

Introduction

- Chronic constipation is a common and bothersome condition.
- Though there are several medications available, 50% of patients find relief. Additionally, many patients are interested in trying non-pharmacologic options.
- A recent phase III trial found an orally ingested, non-pharmacologic vibrating capsule (VC) (Vibrant, Yokneam, Israel) significantly improved key constipation symptoms including stool frequency, straining, consistency and quality of life in patients with chronic idiopathic constipation (CIC)¹.

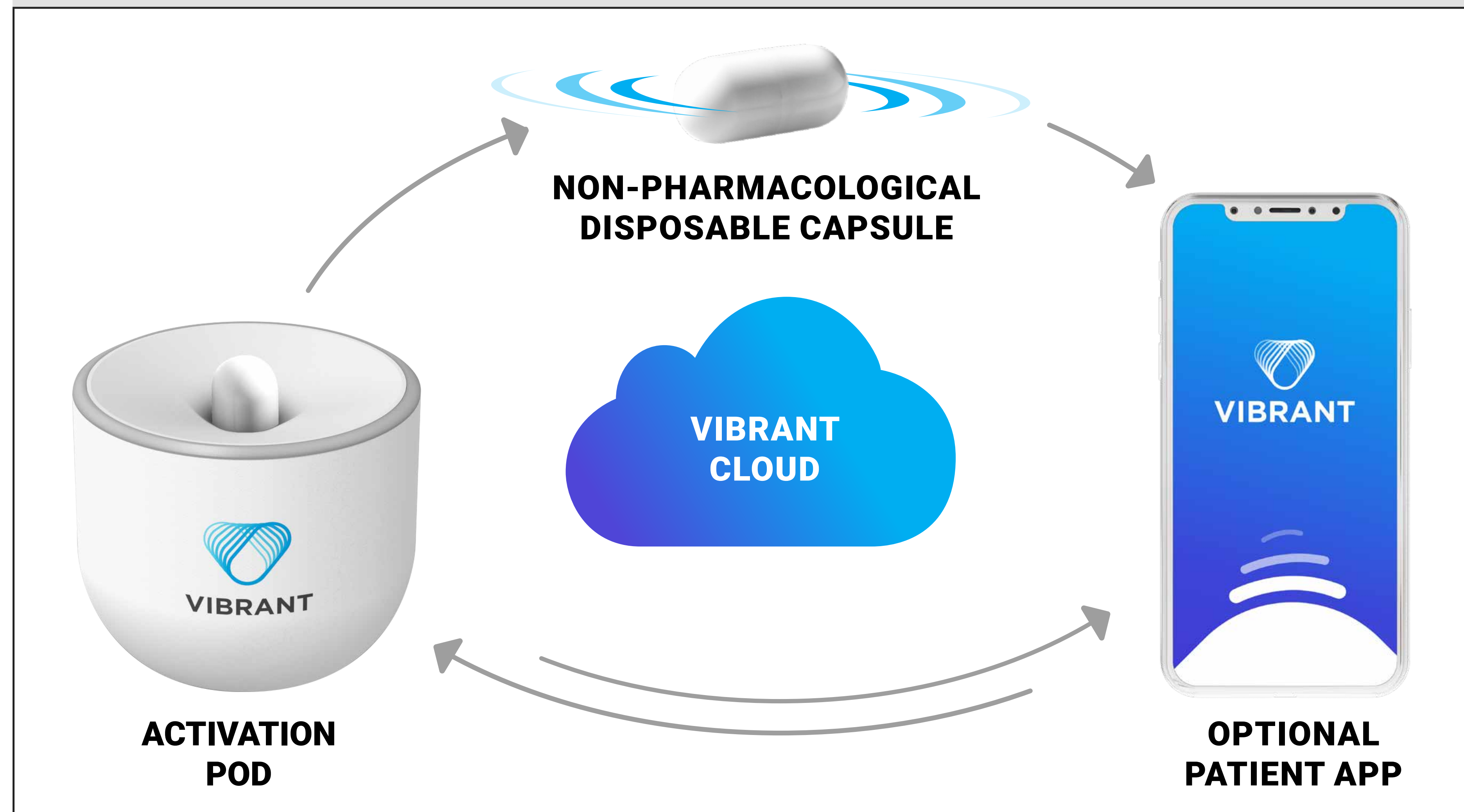
Aim

- The aim of the study was to determine the safety, tolerability and ease of use of the VC in patients with CIC.

Methods and Materials

- This was a secondary analysis from a prospective, randomized, multi-center, double-blind, placebo-controlled study in patients with CIC. Patients received either VC (2 modes) or placebo capsule.
- Once daily, five days a week for 8 weeks.
- Patients in the VC and placebo arms were taught how to activate the VC system which included connecting to Wi-Fi, using a mobile app, and activating the capsule using a base station (Fig 1).
- An ease of use questionnaire evaluated the functionality of the VC.
- Adverse events and tolerability were assessed

Figure 1: The Vibrant System



Results

Adverse events

- A total of 79 AEs were considered possibly related to the study treatments (44 in the VC Mode 1, 9 VC mode 2) and 26 in the placebo arms. (Table 1)
- No serious AEs (SAE) or treatment related diarrhea were reported in the VC arm.
- Two AEs in the placebo arm were considered severe (one transient ischemic attack and one with abdominal pain) but neither were considered related to the study treatment by the investigator.
- A sensation of vibration was reported by 11% in VC arm, but no subject withdrew because of this.

Ease of use of the Vibrant system

- 94% of patients found 'Connecting the base unit to Wi-Fi' - easy. 5% ranked it medium, 2% found it hard.
 - 97% of patients found 'Setting up the base unit for use' - easy. 3% ranked it moderately difficult.
 - 82% of patients found 'Activating capsules' - easy. 13% ranked it moderately difficult, 5% found it hard.
- For the question, 'Following the treatment for several months, once it is commercialized - 85% of patients reported that they would find it easy to use, 12% ranked it moderately difficult and 3% ranked it hard.

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

Adverse event	Vibrating Capsule, Mode 1 (n=89) No. of patients (%)	Placebo (n=86) No. of patients (%)
*Adverse events during treatment (combined safety populations including interim analysis groups)		
Any event	23 (25.84)	15 (17.4)
**Sensation of vibration	10 (11.24)	.
Headache	1 (1.2)	1 (1.16)
Urinary tract infection	1 (1.2)	1 (1.16)
Abdominal pain		2 (2.23)
Abdominal discomfort	2 (2.25)	
Vomiting	2 (2.25)	1 (1.16)
Nausea	3 (3.37)	1 (1.16)
Abdominal distention		2 (2.23)
Diarrhea	2 (2.25)	.
Covid-19	1 (1.2)	1 (1.16)
Nasopharyngitis/Bronchitis	2 (2.25)	
Musculoskeletal	2 (1.2)	1 (1.16)

* Data shown for adverse events in at least 1% of the subjects
 ** Sensation of vibration means: "I think I felt vibration". In previous vibrant studies the reports were in both active and placebo arms

Conclusions

- In this large phase III trial, this first in class VC, was found to be safe and well tolerated.
- No AEs of diarrhea were reported.
- In addition, 82-94% of study participants found the VC system easy to use and 85% were willing to try this treatment.
- The VC was found to be safe, well tolerated and easy to use in CIC patients.