Clinical, Safety, and Quality Outcomes of a Hypertrophic Cardiomyopathy Clinical Pharmacy Management Program

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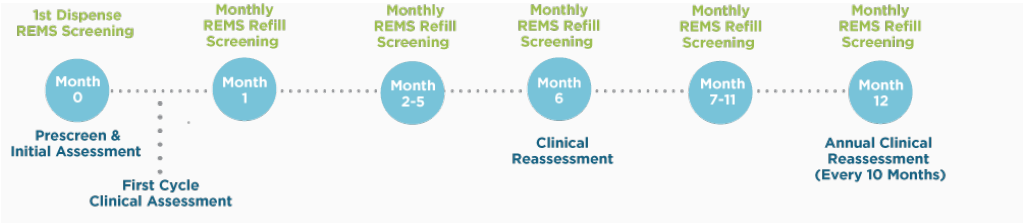
SCAN ME

BACKGROUND

Mavacamten is a first-in-class treatment for hypertrophic cardiomyopathy (HCM) that in clinical trials demonstrated improvement in New York Heart Association (NYHA) class by ≥ 1 class in 63% of patients versus 21% with placebo.[1] Due to the risk of heart failure (HF), mavacamten is only available through a Risk Evaluation and Mitigation Strategy (REMS) program. NYU Langone Health incorporates REMS requirements into its integrated health system specialty pharmacy (HSSP) clinical services model through monthly patient assessments for HF symptoms and drug interactions. The objective of the study is to evaluate the clinical, safety, and quality outcomes of a pharmacist-led HCM clinical management program.

Figure 1: HCM Specialty Pharmacist Workflow



METHODS

Inclusion Criteria: NYU Langone Health HCM patients new to mavacamten therapy with NYHA documentation and enrolled in the patient management program for a minimum of six months from May 2022 through December 2024.

Primary Outcome: percentage of patients with a change in NYHA class from baseline to the most recent assessment

Secondary Outcomes: emergency room (ER) visits or hospitalizations due to HCM, number of serious adverse events, adherence measured by proportion of days covered (PDC), number and type of pharmacist interventions, and REMS audit results

Analysis: Patients were identified from prescription fill records. Clinical, safety, and quality data points were obtained through the specialty pharmacy patient management platform while PDC was calculated using fill data.

RESULTS

Table 1: Patient Characteristics and Outcomes

Characteristic	N=92
Mean age (years)	71
Sex (n, %)	
M	31 (34)
F	61 (66)
Mavacamten Dose (mg) (n, %)	
2.5	24 (26)
5	33 (36)
10	29 (32)
15	6 (6)
Initial NYHA Class (n, %)	
I	1 (1)
II	29 (32)
III	62 (67)
Insurance Type (n, %)	
Medicare	60 (65)
Commercial	29 (32)
Medicaid	3 (3)
Clinical Outcomes	
ER visits (n)	5
Hospitalizations (n)	8
Serious adverse events (n)*	12
PDC (%)	96
Successful REMS audits	3

*Serious adverse events were defined as hospitalization, disability or permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage, other serious medical event, life-threatening, or death.

Figure 2: Change in NYHA Class

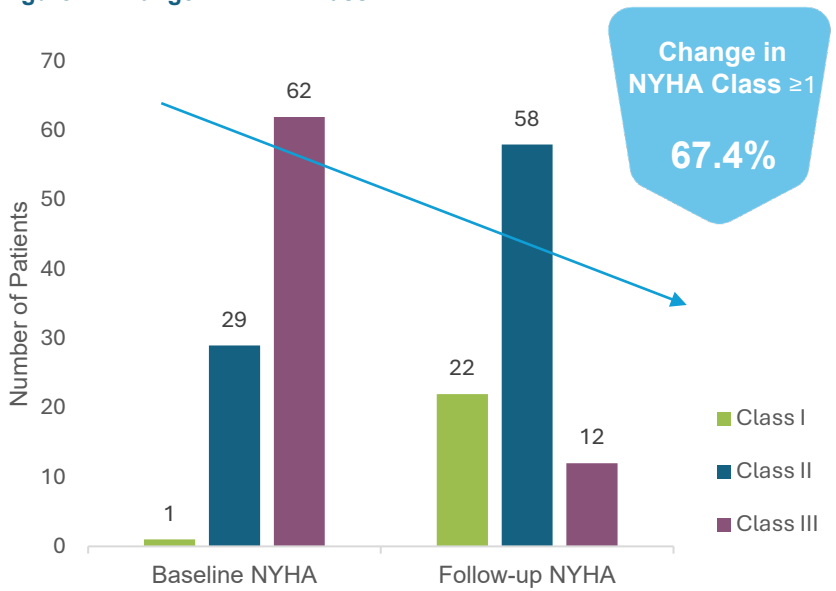
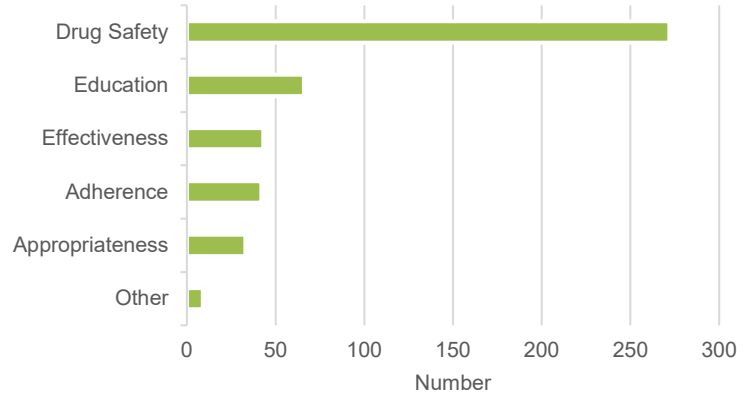


Figure 3: Clinical Interventions (N=465)



CONCLUSION

- The real-world evaluation of a HSSP model for managing HCM patients demonstrated positive clinical outcomes and a reduction in NYHA Class consistent with clinical trial results.
- The implementation of a pharmacist-led patient management program promoted improved clinical, safety, and quality outcomes for patients on mavacamten therapy.

REFERENCE

1. Desai MY, Owens A, Wolski, K, et al. Mavacamten in Patients with Hypertrophic Cardiomyopathy Referred for Septal Reduction Week 56 Results from the VALOR-HCM Randomized Clinical Trial. JAMA Cardiol. 2023;8(10):968-977. doi:10.1001/jamacardio.2023.3342