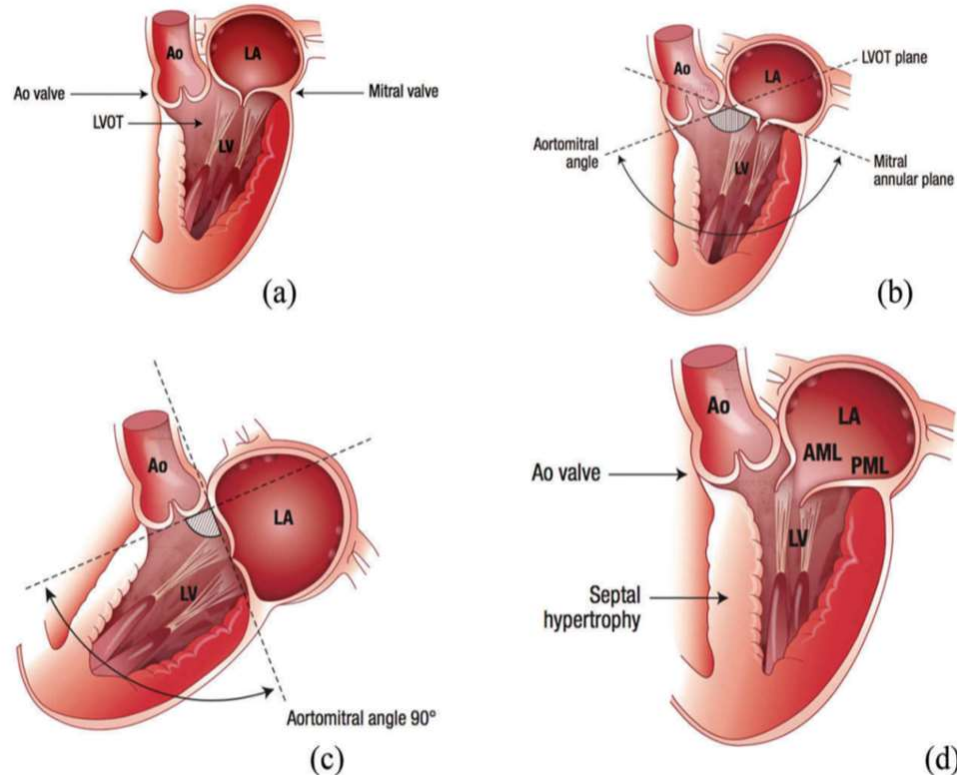
Myosin Inhibitors (e.g., mavacamten)

Approved 2022

- Lifelong obligation
- Requirement for frequent monitoring and dose adjustment for iatrogenic left ventricular dysfunction
- Intolerance rate is probably higher than reported ~10%

SESAME (Septal Scoring Along Mid-Line Endocardium) for Pre-TMVR

Problem - Many Patients Excluded for a TMVR



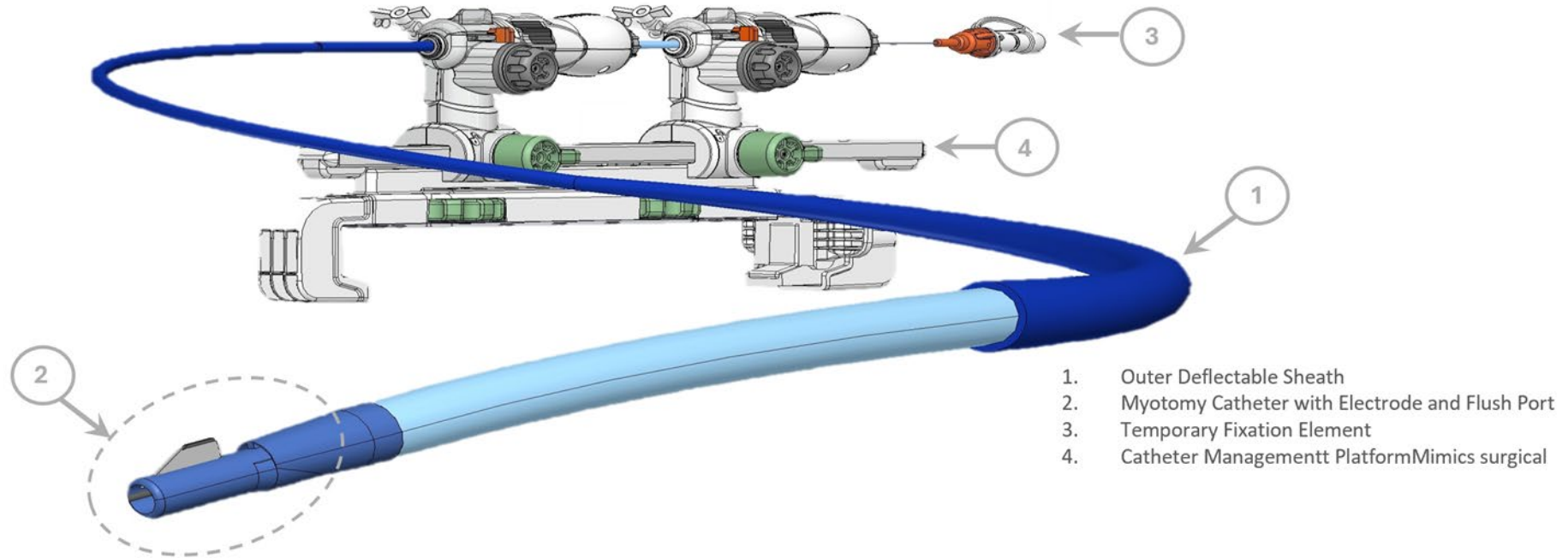
- Many patients that could be candidates for mitral valve replacement are excluded because of the risk of developing left ventricular outflow tract obstruction (neo-LVOT)*
- In a recent series from a TMVR clinical trial site, **47%** of consented patients were excluded because of risk of LVOT development**
- SESAME can be used to increase the LVOT area prior to TMVR; interest expected to spike with TMVR systems after SESAME approval

* Blanke P, Naoum C, Dvir D, et al. Predicting LVOT obstruction in transcatheter mitral valve implantation: concept of the Neo- LVOT. JACC Cardiovasc Imaging. 2017;10(4):482–485

** Hasan S, Morsi M, Frakes B et al. Management strategies and prognosis of patients' ineligible for transcatheter mitral valve replacement, Cardiovasc Revasc Med. 2024 Jul;64:1-4.

Transmural SESAME

First-in-Class Transcatheter Myotomy Device



Principal characteristics of SESAME

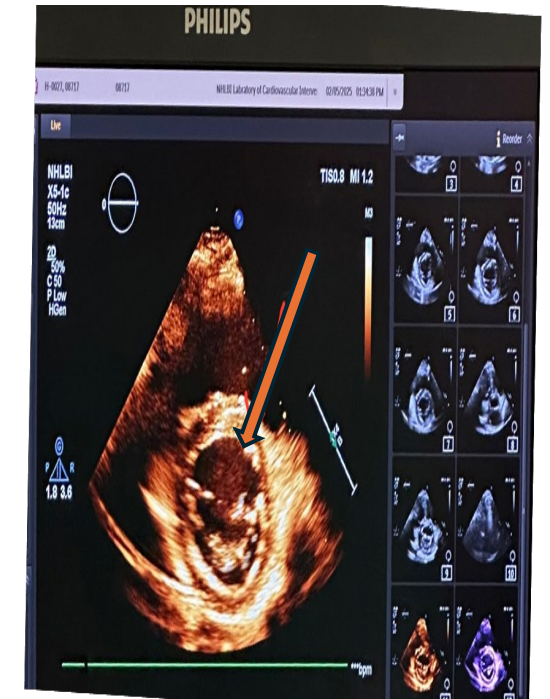
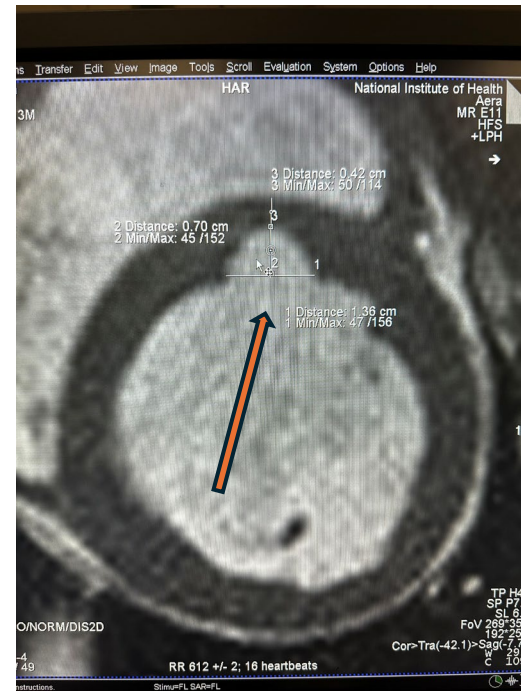
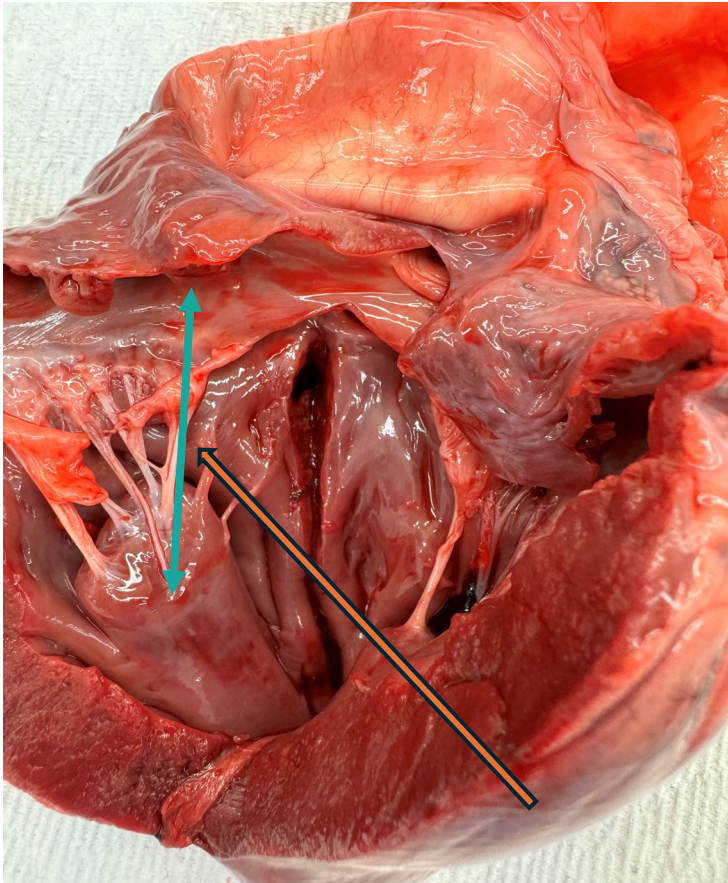
- Mimics surgical myectomy
- Designed to lacerate myocardium along the septal left ventricular endocardium with radiofrequency (RF)
- Relieve left ventricular outflow tract obstruction (LVOTO)

Advantages of SESAME

- “One & Done” procedure vs. lifetime of drug therapy
- Simple and fast transfemoral percutaneous procedure
- Significantly increases eligible patient population
- Compatible with variety of RF generators

**Need for a treatment that is simple, effective, safe and ideally
“one and done”**

Transmural SESAME Preclinical result



Axial view and Echo
Confirms that 5mm depth, 2cm length CUT using SESAME System – Yorkshire Pig

The Growing Market

- Hypertrophic cardiomyopathy (HCM) is the most common genetic heart condition
 - Prevalence 1:200 to 1:500, estimated 15-20 million worldwide with U.S represents $\geq 83\%$ ⁽¹⁾
 - It is estimated there are between 700,000 to 900,000 patients in the U.S. at risk for HCM. ⁽²⁾
 - HCM is underdiagnosed - estimated only 25% of individuals with obstructive HCM and 10% of individuals with non-obstructive HCM have received a diagnosis.
 - Left ventricular outflow tract obstruction (LVOT) is present in about 70% of patients with HCM ⁽³⁾ and treatments include medical therapy, surgical septal myectomy (SM), and alcohol septal ablation (ASA)
- The market size of HCM globally was approx. 300 million in 2020 ⁽⁴⁾
 - The market is estimated to grow approx. 22% annually
- HCM has come into the limelight at cardiology conferences
- Efforts underway to standardize and expand HCM screening, diagnosis and treatment
- FDA's de novo approval of Viz.ai an artificial intelligence (AI) algorithm

[1. Hypertrophic cardiomyopathy epidemiology and demographics - wikidoc](#)

[2. All eyes are on hypertrophic cardiomyopathy now that a drug treatment is in place \(cardiovascularbusiness.com\)](#)

[3. Hospital Procedural Volume and Clinical Outcomes Following Septal Reduction Therapy in Obstructive Hypertrophic Cardiomyopathy | Journal of the American Heart Association \(ahajournals.org\)](#)

[4. Hypertrophic Cardiomyopathy \(HCM\) Market Insight, Epidemiology and Research Report 2021-2030 - ResearchAndMarkets.com | Business Wire](#)

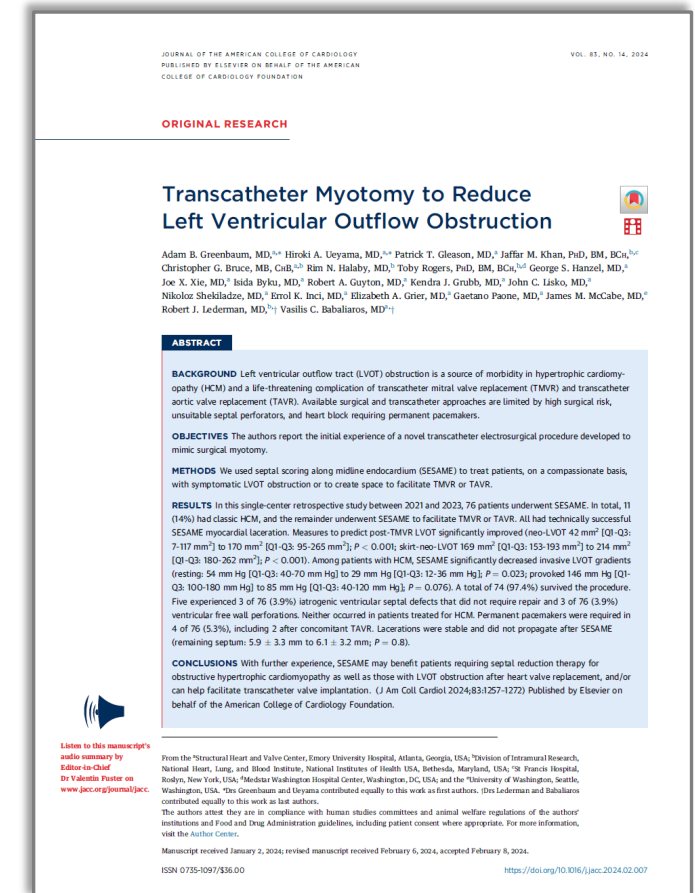
Compassionate Use Experience with “Classic SESAME”

- Transcatheter myotomy performed in 200+ U.S. patients* using off-shelf/off-label tools with positive results:

- 100% procedural success
- Among 11 **HCM patients**:
 - Decrease of resting LVOT gradient from 54mmHg to 29mmHg,
 - Decrease of provoked LVOT gradient from 146mmHg to 85mmHg
 - Zero new permanent pacemakers
- Among 65 **pre-TMVR patients**:
 - Neo-LVOT from 42mm² to 170 mm²
 - Skirt new-LVOT from 169mm² to 214mm²
- NYHA I or II of 9.5% pre procedural increased to 54.8% in 30-days

- Editorial conclusion:

“This new transcatheter electrosurgical technique may fill an unmet clinical need in patients who require LVOT modification, thereby offering a feasible option for patients with HCM and enlarging the field of TMVR and TAVR.”



* Greenbaum A, Ueyama H, Gleason P, et al. Transcatheter Myotomy to Reduce Left Ventricular Outflow Obstruction, JACC 2024;83 (4):1257-1262; associated editorial Nickenig G, Sugiyama A, Transcatheter Myotomy for LVOT challenges, JACC 2024;83(4): 1273-1274

SESAME: Clinical Use for HCM

- SESAME is targeted for those patients that remain symptomatic after the use of Beta Blockers and Calcium Channel Blockers
 - Symptomatic at rest are 25% of the total patients (165,000 in the U.S.) while another 50% (330,000 in the U.S.) develop symptoms at exercise
 - We estimate that 5-10% of those would be candidates for the SESAME procedure annually (~25-50,000 patients) once the device is launched
 - Successful trials could allow the expansion of the therapy for intermediate and low-risk patients, similar to the TAVR model

Procedural Steps for SESAME System

Obtain access and set up required accessories

Step 1 - A .035” guidewire is introduced through the pigtail catheter in the right femoral artery and placed in the left ventricle. The pigtail catheter is then removed.

Step 2 - The SESAME outer deflectable catheter and dilator are advanced over the 0.035” guidewire into the left ventricle, below the aortic valve. The dilator and guidewire are removed, leaving the outer catheter as a supportive conduit for the inner deflectable catheter.

Step 3 - The SESAME inner deflectable radiofrequency (RF) catheter is then advanced through the outer deflectable catheter to the left ventricle. While the inner catheter is positioned inside the outer catheter, the distal end of the outer catheter is deflected to achieve perpendicular orientation to the septum below the target site of the myotomy. After achieving desired deployment orientation and location, using the stabilizer rail pusher, the temporary fixation element is inserted into the septum. If necessary, engagement of stabilizer element with tissue is confirmed using angiography.

Procedural Steps for SESAME System continued

Step 4 - The outer deflatable catheter then is pulled back into the aortic arch to expose the inner deflatable catheter. Using the catheter management platform rotation knob, adjust the orientation of inner deflatable catheter to ensure electrode is in direct contact with tissue.

Step 5 – To achieve the laceration, the inner deflatable catheter is retracted and advanced over the rail between the temporary fixation element and pig tail (using as landmark to locate aortic valve), while it is connected to an RF generator and energized at 10-25W.

Step 6 - Once the myotomy is complete, the inner catheter is advanced to the temporary fixation element, and the temporary fixation element is retracted into the inner deflatable catheter. The system is then removed from the body.

Procedural Documentation

Use of the SESAME system is documented in the Catheterization lab procedure report

Transcatheter Myotomy using the SESAME system may be referred to using various terms:

- SESAME
- SESAME Procedure
- Septal Scoring Along the Midline Endocardium
- Transmural SESAME
- Transcatheter Myotomy
- Lacerate myocardium
- SESAME coaxial deflectable catheters
- SESAME Stabilizer System
- SESAME Catheter Management Platform
- Temporary fixation element

Thank You