Evaluation of real world mavacamten clinical outcomes at an integrated health system specialty pharmacy

Sarah E. Wright, PharmD, BCACP; Kimhouy Tong PharmD, BCPS; Bisni Narayanan, PharmD, MS, MBA;
Tina Do, PharmD, MS, BCPS; Terri Sue Rubino, PharmD, CSP; Vinay Sawant, RPh, MPH, MBA

Background

- Mavacamten is a cardiac myosin inhibitor approved for the treatment of symptomatic New York Heart Association class II-III obstructive hypertrophic cardiomyopathy (oHCM).
- Previous studies of mavacamten have shown a lower risk of adverse cardiovascular outcomes in patients with oHCM[1]
- In November 2023, the integrated health system specialty pharmacy (HSSP) at Yale New Haven Health (YNHHS) began dispensing mavacamten.[2]
- An optimized clinical and dispensing workflow achieved 100% compliance with strict REMS requirements and high medication adherence as demonstrated by an early evaluation of 67 patients treated within the first year of dispensing mavacamten.[3]

Objective

To undertake an interim evaluation of serious clinical outcomes in patients with oHCM after initiating mavacamten

Methods

Study Design

Retrospective chart review of YNHHS patients ordered to start mavacamten between May 2024 through April 2026

Patient Selection

18 years and older with a diagnosis of oHCM prescribed mavacamten by a YNHHS prescriber

Exclude

- Prior VT, VF, or MI based on ICD-10 code
- Orders sent to both the HSSP and external pharmacies

Data Collection

Order and fill history were obtained from

- Dispensing records
- EHR

Events between September 2024 through July 2026 for patients on therapy 12 weeks or more

Outcomes

Primary outcome

- Composite outcome defined as first occurrence of VT, VF, MI, or all-cause mortality after starting mavacamten

Secondary outcome

- Primary medication non-adherence rate
- Time on therapy
- Patient perceived effectiveness

Results

Figure 1: Patient enrollment

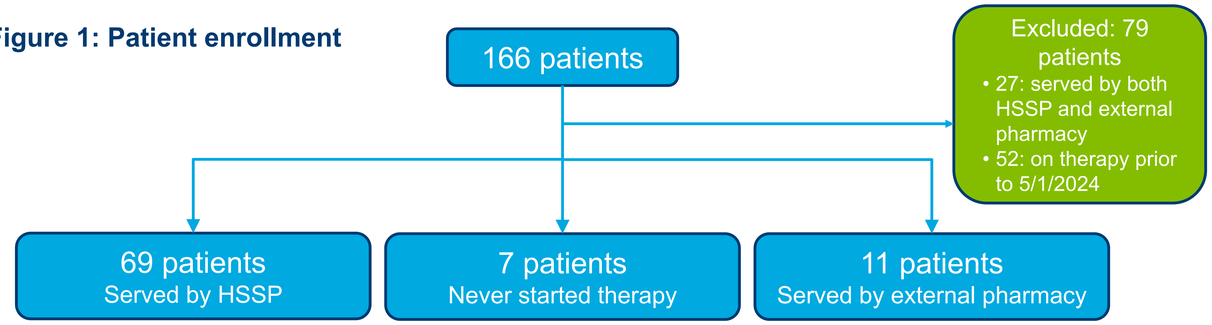
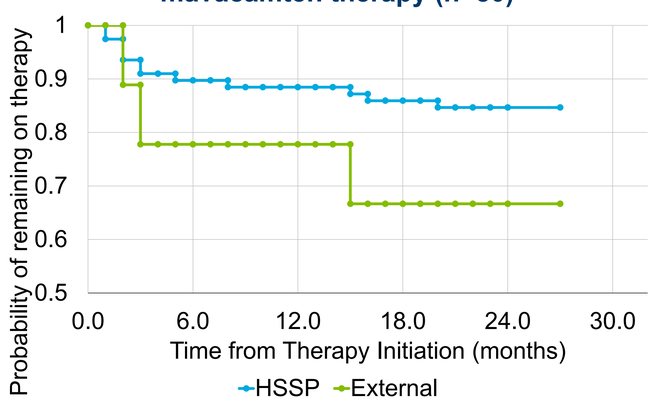


Table 1: Clinical characteristics

	HSSP patients (n=69)	Never started therapy (n=7)	External patients (n=11)
Age at therapy initiation (years), median, IQR	69 (62, 76)	70 (67,74)	59 (51, 65)
Female, %	54%	29%	46%
Time on therapy (months), median IQR	10.5 (3,17.5)	N/A	11 (3.25,20.5)
Composite outcome n,%	1, 1.1%	0,0.0%	3, 3.4%

Figure 2: Kaplan Meier plot of mavacamten therapy (n=80)



HSSP patients
Mean MPR: 98% ± 3.8%
Percent of patients classified as good adherence (greater than or equal to 80%)[4]: 100%

Figure 3: How do you feel the medication is working? (n= 85)

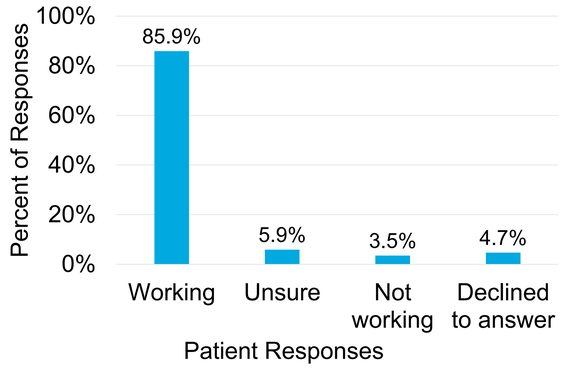
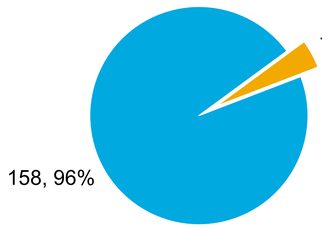


Figure 4: Percent of primary medication non-adherence



Reason for Non-adherence	Percent
Prior authorization denial	57%
Patient preference	29%
Other	14%

Started medication Never started medication

Discussion

- There were more events in patients served by external pharmacies compared to HSSP patients, despite fewer patients served by external pharmacies (Table 1).
- Two patients experienced VT and one patient experienced all-cause mortality in the external pharmacy group. There was one all-cause mortality event in the HSSP group.
- The median age of patients served by HSSP is 10 years older than patients served by external pharmacies.
- Although the median time on therapy is similar between HSSP and external pharmacy patients, fewer external pharmacy patients were still on therapy at 6 months, 1 year, and 2 years after therapy start.
- An MPR of 98% is generally recognized as a high adherence rate.
- Overall, the rate of primary non-adherence was low. Beyond insurance denial and patient preference, reasons for primary medication non-adherence include provider decision and lack of information in the patient chart.

Barriers and Limitations

- HSSP is well integrated into health system and there were few patients served by external pharmacies that could be included in the comparison group.
- Convenience sampling of the population may have led to a non-representative study sample and may limit generalizability of findings.
- Small sample size limits the ability to detect statistically significant differences between groups.
- MPR calculation and perceived effectiveness assessment limited to HSSP patients.
- Patients who switched to competitor oHCM therapy may have been censored in survival analysis.

Future Directions

- Follow patient cohorts for longitudinal study.
- Assess effectiveness of therapy regimens.
- Assess whether polypharmacy (patient is served by HSSP and external pharmacy) impacts outcomes.
- Expand analysis to include competitor oHCM therapies.

Conclusion

High rates of integrated HSSP patients on mavacamten are highly adherent to therapy, stay on therapy, report medication effectiveness, and may have improved clinical outcomes compared to non-HSSP patients.

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Cardiac arrest (MI), Electronic health record (EHR), Medication Possession Ratio (MPR), ventricular fibrillation (VF), ventricular tachycardia (VT)