Patient Compliance with Vibrating Capsule Predicts Outcome in Chronic Idiopathic Constipation (CIC)

Quigley EMM[1], Rao SSC[2], Chey WD[3], Brenner D[4], Curtin B[5], Frissora C[6], Spiegel B[7], Lembo A[8]

Introduction

Many patients with chronic idiopathic constipation (CIC) are dissatisfied with available medications, suggesting a need for new therapies.

A recent phase III trial showed that an orally ingested vibrating capsule (VC) improved stool frequency, bowel and abdominal symptoms and quality of life in patients with CIC[1]

Aim

The aim of this study was to evaluate the impact of compliance on efficacy of the VC in a post-hoc analysis of a Phase III trial in CIC

Methods and Materials

- In this 8 week randomized double-blind placebo controlled Phase III trial, activation of the vibrating capsule (Vibrant®, Yokne'am Illit, Israel) was automatically and remotely recorded, permitting an accurate assessment of compliance.
- Two outcomes were analyzed: CSBM1, an increase of ≥ 1 CSBM/week and CSBM2, an increase of ≥ 2 CSBMs/week, averaged over the study period and compared to baseline.

Results

Patients whose compliance to the recommended number of capsules was >32 capsules ingested over the 8 weeks of treatment, (out of the recommended 5 capsules per week X 8 weeks = 40 capsules), had higher response rates for both CSBM1 and CSBM2, compared to either the entire study population or those who ingested <32 capsules per week (Figure and Table).

Figure 1: Primary outcome measures showing proportion of complete spontaneous bowel movement 1 and 2 (CSBM1 and CSBM2) responders according to compliance rate and in comparison to the entire study population (intention-to-treat analysis)

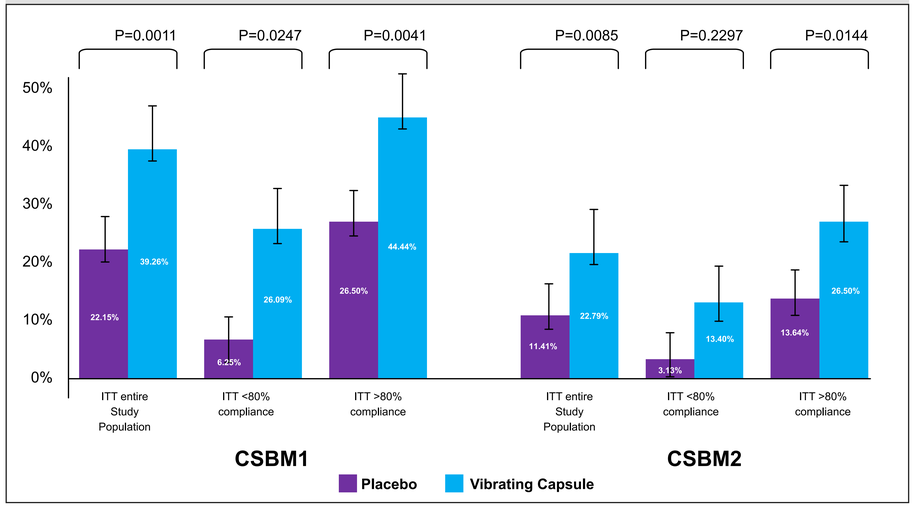

Table 1: Impact of compliance on relative efficacy of vibrating capsule (VC) and placebo

		VC (Vibrant) Mean change from baseline ITT [95% CI]	**Placebo** Mean change from baseline ITT [95% CI]	**P-value** (x^2 test)
Entire Study Population (ITT population from Phase III study) VC n=163 Placebo n=149	$CSBM_1$	39.26% [23.10%;46.93%]	22.15% [16.23%;29.47%]	0.0011
	$CSBM_2$	22.70% [16.94%;29.72%]	11.41% [7.25%;17.51%]	0.0085
ITT <80% compliance VC n=117 Placebo n=117	$CSBM_1$	26.09% [15.601%;40.26%]	6.25% [1.73%;20.15%]	0.0247
	$CSBM_2$	13.40% [6.12%;25.67%]	3.13% [0.55%;15.74%]	0.229
ITT >80% compliance VC n=46 Placebo n=32	$CSBM_1$	44.44% [35.76%;53.48%]	26.50% [19.34%;35.15%]	0.0041
	$CSBM_2$	26.50% [19.34%;35.15%]	13.68% [8.60%;21.06%]	0.0144

Conclusions

- Patients with CIC with >80% adherence to capsule dosing frequency had a superior response, supporting the appropriateness of the proposed dosing schedule.
- By virtue of its design, this first in class system enables accurate monitoring of compliance when assessing clinical response.

[1]Lynda K and David M Underwood Center for Digestive Disorders, Houston Methodist Hospital and Weill Cornell Medical College, Houston, [2]Division of Gastroenterology/Hepatology, Augusta University, Augusta, GA, [3]University of Michigan, Ann Arbor, MI, [4]Northwestern University, Chicago, IL, [5]Center for Neurogastroenterology and GI Motility, Mercy, Baltimore, MD, [6]Division of Gastroenterology & Hepatology, Weill Cornell Medical College, NY, [7]Cedars-Sinai, Los Angeles, CA, [8]Beth Israel Hospital, Boston, MA

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