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A Standardized Digital Device for Performing Goal-Directed Valsalva Maneuver in Clinical Practice

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Human Subjects Statement: This prospective single-center study included patient evaluations performed between August 2025 and August 2026 at the University of Alabama at Birmingham and was approved by the Institutional Review Board (IRB-300014523). Written informed consent was obtained from all participants.

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Background: The Valsalva maneuver is commonly used during echocardiographic evaluation to provoke dynamic left ventricular outflow tract (LVOT) obstruction in patients with hypertrophic cardiomyopathy (HCM). Prior studies have shown that the goal-directed Valsalva maneuver (GDV) provokes higher LVOT gradients than the self-directed Valsalva maneuver (SDV). However, the clinical performance of a digital device designed to standardize GDV has not been well evaluated.

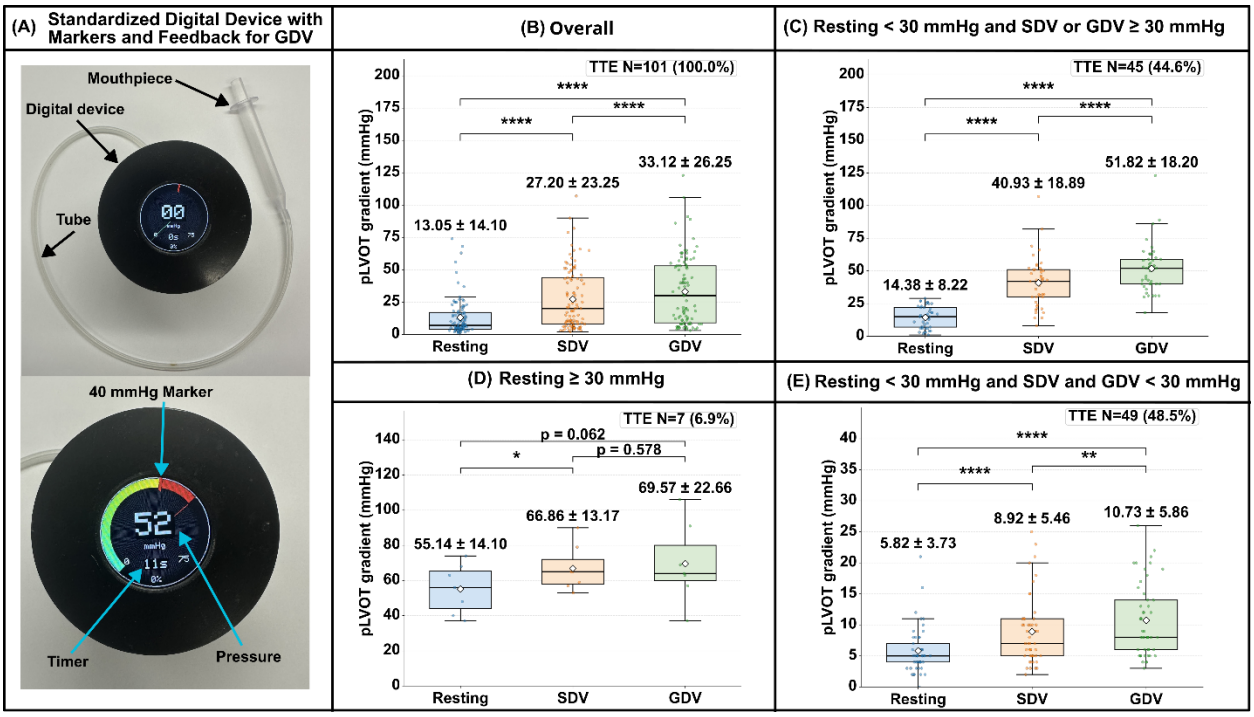
Objective: To compare peak LVOT gradients (pLVOTg) obtained at rest, during SDV, and during GDV performed with a standardized digital Valsalva maneuver device in routine clinical practice.

Methods: In this single-center prospective study performed at University of Alabama at Birmingham, adult patients undergoing initial evaluation or routine follow-up for HCM were included. Resting, SDV, and GDV assessments were performed during transthoracic echocardiography (TTE), with a 1-minute interval between techniques. GDV was performed using a digital device (**Figure 1A**) that provided real-time intraoral pressure and time feedback to the patient. pLVOTg was recorded for each maneuver.

Results: A total of 101 patients were included in this study. Mean pLVOTg was significantly higher during GDV than during SDV and at rest (33.12 ± 26.25 vs. 27.20 ± 23.25 mmHg and 33.12 ± 26.25 vs. 13.05 ± 14.10 mmHg, respectively; all $p < 0.0001$; **Figure 1B**). 45 patients (44.6%) were reclassified from non-obstructive to obstructive HCM during provocation, with pLVOTg 51.82 ± 18.20 and 40.93 ± 18.89 mmHg during GDV and SDV, respectively (**Figure 1C**). Higher pLVOTg during GDV was observed in both the obstructive and non-obstructive groups at rest (**Figure 1D** and **1E**).

Conclusion: GDV performed with a standardized digital device capable of displaying target pressure and maneuver duration in real time was associated with higher provoked LVOT gradients than SDV and resting assessment. These results indicate the clinical usefulness of a standardized digital device during routine echocardiographic evaluation of patients with HCM.

Figure 1. Standardized digital Valsalva device and comparison of pLVOTg at rest and during SDV and GDV maneuvers.



(A) Standardized digital device used for GDV, showing the mouthpiece, tubing, digital pressure display, timer, and 40-mmHg target marker. **(B)** Distribution of pLVOTg at rest, during SDV, and during GDV across all TTE studies (N=116). **(C)** Studies that were non-obstructive at rest (pLVOTg <30 mmHg) and obstructive during either SDV or GDV (pLVOTg ≥30 mmHg; N=53). **(D)** Studies with obstructive physiology at rest (pLVOTg ≥30 mmHg; N=8). **(E)** Studies that remained non-obstructive at rest, during SDV, and during GDV (pLVOTg <30 mmHg; N=55).

Individual observations and summary distributions are shown; values above the plots represent mean ± SD. *P<0.05, ***P<0.001, ****P<0.0001.